Radiological Health, Safety and Environmental Services
A USA Environment, L.P. Company

# QUALITY MANAGEMENT PLAN

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**Contents**


1. OBJECTIVE ..... 3
2. MANAGEMENT AND ORGANIZATION ..... 4
3. QUALITY SYSTEM COMPONENTS ..... 5
   3.1 Quality System Documentation ..... 5
   3.2 Annual Reviews and Planning ..... 6
   3.3 Management Assessments ..... 6
   3.4 Training ..... 7
   3.5 Systematic Planning of Projects ..... 8
      3.5.1 Planning ..... 8
      3.5.2 Data Collection ..... 8
      3.5.3 Documentation ..... 8
      3.5.4 Quality Control Check ..... 8
   3.6 Project-Specific Quality Documentation ..... 9
      3.6.1 Mechanisms To Achieve Quality Objectives ..... 9
      3.6.2 Quality Assurance Objectives For Data ..... 10
   3.7 Project and Data Assessments ..... 10
      3.7.1 Data Verification ..... 10
      3.7.2 Data Validation ..... 11
4. PERSONNEL QUALIFICATION AND TRAINING ..... 12
   4.1 Qualification Requirements ..... 12
   4.2 Capability Demonstration ..... 12
   4.3 Support Personnel ..... 12
5. PROCUREMENT OF ITEMS AND SERVICES ..... 13
6. DOCUMENTS AND RECORDS ..... 14
   6.1 Documentation ..... 14
   6.2 Management Review of Records ..... 14
   6.3 Maintenance of Records ..... 14
   6.4 Records Disposition ..... 14
7. COMPUTER HARDWARE AND SOFTWARE ..... 16
   7.1 Calculations ..... 16
   7.2 Computer Programs ..... 16
   7.3 Logs, Drawings and Tables ..... 16
   7.4 Analysis Verification ..... 17
   7.5 Calculation Checking ..... 17
   7.6 Computer Program Input Checking ..... 17
   7.7 Drawings ..... 18
   7.8 Tables ..... 18
8. PLANNING ..... 19
9. IMPLEMENTATION OF WORK PROCESSES ..... 20

10. ASSESSMENT AND RESPONSE ..... 22
11. QUALITY IMPROVEMENT ..... 23
12. REFERENCES ..... 24
APPENDIX A: TERMS AND DEFINITIONS ..... 25



WLLFOIA4312 - 001 - 0046448

## AUXIER & ASSOCIATES QUALITY MANAGEMENT PLAN

# 1. OBJECTIVE

This Quality Management Plan (QMP) documents the Auxier & Associates (A&A) management practices, including QA and QC activities, used to ensure that the results of technical work are of the type and quality needed for their intended use. Accordingly, this QMP documents the:

- Mission and quality policy of the organization
- Specific roles, authorities, and responsibilities of management and staff with respect to QA and QC activities
- Means by which effective communications with personnel actually performing the work are assured
- Processes used to plan, implement, and assess the work performed
- Process by which measures of effectiveness for QA and QC activities will be established and how frequently effectiveness will be measured
- Continual improvement based on lessons learned from previous experience

The QMP reflects A&A's commitment to quality management principles and practices, tailored, when appropriate, by senior management to meet the organization's needs. The elements that are addressed in the QMP include: management and organization; quality system description; personnel qualifications and training; procurement of items and services; documentation and records; computer hardware and software; planning; implementation of work processes; assessment and response; and quality improvement.

Project quality objectives are that:

- Scientific data will be of a quality to meet scientific and legal scrutiny
- Data will be gathered or developed in accordance with procedures appropriate for the data's intended use
- Data will be of known or acceptable precision, accuracy, completeness, representativeness, and comparability as required for this project

Fundamental mechanisms that will be employed to achieve these quality goals can be categorized as prevention, assessment, and correction. These include:

- Prevention of errors by planning, documented instructions and procedures, and careful selection and training of skilled, qualified personnel
- Quality assessment through a program of audits and surveillance to supplement continual informal review
- Correction to prevent recurrence of conditions adverse to quality



WLLFOIA4312 - 001 - 0046449

# 2. MANAGEMENT AND ORGANIZATION

A&A is committed to ensuring that all activities performed which affect quality are described by and performed in accordance with approved procedures. The Quality Management Plan is implemented for the activities specified in EPA contracts. The responsibility for the overall direction and implementation of the QMP rests with the Quality Assurance/Control Officer. The QA/QC Officer is responsible for maintaining the QA Program and verifying its implementation through audits and surveillance.

The QA/QC Officer is responsible for the organization chart that identifies all of the components of the organization and, in particular, the organizational position and lines of reporting for the QA Manager. The proposed organizational chart is shown in Figure 1.

The QA/QC Officer is independent of the program organization and has ultimate authority for ensuring the quality of the work performed. The QA/QC Officer has access to the appropriate levels of management in order to plan, assess, and improve the organization's quality system.

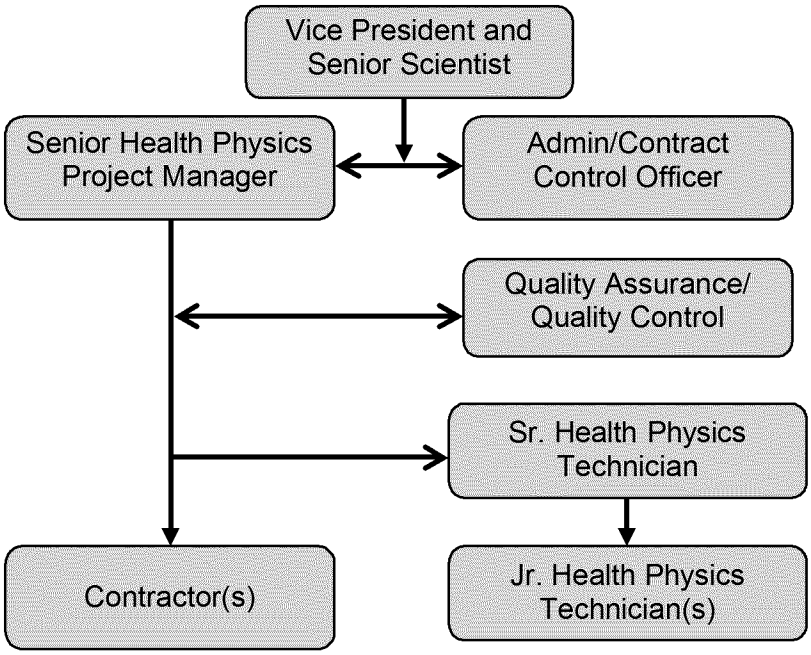


**Figure 1: Proposed Organizational Chart forEPA Support**



WLLFOIA4312 - 001 - 0046450

# 3. QUALITY SYSTEM COMPONENTS

This section includes a description of the organization's quality systems and includes the principal components of the system. These components include:

- Quality system documentation
- Annual reviews and planning
- Management assessments
- Training
- Systematic planning of projects
- Project-specific quality documentation
- Project and data assessments

## 3.1 QUALITY SYSTEM DOCUMENTATION

The following documents will be developed and used on a program or project-specific basis as appropriate.

- Quality Management Plans (quality system documentation)
- Quality Systems Audits (management assessments)
- Training Plans (training)
- QA Project Plan (project-specific quality documentation)
- Data Verification and Validation (data assessments)

Quality System Documentation shall be issued as controlled document to assure that the current approved revision is in use. Controlled copies of these documents will be issued to project personnel by the QA/QC Officer or designated alternate who will maintain a distribution list of recipients of the controlled copies. Personnel assigned controlled documents will be required to acknowledge initial receipt of the document and receipt of subsequent revisions to the document.

A Document Distribution Record shall be maintained to assure that current documents are distributed. Issue of controlled copies shall be submitted to the recipient by means of a Document Transmittal Record, which will demonstrate that current documents have been issued and are in use. Receipt of the Document Transmittal Record shall be acknowledged by the recipient and returned to the QA/QC Officer or designee.

The recipient of the controlled document shall return the document to the QA/QC Officer or his designee when the requirements for its use end. Upon return of the controlled document, the QA/QC Officer or designee shall enter the date of return on the Document Distribution Record.



WLLFOIA4312 - 001 - 0046451

## 3.2 ANNUAL REVIEWS AND PLANNING

The QMP shall be reviewed annually or when deemed appropriate by the QA/QC Officer based on modifications to the program or work practices, which warrant QMP review. Based on the results of the review, the QA/QC Officer will make a determination regarding a revision to the QMP. Any revisions deemed appropriate will be reviewed and signed by the appropriate individuals, e.g., the same job function(s) that reviewed and approved the original document.

## 3.3 MANAGEMENT ASSESSMENTS

To verify compliance with QMP requirements, the QA/QC Officer and other technically qualified personnel (if required) may perform planned and documented audits of project activities. These audits will comprise, as appropriate, an evaluation of QA procedures and the effectiveness of their implementation, an evaluation of work areas and activities, and a review of project documentation. Audits will be performed in accordance with written checklists and, as appropriate, with the guidance of technical specialists. Audit results will be formally documented and sent to the Project Manager.

Audits may include, but not be limited to, the following areas:

- Field operation work procedures and records
- Laboratory testing and records
- Equipment calibration and records
- Numerical analyses
- Computer program documentation and verification
- Transmittal of information
- Record control and retention
- Final Reports

An audit may examine, as appropriate, the documentation and verification of field and laboratory data and results; performance, documentation, and verification of analyses; documentation and verification of computer programs; preparation and verification of drawings, logs, and tables; content, consistency, and conclusions of the report; compliance with regulatory and project requirements; and maintenance and control of project records.

The records of field operations will be reviewed to verify that field-related activities were performed in accordance with appropriate project procedures. Items reviewed will include, but not be limited to, the calibration records of field equipment; laboratory notebook dedicated to project activities; daily field activity logs; photographs; and data, logs, and data sheets resulting from the field operations.

Auditing of analyses may include a complete review of calculations, computer input, sketches, charts, tables, and their associated documentation that was prepared by the project group.

The report preparation process may be reviewed to verify that the:

- Report correctly and accurately presents the results obtained by the project work



WLLFOIA4312 - 001 - 0046452

- Information presented in the report is substantiated by project work
- Logs, tables, and figures presented in the report are prepared and checked according to applicable requirements
- Report satisfies the scope of work, applicable requirements, and any pertinent regulatory requirements.

An audit may also, as appropriate, review the maintenance of project documents to verify that applicable procedures have been implemented.

Checklists should be prepared by the auditors and used to conduct all audits. The checklists will be developed to accomplish the review of necessary items and to document the results of the audit.

Following completion of an audit, the auditors will prepare and submit an audit report to the Project Manager, which will serve to notify management of audit results. The report may also be sent to individuals contacted during the audit.

The report will be prepared as soon as possible (within 30 days) after the audit and contain, as appropriate:

- Date(s) of the audit
- Identification of audit participants
- Identification of activities audited
- Audit results
- Description of items requiring corrective action
- Due dates for completion of corrective actions and/or audit response
- Means for audit response (in writing)

If the audit report indicates corrective action is required, the corrective action will be undertaken and completed on schedule. If required, all personnel are empowered to stop work on the project pending resolution.

Response to the audit report shall be in writing. The response shall clearly state the corrective action taken or planned. If all corrective actions have not been completed prior to issuance of the audit response, a scheduled date for completion shall be provided. It is noted that all requests for corrective action must be addressed to the satisfaction of the QA/QC Officer.

The auditors through written communication, re-audit, or other appropriate means will verify completion of corrective action. After acceptance and verification of corrective actions, an audit closure report will be issued to the same individuals who received the audit report.

## 3.4 TRAINING

The A&A personnel, and others working on this project will be properly trained and qualified to perform the tasks to which they are assigned. A documented briefing of team members will occur prior to commencement of work. The team members will be given instructions specific to this project covering the following areas:



WLLFOIA4312 - 001 - 0046453

- Organization and lines of communication and authority
- Description of the work areas
- Overview of the Work Plan and the QAPP
- Documentation requirements
- Documentation of recurring training
- Test Procedures

## 3.5 SYSTEMATIC PLANNING OF PROJECTS

### 3.5.1 Planning

The work tasks necessary to complete a project will be performed in a planned, systematic manner. To assure adequate project planning, the Final Work Plan will be approved prior to the start of work. The Final Work Plan will specify the required data collection and records to verify that the contract commitments have been met.

### 3.5.2 Data Collection

Data collection will be performed in accordance with the Final Work Plan and the A&A Quality Assurance Project Plan. The on-site QA/QC Designee will perform a daily QA/QC review of data collection activities.

### 3.5.3 Documentation

Data collection shall be fully documented on the appropriate data records and daily project logs. All records shall be complete and as thorough as possible, legibly hand written in ink. Personnel making a change to a record shall cross out the old entry with one line, add the new information and initial and date the change. Under no circumstances shall the old entry on the original copy be scratched out, erased using white-out, erased, or otherwise removed or made illegible. When applicable, an explanation should accompany the change or correction.

### 3.5.4 Quality Control Check

All data submitted by the qualified technicians will undergo a quality control check by the QA/QC Designee. These quality control checks shall be made to assure that both the technical, operational, and quality assurance requirements have been met. The following guidelines will be used to perform the quality control checks:
Verify that the record contains:

- Project name and task description
- Name or initials of the performer
- Date of performance
- Page number if pertinent



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If pertinent, verify that the record:

- Conforms to the appropriate procedures
- Instrument calibration data (instrument identification, calibration date, certificate of calibration, etc.) of survey instruments used are current
- Completeness and adequacy of the performance and its documentation is legible/reproducible
- The completed record is accurate

If the material being checked conforms to the guidelines, the individual performing the quality control check shall sign and date the record. If the material is rejected, it shall be handled in one of two ways:

- Discuss and correct minor deviations with responsible personnel resulting in subsequent acceptance.
- If discussion and correction described above is not effective, initiate corrective action procedures in the form of an A&A Nonconformance Report, Form EPA/HOA-003

## 3.6 PROJECT-SPECIFIC QUALITY DOCUMENTATION

Project quality objectives are that:

- Scientific data will be of a quality to meet scientific and legal scrutiny
- Data will be gathered or developed in accordance with procedures appropriate for the data's intended use
- Data will be of known or acceptable precision, accuracy, completeness, representativeness, and comparability as required for this project

### 3.6.1 Mechanisms To Achieve Quality Objectives

Fundamental mechanisms that will be employed to achieve these quality goals can be categorized as prevention, assessment, and correction. These include:

- Prevention of errors by planning, documented instructions and procedures, and careful selection and training of skilled, qualified personnel
- Quality assessment through a program of audits and surveillance to supplement continual informal review
- Correction to prevent recurrence of conditions adverse to quality

A Quality Assurance Project Plan (QAPP), project-specific quality documentation, will be developed for each project. The QAPP is prepared in direct response to these goals. This plan describes the QA Program to be implemented and the QC procedures to be followed during the course of this project.

The QAPP describes the project organization structure and specifies the procedures, documentation requirements, sample custody requirements, acceptance criteria, audit and corrective action provisions, etc., to be applied to provide confidence that all operations and



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activities meet the intent of the Quality Management Plan.

### 3.6.2 Quality Assurance Objectives For Data

QA objectives for data are discussed in the Data Quality Objectives section. Definitions for precision, accuracy, completeness, representativeness, and comparability are as follows:

- Precision: A measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Precision is best expressed in terms of the standard deviation. Comparison of replicate values is best expressed as the relative percent difference (RPD). Various measures of precision exist depending upon the "prescribed similar conditions."
- Accuracy: The degree of agreement of a measurement (or an average of replicate measurements), X, with an acceptable reference or true value, T, usually expressed as the difference between the two values, X-T, or the difference as a percentage of the reference or true value, 100 (X-T)/T, and sometimes expressed as a ratio, X/T. Accuracy is a measure of the bias in a system.
- Completeness: A measure of the amount of valid data obtained from a measurement system compared to the amount that is expected to be obtained under correct normal conditions.
- Representativeness: Expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental concern.
- Comparability: Expresses the confidence with which one data set can be compared to another.

## 3.7 PROJECT AND DATA ASSESSMENTS

### 3.7.1 Data Verification

Numerical analyses, including manual calculations, and computer modeling and data plotting will be documented and subjected to quality control review and peer review. Records of numerical analyses will be legible and complete enough to permit reconstruction of the work by a qualified individual other than the originator. Reduction, validation, and reporting of data collected will be performed in accordance with the QAPP.

1. Calculate QC data before completing other calculations and before reporting data
2. Calculate analysis results and complete data sheets; sign and date each page
3. Request that another analyst or supervisor approve the notebook data sheets by formal checking
4. Record data on project data summary sheets as necessary; initial and date forms
5. File instrument charts in appropriate data files; enter required information on form
6. Enter QC data on appropriate forms and charts



WLLFOIA4312 - 001 - 0046456

### 3.7.2 Data Validation

Data will be generated in accordance with the project-specific Work Plan. This data will be validated by review of the project documentation to check that all forms specified in the Work Plan and QAPP have been completely and correctly filled out and that documentation exists for the required instrument calibration. This documentation will be considered sufficient to provide that proper procedures have been followed during these activities.



WLLFOIA4312 - 001 - 0046457

# 4. PERSONNEL QUALIFICATION AND TRAINING

Auxier & Associates, Inc. management will review written statements of qualification and resumes to establish personnel capabilities and ability to perform the assigned tasks. If comparison of personnel qualifications, (including education, experience, and training) do not fulfill the requirements of the position description to meet project needs, appropriate training including "read and study" and "on-the-job" training will be performed and documented, or other appropriately qualified individuals will be assigned to perform the task.

The A&A Project Manager or designated alternate shall review all personnel qualifications and determine the type of training or experience required to ensure that an individual is qualified to perform the work. This review will be documented on the A&A Review of Personnel Qualification, Form SUP-002. Personnel records shall be maintained in the quality assurance record file and shall include: a record of the initial qualifications, documentation of review by the Project Manager or designated alternate, and acceptance of current qualifications or the need for additional training and a record of the completion of training.

Project management shall monitor the performance of individuals involved in activities affecting quality and shall determine if there is a need for retraining or replacement. Retraining or replacement of individuals will be initiated immediately upon identification of the need for such actions. Retraining shall be documented. The following guidelines shall be used to determine the proficiency and ability of the workers assigned to this project.

## 4.1 QUALIFICATION REQUIREMENTS

- Physically capable of performing the work tasks
- Demonstrated capability to perform the specific function in accordance with approved procedures
- Familiarity with technical aspects of the equipment and procedures, and capability to verify that the equipment is in proper working condition

## 4.2 CAPABILITY DEMONSTRATION

The A&A Project Manager or designated alternate shall determine the type of training or experience required to determine if personnel are qualified to perform the specific tasks. The individual workers shall review the approved Final Work Plan and demonstrate their understanding of the plan, as indicated by signature on the A&A Training Record, Form SUP-001.

## 4.3 SUPPORT PERSONNEL

The minimum number of personnel will be used to support the radiological survey efforts. All support personnel will be trained on the applicable hazards on which they are working. This training shall be documented on the A&A Training Record Form SUP-001. All support personnel involved in this project shall be monitored for internal radiation exposures, and internal exposure if deemed necessary.



WLLFOIA4312 - 001 - 0046458

# 5. PROCUREMENT OF ITEMS AND SERVICES

Procurement of equipment, supplies, and services for project-related activities, which may, by virtue of their nature and/or intended use, directly affect the quality of the survey data, is managed to assure that appropriate specifications and requirements are established and satisfied. The requesting party (usually the Project Manager, Site Manager, or a member of a survey team) is responsible for assessment/inspection of items or services and approving acceptance. Control of records related to this process is the responsibility of the Project QA/QC Officer.



WLLFOIA4312 - 001 - 0046459

# 6. DOCUMENTS AND RECORDS

## 6.1 DOCUMENTATION

Data collection shall be fully documented on the appropriate data records and daily project logs. All records shall be complete and as thorough as possible, legibly hand written in ink. Personnel making a change to a record shall cross out the old entry with one line, add the new information and initial and date the change. Under no circumstances shall the old entry on the original copy be scratched out, erased using white-out, erased or otherwise removed or made illegible. When applicable, an explanation should accompany the change or correction.

## 6.2 MANAGEMENT REVIEW OF RECORDS

A qualified staff member shall review all data records prior to submitting them in the Final Report. The same steps shall be taken with the reviews that are taken with the quality control checks.

## 6.3 MAINTENANCE OF RECORDS

A quality assurance records system for the project will be implemented and maintained. Records shall be in ink, legible, identifiable, and retrievable. The quality assurance records will be sufficiently detailed to properly reflect all work activities in the performance of this contract.

These records may be in the form of verified/authenticated data sheets, notes, graphs, comments, computations, and other graphic or written data generated in connection with the work activities. Records will be considered valid only if the individual completing the record has initialed or signed and dated the record. If revisions or changes to the quality assurance records are required, the changes will be made to the original records by crossing out the old entry with one line, adding the new information and initialing and dating the change.

The Project Manager, or designated alternate, will be responsible for maintaining and protecting the records. The records will be maintained on site with the project files. File access will be limited to project personnel and authorized contract personnel. At the completion of the project, the Project Manager, or designated alternate, will submit all project Quality Assurance records to client representatives.

## 6.4 RECORDS DISPOSITION

Designated personnel will receive project records at the various storage areas. Designated personnel will check that incoming records have proper identification for filing, are legible, and are in suitable condition for storage. Only the designated personnel will perform indexing and filing of records. For the project file, the individual file folders will be divided into appropriate categories based on content, and numbered and filed sequentially within each category.



WLLFOIA4312 - 001 - 0046460

A numbered index for the project files will be prepared and maintained. The index will list the individual file folders and identify the records therein to facilitate locating the records. The index will be kept in a separate folder at the front of the file. If appropriate, information on project material not stored in the project files should be included with the index.

Record storage in the project files will utilize facilities that provide a suitable environment to minimize deterioration or damage and that prevent loss. The facilities will, when possible, have controlled access and will provide protection from excess moisture and temperature extremes. Records will be secured in binders, placed in folders or envelopes, or otherwise secured for storage in containers (e.g., steel file cabinets).

Storage systems will provide for the prompt retrieval of information for reference or use outside the storage areas. Sign-out sheets will be maintained so that a record of files removed is available. All original records will be sent to A&A for storage in the Knoxville project files.



WLLFOIA4312 - 001 - 0046461

# 7. COMPUTER HARDWARE AND SOFTWARE

Analysis activities will be performed in a planned and controlled manner. Performance responsibility ultimately rests with the Project Manager. Prior to initiating the activities, the Project Manager will discuss the scope of the work, contractual and regulatory requirements, and applicable QA/QC procedures with assigned personnel. The QA/QC Officer may perform these oversight duties at the request of the Project Manager.

To provide evidence of satisfactory work performance and the basis for information transmitted externally, analyses and their results will be completely documented and checked. Documentation may include calculations, computer programs, logs, drawings, and tables.

## 7.1 CALCULATIONS

Calculations should be legible and in a form suitable for reproduction, filing, and retrieval. Documentation should be sufficient to permit a technically qualified individual to review and understand the calculations and verify the results.

Calculations should be performed on standardized spreadsheets of Microsoft EXCEL. The use of Internet service calculators deemed to be reliable by the project manager is acceptable. All calculation pages will be individually identified. The spreadsheet should provide spaces for the originator's name and date of work, the checker's name and date, calculation subject, project name, and sheet number. All of this information should be completed for each sheet.

Calculations should, as appropriate, include a statement of calculation intent, description of methodology used, assumptions and their justification, input data and equation references, numerical calculations including units, and results. Input data may include:

- Results of field and laboratory testing or calculations
- Information obtained from external personnel or literature and site data tests

At the end of the calculations, the results should be summarized if this will provide clarity. Calculations shall be verified as specified in Section 7.5, Calculation Checking.

## 7.2 COMPUTER PROGRAMS

Computer spreadsheets used for analysis should be documented and verified in accordance with applicable requirements as specified in Section 7.6, Computer Program Input Checking. Spreadsheets shall be password controlled. Computer output will be dated and clearly identified as to contents. Sets of output should be labeled with project name, program used, analysis title, and the user's name.

## 7.3 LOGS, DRAWINGS AND TABLES

The results of analysis activities may be presented in logs, drawings, and tables of various forms. The format of logs and tables will be governed by the information to be presented. Drawing or figure number and appropriate title will uniquely identify drawings. References to other drawings and sources of information will be provided as necessary.



WLLFOIA4312 - 001 - 0046462

## 7.4 ANALYSIS VERIFICATION

All calculations, computer program input, logs, drawings, and tables should be formally checked using the standard process outlined in the following sections.

## 7.5 CALCULATION CHECKING

Assignments for checking calculations will be made or approved by the Project Manager or QA/QC Officer. An individual(s) other than the person(s) who performed the original work or specified the method or input parameters to be used will perform verification. The individual(s) selected will have technical expertise in the calculation subject.

It is emphasized that a numerical check is not sufficient. The checker is responsible for every item on every sheet, including the completion of the title block and page numbers.

To properly check calculations the following guidelines are recommended but not necessarily required:

- The originator supplies the designated checker with a machine copy of the calculations. Originals should not leave the originator's possession until they are ready for final checker signing
- The checker marks the calculation copy with a yellow marker for all items approved
- If the checker disagrees, for any reason, the checker crosses through the item with a red marker and writes the recommended correction or comment above the item
- The checker initials and dates all pages
- The originator corrects, or "scrubs," the calculation originals so they agree with the checked copies. A one-to-one correspondence between the originals and checked copies must exist
- The originator corrects, or "scrubs," the calculation originals so they agree with the checkprints. A one-to-one correspondence between the originals and checkprints must exist
- The originator gives the originals and checkprints to the checker who compares them to verify agreed-to corrections have been made
- When the checker is satisfied, he signs and dates the originals
- Checkprints are maintained in the project files.

## 7.6 COMPUTER PROGRAM INPUT CHECKING

Computer input should be formally checked using the standard process outlined in 7.5 Calculation Checking, above. A single exception to this process is that the checking may be performed on the input originals. The verification will include a conceptual review of the program itself based on the problem being solved, a review of the computer model employed, a check that the program has been verified, and a formal check of the input data.



WLLFOIA4312 - 001 - 0046463

## 7.7 DRAWINGS

Drawings should be checked like calculations using yellow and red markers. Checkprints of the same drawing will be marked to show progression of the checking process. If a drawing is revised, the entire checking process will be repeated for the revised areas only. A new check print will be prepared.

## 7.8 TABLES

All final tables presenting information, data, or the results of analyses should be checked using the standard process for calculations. Checkprints of the same table will be marked to show progression of the checking process.



WLLFOIA4312 - 001 - 0046464

# 8. PLANNING

The Quality Assurance Program Plan (QAPP) for a project governs the performance of work to ensure that the data collected are meaningful, valid, defensible, and can be used to achieve the project objectives. This plan includes all the essential elements of a QAPP as defined in EPA's Guidance for Quality Assurance Project Plans (EPA 2002).



WLLFOIA4312 - 001 - 0046465

# 9. IMPLEMENTATION OF WORK PROCESSES

To provide evidence of satisfactory work performance and the basis for subsequent activities, the results of field investigations will be completely documented. Whenever possible, information will be recorded on a standardized form. Documentation will include a standard laboratory notebook dedicated to project activities, test and survey data forms, monitoring equipment installation records, photographs, and chain-of-custody forms as applicable.

The Site Manager shall be the central collection point for field records. The Site Manager or designated survey team member shall review all submitted forms for completeness and accuracy. The initials and date of the Site Manager or designee performing this QA/QC check shall be included on the form.

Members of the survey team working in field operations will keep a standard laboratory notebook dedicated to project activities, either by using the laboratory notebook or a Field Activity Daily Log (Figure 1). Items to be included in the records, as appropriate, are:

- Project identification
- Field activity subject
- Field data and field calculations
- Ancillary information pertinent to the project
- Description of daily activities and events- General work activity, unusual events, and progress or problems
- Changes to plans and specifications
- Action Items
- Communication with the client or others
- Safety Topics Discussed
- Records of A&A personnel on site

The Site Manager will review laboratory notebooks dedicated to project activities and copies may be routed to other members of the project staff as needed. If laboratory notebooks are not submitted as required, it is the responsibility of the Site Manager, or designee, to contact the survey team members.

As part of field activities, a photographic record or alternately a digital image record (referred to inclusively as photographs below) should be prepared of standard field activities. Photographs are not required otherwise, except to document unusual activities, setups, or events. Photographs should be in color. As examples, photographs should be taken of general site layouts, placement of equipment, and installations, sampling sites, and field testing.

Photographs are to be identified by the project name, date taken, and a brief description. This may be done individually on the back of each photograph or in an album in which the photographs are mounted. Album photographs must be labeled with individual descriptions and



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dates taken. The client will be notified prior to photographs being taken. Where activities are under way on private or public property, permission should be obtained before pictures are taken.



WLLFOIA4312 - 001 - 0046467

# 10.ASSESSMENT AND RESPONSE

A quality assurance audit may be performed at any time during the project if the A&A Project Manager or QA Designee deems one to be needed. Quality Assurance records will be evaluated and reviewed by the QA Designee at the end of the project.



WLLFOIA4312 - 001 - 0046468

# 11.QUALITY IMPROVEMENT

A&A implements continuous quality improvement through identification of nonconformances. Nonconforming items and activities are those, which do not meet the project requirements, procurement document criteria, or approved work procedures. Nonconformances may be detected and identified by:

- Project Staff: During the performance of field investigation and testing, performance of field inspections, and preparation and verification of numerical analyses
- Laboratory Staffs: During the preparations for and performance of laboratory testing, calibration of equipment, and QC activities
- QA/QC Officer: During the performance of audits and other quality assurance activities.

The personnel identifying or originating will document each nonconformance affecting quality. For this purpose, a Nonconformance Report form (Figure 4), will be used for documentation of a non-conformance issue and this documentation should include:

- Identification of the individual(s) identifying or originating the nonconformance
- Description of the nonconformance
- Required approval signatures
- Method(s) for correcting the nonconformance (corrective action) or description of the variance granted
- Schedule for completing corrective action

Documentation in the form of the Nonconformance Report should be made available to project management and the QA/QC Officer. It is the responsibility of the Project Manager, Site Manager, and/or QA/QC Officer to then notify appropriate personnel of the nonconformance.

The customer shall be notified in writing of all nonconformances identified. The Project Manager, laboratory management, and/or the QA/QC Officer to determine the cause and appropriate changes to be instituted in project requirements and procedures to prevent future recurrence will evaluate any recurring nonconformances. When such an evaluation is performed, the results will be documented.



WLLFOIA4312 - 001 - 0046469

# 12.REFERENCES

EPA 2002 Guidance for Quality Assurance Project Plans (QA/G-5) EPA/240/R-02/009 United States Environmental Protection Agency, Office of Information, Washington, DC. December 2002.



WLLFOIA4312 - 001 - 0046470

# APPENDIX A: TERMS AND DEFINITIONS

**Assessment** - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

**Audit (quality)** - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

**Data quality assessment** - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

**Design** - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

**Environmental conditions** - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

**Environmental data** - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

**Environmental data operations** - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

**Environmental programs** - work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

**Environmental technology** - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

**Graded approach** - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

**Independent assessment** - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.



WLLFOIA4312 - 001 - 0046471

**Inspection** - examination or measurement of an item or activity to verify conformance to specific requirements.

**Management** - those individuals directly responsible and accountable for planning, implementing, and assessing work.

**Management system** - a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

**Management systems review** - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

**Objective evidence** - any documented statement of fact, other information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

**Organization** - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

**Peer review** - a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.

**Performance evaluation** - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

**Process** - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

**Quality** - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

**Quality assurance (QA)** - an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

**Quality assurance project plan** - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

**Quality control (QC)** - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

**Quality improvement** - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker



WLLFOIA4312 - 001 - 0046472

recommendations with timely management evaluation and feedback or implementation.

**Quality management** - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to the quality system.

**Quality management plan** - a document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

**Quality system** - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.

**Readiness review** - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

**Record** - a completed document that provides objective evidence of an item or process. Records may include photographs, drawings, magnetic tape, and other data recording media.

**Self-assessment** - assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

**Specification** - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

**Standard operating procedure (SOP)** - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

**Supplier** - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

**Surveillance (quality)** - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

**Technical review** - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

**Technical systems audit** - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.



WLLFOIA4312 - 001 - 0046473