

Quality Management Plan

January 2017

U. S. Environmental Protection Agency

Region III

Land and Chemicals Division

John A. Armstead, Director

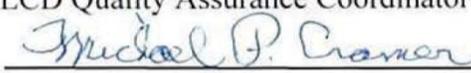
Catherine Libertz, Deputy Director

EPA Region III – Land and Chemicals Division

Quality Management Plan

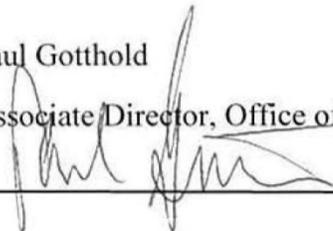
Concurrences and Approvals

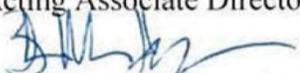
CONCURRENCE

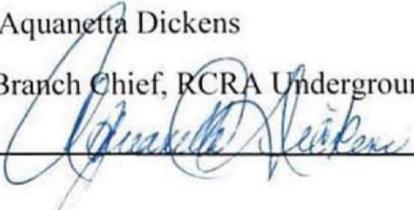
NAME Michael P. Cramer
TITLE LCD Quality Assurance Coordinator
SIGNATURE 

NAME Luis Pizarro
TITLE Associate Director, Office of Remediation
SIGNATURE 

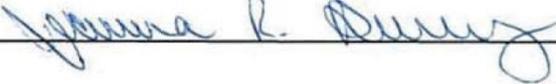
NAME Carol Amend
TITLE Associate Director, Office of RCRA Programs
SIGNATURE 

NAME Paul Gotthold
TITLE Associate Director, Office of Pennsylvania Remediation
SIGNATURE 

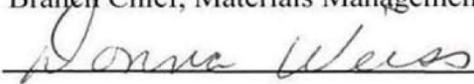
NAME Zelma Maldonado
TITLE Acting Associate Director, Office of Toxics and Pesticides
SIGNATURE 

NAME Aquanetta Dickens
TITLE Branch Chief, RCRA Underground Storage Tanks
SIGNATURE 

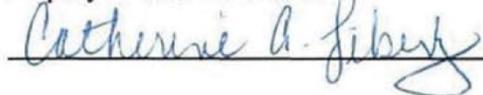
NAME Fatima El Abdaoui
TITLE Branch Chief, Pesticides and Asbestos
SIGNATURE 

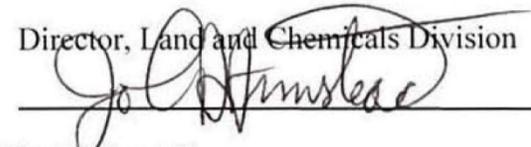
NAME Jeanna R. Henry
TITLE Branch Chief, Waste Programs Branch
SIGNATURE 

NAME Stacie Pratt
TITLE Branch Chief, Toxics Program Branch
SIGNATURE 

NAME Donna Weiss
TITLE Branch Chief, Materials Management
SIGNATURE 

APPROVAL FOR THE LAND AND CHEMICALS DIVISION

NAME Catherine Libertz
TITLE Deputy Division Director
SIGNATURE 

NAME John A. Armstead
TITLE Director, Land and Chemicals Division
SIGNATURE 

APPROVAL FOR EPA Region III

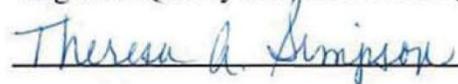
NAME Theresa A. Simpson
TITLE Regional Quality Assurance Manager
SIGNATURE  1/3/17

Table of Contents

SECTION A: LCD QUALITY SYSTEM FOUNDATION	1
A.1 Introduction	1
A.1.a Principal Components of the LCD Quality System	1
A.1.b Documentation of Quality Systems	2
A.1.b.1. LCD Quality Management Plan (QMP)	2
A.1.b.2 Quality Assurance Plans (QAPrP and QAPP)	3
A.2 LCD Organization	4
A.3 Quality System Roles and Responsibilities.....	5
A.3.a LCD Director.....	5
A.3.b LCD Quality Assurance Coordinator.....	5
A.3.c LCD Project Officers.....	6
A.3.d Regional Quality System Components	7
A.3.d.1 Regional Quality Assurance Manager	7
A.3.d.2 OASQA Quality Assurance Team	7
A.4 Communication	7
A.5 Dispute Resolution	8
A.6 Resources for LCD’s Quality System	8
SECTION B: PLANNING.....	8
B.1 Program-Level Planning.....	9
B.2 Project-Level Planning	9
B.3 Documentation and Approval for Quality Assurance Project Plans (QAPrP, QAPP).....	10
B.3.a Program Quality Assurance Project Plan (QAPrP)	11
B.3.b Project-Specific Quality Assurance Project Plan (QAPP)	12
B.4 Secondary Use of Environmental Information or Data.....	13
B.5 Information Quality Guidelines.....	14
SECTION C: IMPLEMENTATION OF WORK PROCESSES	14
C.1 Program Implementation and Governance (QMP/QAPrP).....	14
C.2 Program/Project Quality Assurance Implementation.....	15
C.2.a Quality Assurance Program/Project Plans.....	15
C.2.b Standard Operating Procedures	15
C.2.c Inspection and Oversight of Facilities and Work Processes.....	16

SECTION D: EVALUATION.....	16
D.1 Assessment Tools.....	16
D.1.a Internal Quality System Assessments	16
D.1.b External Quality System Assessments	17
D.2 Technical Systems Audits	18
D.3 Data Verification and Validation	18
D.4 Data Quality Assessment	19
D.5 Peer Review	19
D.6 Quality Improvement	20
SECTION E: INFRASTRUCTURE.....	20
E.1 Qualifications and Training	20
E.1.a LCD QA Training Requirements.....	20
E.1.b. Courses	21
E.1.c. Documentation of Training.....	21
E.2 Procurement and Financial Assistance	21
E.2.a Procurement – Contracts.....	21
E.2.a.1 Small Purchases	22
E.2.b Financial Assistance	22
E.2.b.1 Grants and Cooperative Agreements	22
E.2.b.2 Interagency Agreements	23
E.2.b.3 Evaluation of Deliverables	23
E.3 Documentation and Records Management.....	24
E.4 Computer Hardware and Software	24
E.4.a Roles and Responsibilities	25
E.4.b LCD Data Systems	25
E.4.c Data Standards	26
APPENDIX 1: Programs Covered by the LCD Quality System	27
APPENDIX 2 Table E.1. Core Quality Assurance Training Courses	28
REFERENCES.....	29

FIGURES

Figure 1 Region III Land and Chemicals Division Organizational Chart 4
Figure 2 LCD QA/QC Review and Approval Process 11

LIST OF ABBREVIATIONS

Abbreviation Meaning

AHERA	Asbestos Hazard Emergency Response Act
ASHAA	Asbestos School Hazard Abatement Act
CERCLA	Comprehensive Environmental Compliance Response, Compensation and Liability Act
COR	Contracting Officer's Representative
CSB	Computer Services Branch
DQO	Data Quality Objectives
EAID	Environmental Assessment and Innovation Division
ECAB	Enforcement Compliance Assistance Branch
ECMS	Enterprise Content Management System
EPA	U.S. Environmental Protection Agency
FAR	Federal Acquisition Regulations
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FTTS	FIFRA/TSCA Tracking System
GAO	General Accounting Office
GLP	Good Laboratory Practice
IA	Interagency Agreements
IQG	Information Quality Guidelines
ISB	Information Services Branch
MOU	Memorandum of Understanding
LCD	Land and Chemicals Division
NESHAP	National Emissions Standards for Hazardous Air Pollutants
OASQA	Office of Analytical Services and Quality Assurance
OECEJ	Office of Enforcement, Compliance, and Environmental Justice
OEI	Office of Environmental Information
OES	Office of Environmental Services
OIG	Office of Inspector General

Abbreviation Meaning

OPM	Office of Personnel Management
ORC	Office of Regional Counsel
OSWER	Office of Solid Waste and Emergency Response
PCB	Polychlorinated Biphenyl
PE	Performance Evaluation
QA	Quality Assurance
QAC	Quality Assurance Coordinator
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QAPrP	Quality Assurance Program Plan
QAT	Quality Assurance Team
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Assessment
RCRA	Resource Conservation and Recovery Act
RQAM	Regional Quality Assurance Manager
RQC	Regional Quality Council
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
SSTS	Section Seven Tracking System
TSA	Technical Systems Audit
TSCA	Toxic Substances Control Act
USACE	United States Army Corps of Engineers

SECTION A: LCD QUALITY SYSTEM FOUNDATION

A.1 Introduction

EPA's overarching mission is to protect human health and the environment. While accomplishing its mission, EPA utilizes environmental information from a variety of sources. The primary goal of LCD's Quality System is to ensure that all environmentally-related data activities performed by or for the Division will result in the production of data that is of adequate quality to support specific decisions or actions. Anyone in LCD who is directly or indirectly involved with environmental data collection activities has responsibility for ensuring data quality. This includes staff, supervisors, program managers and senior managers.

The Regional Quality Management Plan (QMP) describes the quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. The Land and Chemicals Division (LCD) QMP describes the quality control activities for environmental information collection and/or use for the statutes under its responsibility, including the Toxic Substances Control Act, Resource Conservation and Recovery Act, Clean Air Act, Federal Insecticide, Fungicide, Rodenticide Act, etc. and is consistent with the requirements found in the [EPA Quality Manual for Environmental Programs \(CIO2105-P-01-0\), May 2000](#) and [EPA Order Policy and Program Requirements for the Mandatory Agency-Wide Quality System \(CIO 2105.0\)](#). A full list of LCD's programs are provided in Appendix 1.

A.1.a Principal Components of the LCD Quality System

The Region III QMP mandates that a Quality System be created and implemented by each division, and a variety of tools and procedures which are employed for planning, implementing, and evaluating the LCD Quality System are described below. These tools ensure uniform implementation of QA requirements for all of LCD's environmental data collection activities. Successful implementation of LCD's Quality System requires a consistent and graded approach, with QA practices implemented in a manner appropriate to the complexity of the environmental data collection activity and the intended data use. Systematic planning to accomplish the data quality objectives for specific activities is described in more detail in Section B.

The principal components of the LCD Quality System at the program and project level, and are listed below:

Program Level

- Quality Management Plan
- Quality Assurance Program Plans
- QA Annual Report and Work Plans
- Quality System Assessments
- Training Plans
- Information Quality Guidelines

Project Level

- Data Quality Objectives
- Quality Assurance Project Plans
- Standard Operating Procedures
- Data Quality Assessments
- Pre-Dissemination Reviews

A.1.b Documentation of Quality Systems

A.1.b.1. LCD Quality Management Plan (QMP)

The LCD QMP subscribes to the [Region III Quality Policy](#) which is reproduced below:

It is Region III policy that all environmental data and information collected and/or used in the process of decision-making are of known and documented quality, suitable for its intended use, with all aspects of collection and analysis thoroughly documented; such documentation being verifiable and defensible. This policy applies to all data collected under environmental operations and environmental technology activities performed directly by or for the Region. This includes all Federal, state, tribal and local partners under interagency and financial assistance agreements; contractors funded by EPA; regulated entities and potentially responsible parties.

The Regional Administrator, Senior Leadership and managers ensure that adequate resources (intramural and extramural money, travel and training funds, and personnel) are allocated to achieve the Region's quality policy.

In conformance with the Region's quality policy, LCD's Quality System includes the following activities involving environmental information and/or data and the Division's management will ensure that adequate resources are available:

- Characterize and evaluate the states and/or conditions of environmental or ecological systems and the health of human populations;
- Characterize and evaluate chemical and physical constituents in environmental and ecological systems and their behavior in those systems. Including exposure assessment, transport and fate;
- Establish the ambient conditions in air, water, sediment and soil in terms of chemical and physical properties;
- Determine and characterize hazardous and toxic wastes in the environment and establish their relationships with and impact on human health and ecological systems;
- Evaluate environmental technology for waste treatment, storage, remediation and disposal, pollution prevention, and pollution control;
- Map environmental processes and conditions, including remediation-based institutional controls;
- Support enforcement and/or compliance monitoring efforts;
- Develop or evaluate methods for use in the collection, analysis and utilization of environmental data.

The QMP shall be reviewed and concurred on by all managers within the Division, and approved for implementation by the LCD Division Director and Deputy Division Director. Final approval of this plan shall be granted by the Regional Quality Assurance Manager (RQAM). The LCD QMP shall be reviewed on an annual basis and updated, as necessary, by the LCD Quality Assurance Coordinator (QAC). Approval of this plan is valid for a period up to five years.

Minor organizational and policy changes shall be documented in the LCD QA Annual Report and Work Plan. Where there are substantial organizational or policy changes that impact the Division's Quality System, the QMP shall be updated and resubmitted to the RQAM for review and approval.

A.1.b.2 Quality Assurance Plans (QAPrP and QAPP)

Quality systems apply to all activities where data is collected and/or used for decisionmaking. This includes both internal program activities and activities that are undertaken by our external partners who are funded by EPA extramurally appropriated funds. Recipients of grants, cooperative agreements, contracts and IAs that involve the use of environmental data must develop and implement QA policies or practices that are sufficient to produce data of adequate quality to meet program objectives.

These policies and practices shall be documented in a Program QMP, or equivalent document and an associated Quality Assurance Plan (QAPP). A QMP is defined as a document that describes a quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. See [Page A-3 of EPA Requirements for Quality Management Plans, March 2001](#).

The QAPP can exist in two basic forms: (1) a Program QAPrP (modified, as needed, for specific data collection project(s), or (2) a Project-specific QAPP prepared for a particular data collection activity.

The purpose, structure and implementation of a program QAPrP is outlined in [Region 9's Guidance for Quality Assurance Program Plans](#) which has been adopted by Region 3. The QAPrP is a document describing in comprehensive detail the necessary decisions and decision criteria to be used by an overall regulatory program and is supported by a quality system. A regulatory environmental program is considered to be a series of activities that are based directly or indirectly on an act of Congress and defined in regulations promulgated by EPA, state, or tribal governments. The QAPrP is intended to define and document policy for the type and quality of data needed for program level environmental decision-making and to describe the methods required for collecting, analyzing, and assessing data to support those decisions. Program activities are usually of a recurring nature, although some specific activities may not be periodic. For example, there may be on-going water monitoring, but sampling locations and frequency might change from year to year.

For externally funded programs, the Program QMP and its associated Program QAPrP will be reviewed for minor changes annually or as directed, in accordance with [the appropriate guidance document](#)¹ for each program (available on LCD's QA/QC Sharepoint site). Both the QMP and the QAPrP are required to be updated on a 5-year cycle and revisions to the approved QAPrP shall be documented in a second or subsequent revision or an addendum.

¹ Electronic copies of LCD program guidance documents can be found on [LCD's QA/QC SharePoint site](#).

For site-specific projects the QAPP outlines and provides documentation for the sampling network design, generation of appropriate data quality indicators, selection of measurement and analytical methodologies, standard operating procedures, and other considerations outlined in Section B of this document. Approval responsibility for both the Program QAPrP and the site-specific QAPP lies with the LCD Project Officer.

A.2 LCD Organization

LCD is one of five divisions and six program offices in Region III. The Division is composed of the Immediate Office of the Director and Deputy Director and four program offices. The program offices are the Office of Remediation, Office of Pennsylvania Remediation, the Office of RCRA Programs, and the Office of Toxics and Pesticides. The Office of Toxics and Pesticides is further divided into two branches which are the Toxics Programs Branch and Pesticides and Asbestos Programs Branch. The Office of RCRA Programs is further divided into the Materials Management Branch, the RCRA Waste Branch, and the RCRA Underground Storage Tank Branch. The current LCD organization is shown below in Figure 1.

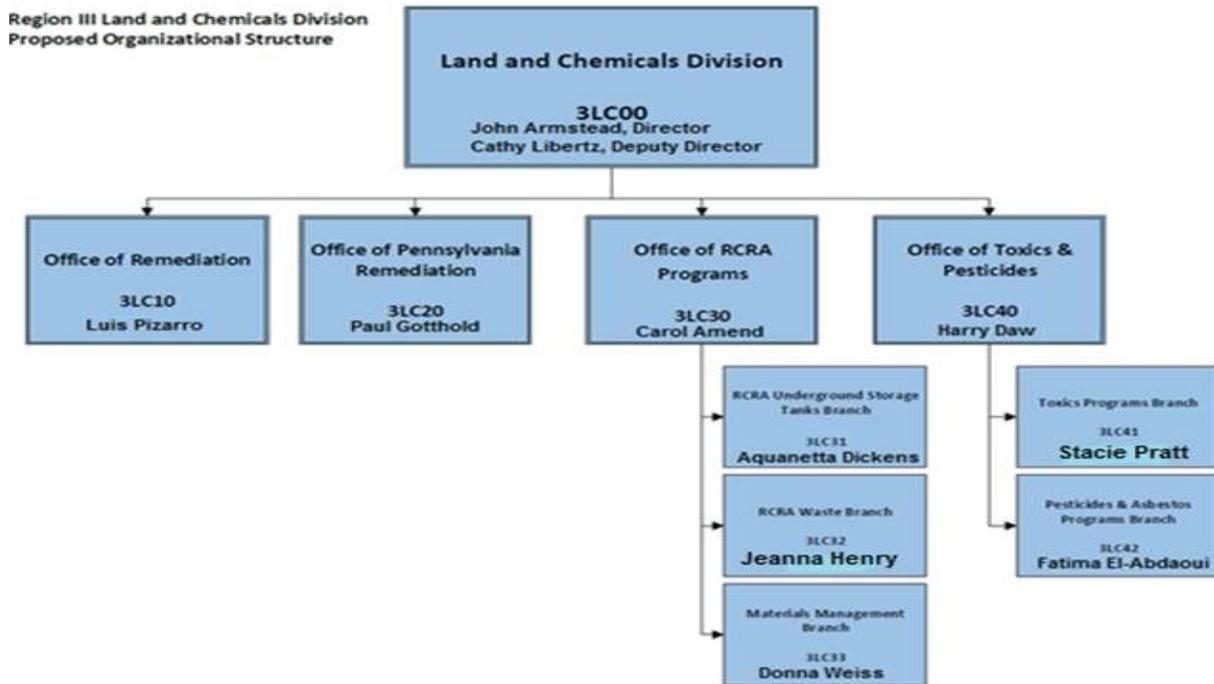


Figure 1 Region III Land and Chemicals Division Organizational Chart

Because the Region employs a decentralized approach in the implementation of its Quality Management System, LCD has assigned a Quality Assurance Coordinator (QAC) to participate on the Region's Regional Quality Council (RQC) to ensure LCD's quality system conforms to Regional policies. LCD's QAC reports directly to the LCD Division Director.

A.3 Quality System Roles and Responsibilities

As noted in the [Region III QMP](#) overall responsibility for the quality assurance program in Region III rests with the Regional Administrator and the responsibility for developing and documenting Regional Quality Assurance (QA) policies, procedures, and guidance; overseeing the implementation and assessment of the Regional Quality System; and providing QA training has been delegated to the Regional Quality Assurance Manager (RQAM). The RQAM is located in the Immediate Office of the Environmental Assessment and Innovation Division (EAID) and this office is also responsible for leading the Regional Quality Council (RQC). The structure and function of the RQC allows each level of the organization to participate in maintaining and improving the Region's Quality System.

A.3.a LCD Director

The Director of LCD has overall responsibility for the LCD Quality Management Program. This includes the development, implementation and continued operation of all QA activities. Specifically, the Director of LCD has the following responsibilities:

- Ensuring that all intramural and extramural projects involving the generation of environmental data are performed in accordance with the LCD QMP;
- Ensuring that resources needed to implement QA requirements identified and provided;
- Ensuring that adequate procedures are in place to address QA requirements in all applicable program operations, including those delegated to state agencies;
- Ensuring that quality assurance training is available for state, local and tribal governments performing environmental programs for LCD;
- Cooperating with QA reviews or audits;
- Cooperating with QA reviews or audits;
- Taking appropriate corrective actions based on recommendations contained in QA review findings reports.

A.3.b LCD Quality Assurance Coordinator

The LCD Quality Assurance Coordinator (QAC) is delegated the responsibility by the Director of LCD for ensuring that the implementation of QA requirements by LCD is in accordance with this QMP. Specifically, the LCD QAC has the following responsibilities:

- Serving as the official LCD contact for QA and Quality Control (QC) matters;
- Coordinating all LCD QA matters with the RQAM to ensure that all QA policies and methods are in accordance with current EPA National and Regional guidelines;
- Serving as the official LCD representative on the Regional RQC;
- Identifying LCD QA and QC needs, including, but not limited to, identifying, in conjunction with the LCD project officer, the need to review project-specific QAPPs or program-specific QAPrPs developed for the acquisition of environmental data by LCD grantees, identifying, arranging, and developing LCD QA training, and responding to LCD QA and QC problems or questions with the assistance of the RQAM and the OASQA Quality Assurance Team (QAT);

- Coordinating interviews and file reviews with the RQAM during QA assessments of LCD;
- Preparing and/or revising of the LCD QMP;
- Collecting LCD QA information for the RQAM for consolidation into the Region III QA Annual Report and Work Plan.

A.3.c LCD Project Officers

LCD Project Officers, RCRA Project Managers and Work Assignment Managers have primary responsibility for ensuring that environmental data generated for projects which they administer or oversee are collected in accordance with the procedures established in this QMP. LCD Project Officers include all individuals responsible for direct environmental data generation (i.e., the program itself collects samples for analysis) as well as individuals or entities who generate environmental data indirectly through the administration of permits or orders or who administer projects supported by EPA through contracts, grants or IA. LCD Project Officers fulfill this responsibility in cooperation with the LCD QAC and other Division staff, as appropriate.

Specific responsibilities of the Project Officers depend on the nature of the data collection activity and on the specific program for which data is being collected. All Project Officers will ensure that each data collection activity conducted or funded by LCD and administered or overseen by the Project Officer is done only after a QAPrP or QAPP is reviewed and approved.

Many of LCD's continuing environmental grant programs (i.e., state program grants in RCRA Subtitle C and Subtitle I, the TSCA lead program or other programs listed in Appendix I) require only a program QAPrP from the grantee. This program QAPrP is reviewed for completeness, and sent to the OASQA QAT (or other qualified entity) and to the LCD QAC by the grant Project Officer for technical review in accordance with the procedures set forth in this QMP. In some cases, qualified grant Project Officers may also perform a technical review of the program QAPrP, in addition to the other qualified reviewers.

LCD's compliance and enforcement programs frequently use the services of the Enforcement and Compliance Assistance Branch (ECAB) in the Office of Enforcement, Compliance, and Environmental Justice (OECEJ) for support with inspections, investigations and collection of environmental data. In these situations, [the program QAPrP and Standard Operating Procedures \(SOP\) of the ECAB](#) and the Region's Quality Assurance Field Activities Procedures govern the data collection activities. Any environmental data collection activities conducted using contracts or IA will be done according to an approved program QAPrP or if related to a specific project, according to the guidelines set forth in a site-specific QAPP previously reviewed by the OASQA QAT or other qualified entity. It is the responsibility of the compliance and enforcement project officer to ensure that an appropriate program QAPrP or site-specific project QAPP has been approved prior to the data collection activity.

Some LCD programs (i.e., RCRA corrective action) require site-specific project QAPPs from facilities doing site investigations or remedial activities. These QAPPs will also be sent to

the OASQA QAT (or other qualified entity) for technical review, and may also be reviewed by the technical Project Officer or other technical staff, as appropriate.

Regardless of who reviews the program QAPrP or site-specific project QAPP, the project officer is responsible for requesting that an appropriate and timely review be done, and is ultimately responsible for its approval.

A.3.d Regional Quality System Components

A.3.d.1 Regional Quality Assurance Manager

The RQAM and OASQA QAT are responsible for overseeing the implementation of the Regional QMP. Specifically, these responsibilities include:

- Reviewing and approving the LCD QMP and QMPs, QAPrPs for extramural agreements and QAPPs for site-specific projects;
- Distributing Agency QA guidance documents, policies, and procedures;
- Conducting formal reviews and assessments of QA activities within LCD in cooperation with the Regional Quality Council and the OASQA QAT, and providing the results of these reviews and assessments to the Division in the form of a report;
- Assessing Regional QA training needs, and arranging, developing and/or presenting training courses on QA topics. The assessment of LCD training needs, and the arrangement and development of training courses will be done, where appropriate, in coordination with the RQC.

A.3.d.2 OASQA Quality Assurance Team

The OASQA QAT is located within EAID, and its functions consist exclusively of review of QA documents to ensure they meet Agency standards. Specifically, their role includes:

- Providing assistance to LCD on QA and QC issues, as resources permit;
- Assisting the RQAM in conducting internal assessments of the LCD QA program;
- Assisting with technical review of QAPrPs for extramural agreements and QAPPs for site specific projects.

A.4 Communication

To be effectively implemented, the LCD QMP must not only be completed, circulated and updated, but understood by those responsible for its implementation. This will be accomplished through effective communication as well as use of Agency electronic tools such as the LCD Intranet and SharePoint sites to facilitate sharing and collaboration during the approval process.

This QMP will be made available to all individuals responsible for implementing the policies and procedures found in this document. The LCD QAC will keep the LCD Director and other managers in the Division apprised of QA issues that impact the Division's Quality System. In addition, new QA developments, policies and procedures will be made available to all affected

Division personnel, as applicable. When the QMP is revised, the new version will be made available on the [LCD Quality Assurance and Quality Control SharePoint site](#), and older versions archived.

As mentioned previously, the LCD QAC represents the Division on the Regional Quality Council (RQC) to ensure that LCD quality system policies and procedures are aligned with and express Regional policies. The RQC functions as the primary Regional group addressing QA topics that impact the entire Region. This group meets quarterly to discuss and resolve issues about QMP implementation and its impact on data quality. The RQC also discusses ways to improve the Region's Quality System.

A.5 Dispute Resolution

In order to resolve disputes related to quality assurance, the Region will strive to resolve the issue at the lowest administrative level practicable. The dispute resolution process shall begin when either disagreeing party declares an issue to be irresolvable and send written correspondence to the other party defining the disputed issue, and presents supporting arguments for the first party's position on the issue. All parties shall make every effort to resolve disputes through discussion and negotiation in consultation with the LCD QAC or LCD QACs (if another Division is involved in the dispute). Should agreement not be reached at this level, it will be directed to the RQAM. If necessary, the RQAM will work to resolve the problem with the Senior Management Representative to the RQC and ultimately the Regional Administrator or Deputy Regional Administrator. The resolving officials will document the resolution and provide it to the disputing parties.

A.6 Resources for LCD's Quality System

The level of QA resources needed for a specific program or project is determined by the relevant Division program. Since an assigned national program element for QA does not exist, most resources needed for QA are derived from a variety of program elements which utilize QA functions and services. The LCD Division Director will ensure that there are adequate resources available to successfully implement QA requirements.

SECTION B: PLANNING

The acronym **PIE** is used to describe Region III's and LCD's Quality System components. **"P"** stands for **planning**; **"I"** for **implementation**; and **"E"** is for **evaluation**. Planning is described here in Section B, Implementation is described in Section C, and Evaluation is described in Section D of this document.

While effectively planning for collection, analysis and processing environmental information and data, LCD quality planning occurs at both the program-specific and project levels, ensuring data meets programmatic and quality goals.

B.1 Program-Level Planning

LCD develops an annual action plan which is tied to the Region III Strategic Plan, the budget distribution process, and the priorities established by applicable National Program Offices. Functional areas of work defined within LCD programs are authorized by statutory reference, or by Executive direction, or by Agency direction.

LCD administers several programs in Region III and those programs covered by LCD's Quality System are described in Appendix 1. All LCD environmental data operations conducted in support of these programs are covered by this QMP, though not all require the same level of quality assurance. The appropriate guidance documents outlining the QA requirements relevant to each program are housed on [LCD's QA/QC SharePoint site](#). When initiating a new program or incorporating major statutory changes, the program shall establish the minimum quality system components required to achieve program compliance as noted in these documents.

B.2 Project-Level Planning

A systematic planning process is a mechanism for balancing conflicting demands and data quality needs to ensure that environmental data operations will effectively support decision making. [EPA's Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4, February 2006](#) describes one such process, but any other systematic planning process may be used as long as it is based on the scientific method and complies with [Chapter 3 of the EPA Quality Manual for Environmental Programs, May 2000 \(CIO 2105-P-01-0\)](#).

Elements of a systematic planning approach shall include:

- Identification and involvement of the Project Officer, sponsoring organization and responsible official project personnel, stakeholders, scientific experts (e.g., all customers and suppliers);
- Description of the project goal, objectives and questions/issues to be addressed; Identification of project schedule, budget, milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements);
- Identification of the type of data needed and how the data will be used to support the project's objectives;
- Determination of the quantity of data needed and specification on the performance criteria for measuring quality;
- Description of how, when, and where the data will be obtained, including existing data and identification of any constraints on data collection;
- Specification of needed QA and QC activities to assess the quality performance criteria (e.g., QC samples for both the field and laboratory, audits, technical assessments, performance evaluations, etc.);
- Description of how the acquired data will be analyzed (either in the field or laboratory), evaluated (i.e., QA review, validation, verification), and assessed against its intended use and the data quality performance criteria.

The Project Officer is responsible for ensuring that a systematic planning process is used and documented and that all organizations and/or parties who contribute to the quality of the environmental project or use the results are identified and participate in the planning process.

B.3 Documentation and Approval for Quality Assurance Project Plans (QAPrP, QAPP)

As mentioned above, Quality Assurance Plans (QAPP) can exist in two basic forms: (1) a program QAPrP (modified, as needed, by the user for a specific data collection project), or (2) a project-specific QAPP prepared for a particular data collection activity. LCD has embraced the “graded approach,” as defined in the program guidance documents on [LCD’s SharePoint site](#) and [Section 2.4.2 of EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5, March 2001](#). The level of detail found in a QAPrP or QAPP shall be appropriate for the nature of the work being performed and the intended use of the data.

Both Program QAPrPs and Project QAPPs undergo technical review for accuracy, completeness and compliance with programmatic guidance and these reviews are managed through LCD’s newly established QA/QC SharePoint site. The process is outlined in Figure 2 below. Generally, QAPrPs and QAPPs that are received by LCD are initially screened by the Project Officer using the revised [QA/QC checklist for Project Officers](#) and then uploaded to the LCD SharePoint site along with the checklist and the [OASQA QAT Document Request form](#) and the documents are shared with the OASQA QAT staff at R3_ESCQA@epa.gov. The SharePoint site also acts as a central repository for completed reviews. The OASQA QAT or other qualified individual(s) may use the [Region III Quality Assurance Project Plan Preparation Checklist](#), referring to the “Preparing Quality Assurance Project Plans” section. During the process, the RQAM or designee may determine that additional individuals within the Division are capable of performing QAPrP or QAPP reviews if they demonstrate that they meet the requirements noted below.

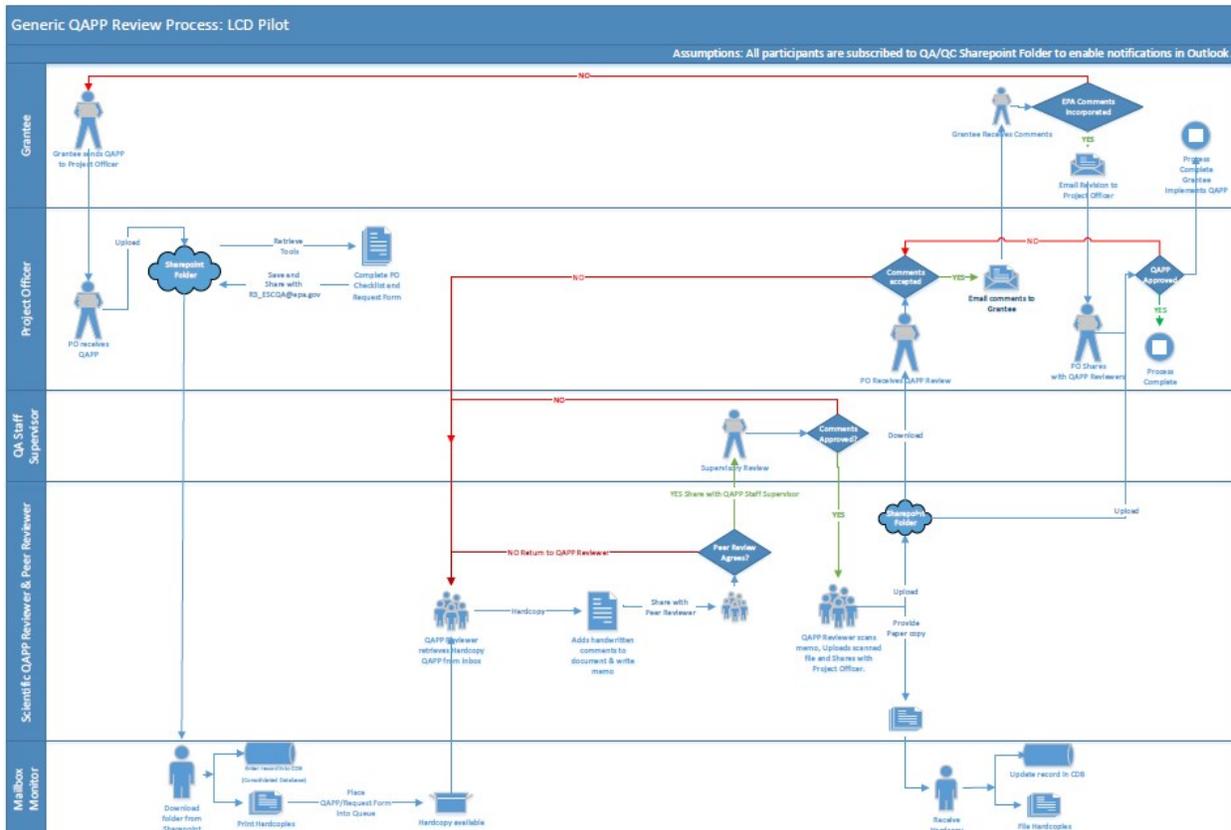


Figure 2 LCD QA/QC Review and Approval Process

As noted in Section B.3.b below, all individuals assigned the responsibility for project specific QAPP reviews shall be knowledgeable of the information presented in [Section 2.4.2 of EPA Requirements for Quality Assurance Project Plans](#) and/or [Uniform Federal Policy for Quality Assurance Project Plans \(UFP-QAPP\)](#), and have completed the Region’s required training for QAPP reviewers. These individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency programs is also required.

All individuals assigned the responsibility for program QAPrP reviews shall also have this knowledge as well as a familiarity with the programmatic guidelines pertinent to the subject of the QAPrP.

B.3.a Program Quality Assurance Project Plan (QAPrP)

For continuing environmental grants and assistance contracts or IA, a Program QAPrP may be prepared. A Program QAPrP shall adhere to the QAPrP requirements specified in Section B of this plan. The Program QAPrP shall include the elements which remain constant in the grant, contract or IA. Most Program QAPrPs will be amended by a site-specific or project-specific plan

which addresses the QA elements that are unique to that site or project. The Program QAPrP shall include the procedures being used for the preparation, review and approval of site-specific or project-specific plans. If the site-specific or project-specific plan contains analytical and/or sampling procedures that are not found in the Program QAPrP, the site-specific or project specific plan must be reviewed in accordance with the procedures in Section B.2 of this plan.

As described in Section A.3.c above, Program QAPrPs received by the Project Officer are shared with OASQA (or other qualified entity), the LCD QAC and reviewed for completeness and conformance according to the guidelines set forth in this QMP. Similarly, LCD's compliance and enforcement programs that use Program QAPrPs for their environmental data collection activities, (i.e. the approved program QAPrP for the Philadelphia, Baltimore, Norfolk and Huntington Districts of the U.S Army Corps of Engineers (USACE), frequently use the services of the Enforcement and Compliance Assistance Branch (ECAB) in the Office of Enforcement, Compliance, and Environmental Justice (OECEJ) for support with inspections, investigations and environmental data collection. As described in Section A.3.c above, in these situations, the Program QAPrP and [the Standard Operating Procedures \(SOP\) of the ECAB](#) and the Region's Quality Assurance Field Activities Procedures are used to govern the data collection activity. It is the responsibility of the compliance and enforcement project officer to ensure that an appropriate program QAPrP or site-specific project QAPP has been approved prior to the data collection activity.

The appropriateness of a Program QAPrP is determined on a case-by-case basis by the Project Officer ensuring alignment with the program guidance and in cooperation with the RQAM, LCD QAC or Quality Assurance Staff. The Project Officer shall ensure that the approved Program QAPrP is reviewed annually for changes to organization, policy, and/or procedures and updated every three to five years. Any minor changes can be appended to the original document. Substantial changes require that the document be resubmitted for review and approval.

The Project Officer is responsible for the approval of the Program QAPrP. The decision to approve or reject a program QAPrP is based on the Project Officer's technical expertise and the comments received from a qualified QAPrP reviewer which are documented on the LCD sharepoint site.

B.3.b Project-Specific Quality Assurance Project Plan (QAPP)

For a project-specific QAPP, the systematic planning process results in the development of an appropriate sampling network design, generation of appropriate data quality indicators, selection of measurement and analytical methodologies and standard operating procedures. LCD policy requires that the results of the systematic planning process be documented in a Quality Assurance Project Plan (QAPP) and approved by authorized personnel prior to implementation. The only exception to this requirement shall be for environmental projects that require immediate action to protect human health and the environment or operations under police powers. The majority of environmental data collected for LCD programs is collected by regulated facilities, grantees, contractors or other Federal Agencies. All projects and tasks involving the generation of environmental data for specific projects that are done for the Land and Chemicals Division

under a permit, order, grant, contract or IA shall have an approved QAPP in place prior to the start of data generation or use.

The project-specific QAPP shall be prepared in accordance with the [Section 2.4.2 of EPA Requirements for Quality Assurance Project Plans](#) as cited above. EPA's Office of Solid Waste and Emergency Response (OSWER) has also issued [OSWER Directive 9272.0-17](#), stating that the [Uniform Federal Policy for Quality Assurance Project Plans \(UFP-QAPP\)](#), is designated for use in Federal facility projects where environmental data are collected (e.g., CERCLA, RCRA, Brownfields). LCD endorses this policy and encourages the use of the UFP_QAPP for Federal facility and other hazardous waste projects.

Project Officers shall ensure that QAPPs are developed and approved for all projects under their authority. These QAPPs, when completed and submitted to the Project Officer, must be reviewed by a qualified person (such as the designated staff of the OASQA QAT, the project Officer (if applicable) and shared with the LCD QAC.

Regardless of who reviews the QAPP, the Project Officer is responsible for its approval. Once the QAPP has been approved via signature or approval memorandum, the Project Officer is responsible for ensuring it is implemented as written, and will include a copy in the project file and on the LCD SharePoint site. For continuous projects, the QAPP must be reviewed annually by the authorizing organization. Annual reviews shall be documented in the organization's annual report to LCD. Additionally, QAPPs must be revised and submitted to EPA for review every three to five years based on the original approval date to ensure that the documented procedures are still accurate. Revisions to the approved QAPP shall be documented in a second or subsequent revision or addendum. Sometimes the scope of the project can change, which may have the potential to affect the scope and objectives of the project, data use, or data quality. In this case the revised QAPP or addendum must be reviewed and approved in the same manner as the original QAPP. The Project Officer is responsible for ensuring all appropriate personnel receive a copy of the revised QAPP or addendum once it is approved. QAPP requirements apply to all environmental data operations conducted by Division staff or through grants, cooperative agreements, contracts, IA, and compliance orders.

B.4 Secondary Use of Environmental Information or Data

Prior to its use, environmental data collected from secondary sources shall be evaluated to ensure a level of quality that is appropriate for its intended use(s). The Project Officer is responsible for ensuring that such data collection is addressed in a project-specific QAPP, if applicable. The project-specific QAPP shall:

- Identify the types of data needed for project implementation or decision making;
- Describe the intended use of the data;
- Specify any limitations on the use of the data;
- Identify the individual(s) responsible for evaluating and qualifying the data.

For those projects which involve the compilation and use of environmental data from secondary sources exclusively (*i.e.*, there will be indirect environmental data generation performed to accomplish the project), a project-specific QAPP is still required. Per the graded

approach, the level of detail for this QAPP will differ from that for a direct environmental data operation project.

B.5 Information Quality Guidelines

The [Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA, 260R-02-008, December 2002](#), or more commonly known as Information Quality Guidelines (IQG), contain EPA's policies and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates and complements EPA's Quality System for assuring the quality of EPA's products and information. This QMP incorporates by reference all definitions, policies and procedures found in EPA's IQG.

The Division will ensure that LCD disseminated information products are presented in an accurate, clear, complete and unbiased manner. The Division will also ensure that the integrity of the LCD website will be protected from unauthorized access or revision.

SECTION C: IMPLEMENTATION OF WORK PROCESSES

The implementation of the procedures specified in this section shall ensure that all environmental data operations being conducted within LCD conform to the requirements found in the QMP, the EPA order *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* (CIO 2105-P-01-0). These procedures are currently being implemented at the program and project level.

C.1 Program Implementation and Governance (QMP/QAPrP)

The LCD QMP will be reviewed annually by the LCD QAC to ensure that the documented QA policies and procedures are current and accurate. Minor changes to the QMP will be documented in LCD's annual report. A revision to the LCD QMP will be required if there are significant policy and/or procedural changes. The revised QMP will be submitted to the RQAM for approval. After the QMP has been approved, the QAC will distribute the newly revised plan to managers and supervisors. Older versions of the LCD QMP will be removed from circulation.

Approved QMPs and their associated QAPrPs for extramural projects will be updated every five years, or whenever there are major organizational changes that impact the documented Quality System. Extramural agreement holders are required to review the QMP annually and report the outcome of the review in their annual report. If revisions are required, the revised QMP shall be resubmitted to the Project Officer for review and approval by the RQAM and shared with the LCD QAC, in accordance with the procedures specified in Section A. The Region III monthly QMP Status Report is used to document the approval status of QMPs for extramural projects.

The LCD QAC will provide the RQAM information on an annual basis to be compiled into the Region III Quality Assurance Annual Report and work plan activities projected for the coming fiscal year. The information will include a summary of the QA-related resources, training, accomplishments (*i.e.*, innovative practices, technical assessments, QMP revisions, QA guidance, technical assistance, etc.) and quality system assessment/audits that have been

conducted in the previous fiscal year. The information will also include a list of QA activities planned for the upcoming fiscal year.

C.2 Program/Project Quality Assurance Implementation

C.2.a Quality Assurance Program/Project Plans

Once final approval has been received, Project Officers shall ensure that all project personnel have a copy of the newly approved QAPrP/QAPP. The Project Officer shall also ensure that obsolete versions of the QAPrP/QAPP are removed from work areas. Verification of the changes to a QAPP shall be determined during a specific project's technical system audit. The approved QAPrP/QAPP must be implemented as prescribed. However, the QAPrP/QAPP may be modified and/or amended at any time to ensure data quality objectives for the project are met. Modifications and/or amendments to the QAPrP/QAPP must follow the appropriate submission and approval procedures outlined in Section B of the QMP.

C.2.b Standard Operating Procedures

The use of standard operating procedures (SOPs) serves as a mechanism to ensure comparability across programs and individual environmental data operations. SOPs use is encouraged as a means of ensuring that routine or repetitive activities, processes or procedures are performed consistently within acceptable timeframes and with acceptable quality. SOPs can describe both technical and administrative operational elements. SOPs will thoroughly describe steps and techniques, and will be sufficiently clear to be understood by a person with knowledge in the general concept of the procedure or process. Any limitation on the use or applicability of a specific SOP will be documented in the SOP itself.

The need for an SOP for a specific activity or operation can be identified by any staff member in the Division, and can be written by any staff member who is knowledgeable of the activity, equipment, procedure, or process to be addressed. In general, the SOP is implemented by staff that perform the activity, process or procedure to which the SOP pertains. It is the responsibility of the individual users of an SOP to follow the procedures contained in the SOP or to document any deviations. It is the responsibility of managers to ensure that specific SOP that pertain to their program operations are implemented. It is the responsibility of Project Officers to ensure that SOPs referenced in project specific QAPPs are implemented. The implementation of QA-related SOP for LCD activities is the responsibility of the LCD QAC. Implementation of SOP will be assessed through internal quality system assessments (QSA) and technical systems audits (TSA) as described in Section D of this plan.

Currently, LCD has no formal SOP for sampling and analysis, however LCD employs the SOP for field sampling according to policies set forth by OECEJ. In the event that the Division needs to create its own SOP, the EPA document, [*Guidance for Preparing Standard Operating Procedures \(SOP\), EPA QA/G-6, April 2007*](#), may be used to provide guidance on the development and use of SOP. Any SOP created will be reviewed every three years or more often, as needed.

C.2.c Inspection and Oversight of Facilities and Work Processes

Inspections occur at many types of facilities under a variety of programs administered by LCD. These inspections are primarily focused on making compliance determinations based upon facility representative interviews, facility records and documents, and inspector observations. However, samples may be collected to identify whether a potential violation exists.

The majority of sampling conducted during inspections would be considered “opportunistic” sampling. Sampling is initiated based on observations made by the inspector during the course of the inspection. If sampling is performed during the course of a RCRA Subtitle C inspection, it is normally performed in accordance with SOPs developed by the OECEJ Field Inspection Program. Less frequently, sampling and analysis may be performed by the USACE under an approved program QAPrP and sampling SOPs.

Sampling is conducted under the TSCA PCB enforcement program. This program relies on the OECEJ field Inspection Program. In addition, OECEJ uses two EPA Manuals [Verification of PCB Spill Cleanup by Sampling and Analysis” \(EPA-560/5-85-026, August 1985\)](#), and the latest revision of the [Sample Submission Procedures for the Office of Analytical Services & Quality Assurance Laboratory Branch](#). Other specialized protocols may also be used in infrequent situations.

Sampling is conducted by LCD inspectors for asbestos. Procedural guidelines for sample collection are contained in [Safety, Health & Environmental Management Program Guidelines Asbestos Procedures and Programs for Employees, April 2005](#), which is issued by EPA’s [Office of Administration, Safety, and Environmental Management Division](#).

SECTION D: EVALUATION

In order to assess the effectiveness and ensure successful implementation of its quality management system, LCD will use a coordinated system of internal and external management reviews and audits.

The Division uses a variety of tools to ensure that the procedures documented in this QMP are being implemented. These independent audits, reviews and assessments evaluate the conformance of the Division’s Quality System with the procedures described in this QMP.

In addition to the formal procedures outlined below, LCD will attempt to correct any problem with its Quality System through other, informal processes.

D.1 Assessment Tools

D.1.a Internal Quality System Assessments

LCD will help ensure the proper implementation of its QMP with respect to all of its programs through the use of internal quality system assessments (QSA). It is the goal of LCD to conduct an internal QSA on an annual basis on some program element of LCD’s environmental data collection program. More frequent review may be needed if serious deficiencies are

detected. This periodic evaluation will help ensure that the LCD Quality System is continuing to function adequately.

The assessment team will consist of the LCD QAC and at least one other designated person. The assessment team shall be familiar with the QA requirements found in EPA Order CIO 2105.0, and this QMP. The individuals should also have professional knowledge of chemical and biological principles, theories, practices and established methods. Knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency programs is also desired.

Information found in EPA's [*Guidance on Assessing Quality Systems, QA/G-3, March 2003*](#) may be used in the development of the QSA. A standard checklist, developed by the RQAM, [*EPA Region III Quality System Audit Checklist*](#), included as Appendix F in the Region's III Quality Management Plan, October 2008 may be used to help ensure that the appropriate QA requirements are evaluated. During the QSA, managers and active participants in the LCD's Quality System may be interviewed. Project files, previous audit reports and corrective action plans may also be reviewed.

Upon completion of the assessment, the assessment team shall prepare a written findings report documenting the results of the QSA to the Division's manager who is responsible for that part of the LCD environmental data collection program which was assessed. Findings may include noteworthy accomplishments and/or objective evidence of non-conformance with the Division's Quality System.

Upon receipt of the findings report, the responsible Division manager shall prepare a written corrective action plan, if needed, and submit it to the LCD QAC. The corrective action plan must identify the corrective action, responsible official(s), and the projected completion date for each finding requiring corrective action. The LCD QAC shall periodically review the status of the Division corrective action plans.

D.1.b External Quality System Assessments

Independent external assessments are conducted of the Regional Quality System, including the LCD System, by the office of Environmental Information (OEI) Quality Staff, Office of Inspector General, the Government Accountability Office or Headquarters' program office personnel. The frequency of these assessments is determined by the office conducting the Quality System Assessment (QSA). Every three years, the OEI Quality Staff conducts a QSA (or equivalent assessment) of the Region's Quality System. The QSA team consists of members of the OEI Quality Staff and at least one person from another Region or EPA headquarters program office. The scope of this assessment is determined by the OEI QSA team. The LCD QAC shall assist the OEI QSA team with logistics and scheduling of interviews with LCD personnel.

The findings of the OEI QSA are documented in a Findings Report. If corrective actions are required for any of the LCD programs, they shall be consolidated with findings from the other Regional divisions and program offices by the RQAM into a Regional corrective action plan. LCD managers are responsible for ensuring compliance with the approved corrective action plan.

D.2 Technical Systems Audits

The goal of the technical systems audit (TSA) is to determine whether environmental data operations and related results comply with the project's QAPP and other planning documents. A TSA compares the implemented activity against the documented (*i.e.*, QAPP, SOP, etc.) activity. TSA may also be used as an investigative tool when problems are suspected. It is usually project-specific, and is usually conducted in the field or laboratory. Grantees with approved QMPs may conduct TSA of their own environmental data operations.

At a minimum, each QAPP shall include the scope and frequency of TSA to be conducted during the life of the project. The QAPP shall also include the title(s) of individual(s) responsible for conducting the TSA and the procedures to be used to implement corrective actions. The QAPP reviewer shall ensure that information about TSA is documented in the QAPP. The Project Officer is responsible for ensuring the specified TSA are accomplished. The individuals conducting the TSA should be knowledgeable of the procedures being audited. These individuals should also have professional knowledge of chemical and biological principles, theories, and established methods. Extensive knowledge of the principles and practices of quality assurance and the ability to adapt these applications to Agency programs is also required.

All programs in the Region that employ environmental data operations are subject to a TSA. EPA's [Guidance on Technical Audits and Related Assessments for Environmental Data Operations, EPA QA/G-7, January 2000](#), may be used as a resource for planning, conducting, evaluating and documenting technical systems audits and related assessments. The RQAM (or designee) shall ensure that a description of applicable TSA is included in all QMP and that all QMP include the titles of the individual(s) responsible for conducting TSA.

D.3 Data Verification and Validation

Data verification and data validation are key steps in the assessment phase. Data verification is the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements. The goal of data verification is to ensure and document that the reported results reflect what was actually done. Data verification may be performed by personnel involved with the collection of samples or data, generation of analytical data, and/or by an external data verifier.

LCD has a process in place to measure the effectiveness of systems that facilities subject to RCRA corrective actions use to generate data for environmental investigations or remedial activities. LCD has an IA with the USACE, and routinely uses the USACE to provide oversight of facility data generating activities. USACE oversight includes observing and documenting that facilities follow their approved QAPP when collecting samples for analysis or when performing field measurements.

Corrective Action Project Officers will also routinely have the USACE split samples with the facility generating data through sampling and analysis at a specific site, so that the Project

Officer can verify the results obtained by the facility by comparing them to the results obtained by the USACE split sample analyses.

Data validation is an analyte-specific and sample-specific process that extends the evaluation of data beyond verification to determine the analytical quality of a specific data set. The goal of data validation is to evaluate whether the data quality goals established during the planning phase have been achieved. Data validation is typically performed by a person(s) independent of the project activity. The appropriate degree of independence will be determined on a program-specific basis. At a minimum, the individual(s) conducting the validation should not belong to the same organizational unit with immediate responsibility for producing the data set. Data quality indicators (such as precision, bias, comparability, sensitivity, representativeness, and completeness) are typically used as expressions of the quality of the data.

Personnel performing data verification and validation should have professional knowledge of chemical and biological principles, theories, practices and established methods, statistical techniques commonly used in quality control, data assessments, and data management practices. Extensive knowledge of the principles and practices of quality assurance and familiarity with the project-specific data quality indicators is also necessary. The specific procedures and title(s) of the individual(s) responsible for data verification and validation shall be included in the project's QAPP or SAP. Results of the data verification and validation should be documented and provided to the Project officer. EPA's guidance documents [*Guidance on Environmental Data Verification and Data Validation, EPA QA/G-8, November 2002*](#) and [*US EPA Contract Laboratory Program National Functional Guidelines*](#) may be used to conduct the data verification and validation processes.

D.4 Data Quality Assessment

The scope of the Data Quality Assessment (DQA) should be appropriate for the project objectives and intended use of the data. EPA's guidance [*Data Quality Assessment: A Reviewer's Guide, EPA QA/G-9R, February 2006*](#), and [*Data Quality Assessment: Statistical Methods for Practitioners, EPA QA/G-9S, February 2006*](#) may be used to conduct the DQA. The specific procedures to be followed for data quality assessments shall be included in the project's QAPP or SAP. The title(s) of the individual(s) responsible for the DQA process shall also be included in the project QAPP or SAP. The results of the DQA should be documented and provided to the Project Officer.

At a minimum, all environmental data shall be reviewed to ensure that the analytical measurement criteria specified in the approved QAPP have been achieved. Data shall be qualified in accordance with the data validation criteria specified in the approved QAPP.

D.5 Peer Review

Peer review is intended to uncover any technical problems or unresolved issues in a preliminary work product through the use of independent experts. This information is then used to revise that draft product so that the final work product will reflect sound technical information and analyses. Peer review is a process for enhancing a scientific or technical work product so that

the decision or position taken by the Agency, based on that product, has a sound, credible basis. To be most effective, peer review of a scientific and/or technical work product should be incorporated into the up-front planning of any action based on the work product – this includes obtaining the proper resource commitments and establishing realistic schedules. Peer review takes many different forms depending on the nature of the work product, relevant statutory requirements, and office-specific policies and practices. It is LCD practice that Project Officers, in consultation with their first line supervisors, senior managers and technical staff, will make the decision on whether his/her project should be peer reviewed and what level that peer review will take. When applicable, Region III follows the procedures and guidance found in [*EPA's Peer Review Handbook, 3rd Edition, EPA/100/B-06/002, 2006.*](#)

D.6 Quality Improvement

The quality assurance procedures described in this QMP establish a foundation for ensuring that data of acceptable quality for its intended use will be used to make environmental decisions. One of the goals of the LCD Quality System is to incorporate quality assurance as a critical component of all the work functions within our programs.

All LCD staff are encouraged to raise issues that impact the quality of data and information being generated or used by the Division. These issues should be raised to their immediate supervisor, and, if necessary, to the LCD QAC. Issues that affect more than one LCD program will be elevated to the LCD Director.

If the issues cannot be resolved internally, the LCD QAC will consult with the RQAM. If the issue is relevant to other Regional Division or offices, it will also be brought before the RQC.

SECTION E: INFRASTRUCTURE

E.1 Qualifications and Training

All LCD personnel involved with environmental data operations are required to have the appropriate QA training. It is the responsibility of the LCD Division Director and Associate Directors to ensure that the individuals in this Division meet the minimum QA training requirements for their assigned activities. The following sections describe LCD's QA training program and the requirements for Division personnel involved with environmental data operations.

E.1.a LCD QA Training Requirements

While the LCD Quality System is being effectively implemented in a consistent manner throughout all LCD programs, Division personnel must have the appropriate knowledge of quality assurance policies, principles and procedures. Staff who are directly involved in the generation and/or use of environmental data are the primary focus of the QA training program. However, all individuals are active participants in the LCD Quality System. The LCD training program incorporates a graded approach relative to staff function.

The implementation of QA requirements for extramural agreements is a critical component of the LCD Quality System. Project Officers are responsible for assisting grantees, to ensure that they obtain the necessary QA-related training.

E.1.b. Courses

Region III has identified core QA training courses for Region III personnel as well as state and local government agencies. These courses are as follows:

- Region III Quality System Awareness;
- Systematic Planning for Environmental Data Operations;
- Quality Assurance Program and Project Plans;
- Data Evaluation;
- Information Quality Guidelines;
- QA Refresher.

These courses are listed and described in Table E.1 of the Region's Quality Management Plan [*Core Quality Assurance Courses of the Region III Quality Management Plan, October 2015.*](#) This table is reproduced in Appendix 2 of this document.

These courses are typically presented through a collaborative effort between EAID and the RQC. Additional training support for non-routine topics may be provided by OEI Quality Staff, other Regions, other Federal Agencies, local universities, contractor and professional organizations. If additional QA training is required for Division staff, the LCD QAC shall request this training by bringing the training need to the attention of the RQAM and the RQC.

E.1.c. Documentation of Training

After completion of each QA training course, attendees receive a certificate of completion from the organization providing the training and attendance at all courses is recorded. The Region's Office of Personnel Management (OPM) maintains a record of all QA training taken by all Regional personnel. This record is maintained in OPM's training database. Upon request, OPM will provide the Division Director with a list of individuals within the Division who have completed core QA training courses. The Division Director will use this information to determine whether appropriate staff members meet the minimum training requirements for their assigned activities.

Additionally, the Division has compiled a list of training courses completed by each staff member. This list has been provided to the appropriate managers within the Division, who are responsible for maintaining the list. LCD Associate Directors and Branch Chiefs are also responsible for ensuring that staff have completed the minimum required training requirements, and that staff complete required training updates.

E.2 Procurement and Financial Assistance

E.2.a Procurement – Contracts

The Contracts Branch within OPM is responsible for developing and keeping current Regional purchasing policies and procedures. Quality assurance requirements for contracts are

set forth in guidance documents known as [the FAR](#) and the EPA Acquisition Guide. All procurements originating in Region III must meet established administrative and quality assurance requirements in the latest editions of [the FAR](#), and the Acquisition Guide.

In order to assure that contractually procured environmental data operations are scientifically valid, defensible, and of known precision and accuracy, Contract Project Officers, COR, and CO are responsible for adhering to EPA's guidance.

LCD does not currently utilize contracts for the acquisition and/or use of environmental data, and does not anticipate doing so. However, the procedures described in this section will be used in the event that there is a future need to use a contract vehicle for environmental data operations.

E.2.a.1 Small Purchases

Procurement of environmentally-related measurement or data generation which qualify for small purchases must meet established administrative and QA requirements of [the FAR](#), and all other regulations, delegations, policies and orders listed in Section E.2.a.1 of the Region III QMP, September, 2015. Bankcard, blanket purchase orders, and federal supply schedule procurements involving environmental data operations will adhere to these above requirements.

In LCD, small purchases for analytical services are occasionally made by the Pesticides and Asbestos Programs Branch. These services are purchased when analysis is needed for asbestos to support the development of an enforcement case.

Public Law 99-519, "Asbestos Hazard Emergency Response Act of 1986," referred to as AHERA, requires that the NIST develop an accreditation program for labs conducting analyses of bulk samples of ACM.

The purpose of the Bulk Asbestos Program is to accredit testing labs to assure that they are competent to analyze bulk samples for asbestos using polarized light microscopy. The Pesticides and Asbestos Programs Branch requires that any laboratory that it uses for asbestos analysis be accredited under this standard.

E.2.b Financial Assistance

E.2.b.1 Grants and Cooperative Agreements

EPA quality assurance requirements for grants and cooperative agreements are contained in [40 CFR Part 30](#) for universities and other non-profit agencies, and [40 CFR Parts 31](#) and [40 CFR Part 35](#) for state, tribal and local governments.

The QMP will document and describe the Quality System implemented by the applicant. The LCD Project officer will ensure the agreement clearly describes the item or service needed and that associated technical and quality requirements are defined. The Project Officer will also indicate on the Funding Recommendation whether the project involves environmental data operations. If it does, the Project Officer will include a programmatic terms and conditions on the funding recommendations per guidance. The terms and conditions requires the recipient to submit the QMP within 90 days of the start of the project and notifies the recipient that they may

not begin the work involving environmental data operations until the QMP has been approved by the RQAM.

A condition will also be included in the grant award document by the OPM grant specialist requiring that the grantee submit a QAPrP for review and approval by the LCD Project Officer prior to the initiation of projects involving environmental data operations.

For grants consisting of a single project or task, a combined QMP/QAPrP/QAPP may be submitted that describes the organization's Quality System and the application of the Quality System to the work being conducted in the grant. The decision to use a combined QMP/QAPrP/QAPP can only be made by the Project Officer and the RQAM or designee. The RQAM or designee. The RQAM will identify the QA elements that must be addressed in the combined QMP/QAPrP/QAPP. The combined QMP/QAPrP/QAPP must be approved by the RQAM or designee and the Project Officer prior to initiation of the environmental data operations.

E.2.b.2 Interagency Agreements

When LCD is providing funds to another Federal organization for projects involving environmental data operations, the organization receiving the funds is responsible for preparing the QMP or equivalent document. If the external organization's documented Quality System meets the requirements found in the [EPA QA/R2, March 2001](#), or the [EPA-505-F-03-001](#), their QMP or equivalent document shall be acceptable. If comparable QA procedures do not exist, the QA procedures agreeable to both parties must be negotiated for the IA. Before any environmental data operations can be performed, the external organization must have an approved QMP and QAPrP (or equivalent) or successfully negotiated and acceptable to both parties. These QA requirements are in accordance with the specifications provided in [EPA QA/R-5](#), or the [EPA-505-B-04-900A](#), as appropriate.

In order to document compliance with the above policy, the LCD Project Officer shall indicate in the IA Program Decision Memo (Program Office Authorization for the Award) whether QA requirements apply. If yes, the EPA Grants Specialist will include a special condition in the IA. The special condition notifies the other Federal agency that they must submit a QMP and QAPrP to the LCD Project Officer and that EPA will review and concur on the QA documents (*e.g.*, QAPrP, QAPP, SAP, and Workplan).

The QMP for the other Federal agency must be approved by the RQAM or designee. The QAPP must be approved by the Project Officer after review by a qualified person.

After the IA is executed by both parties, it is the responsibility of the LCD Project Officer to assure that the recipient of the IA is in compliance with the QA condition(s).

E.2.b.3 Evaluation of Deliverables

Project Officers establish the framework for monitoring the quality of items or services by incorporating inspection and acceptance criteria into contract statements of work or work plans for grants/interagency agreements. They are responsible for oversight and for ensuring that products delivered are complete, accurate and meet contract, grant, cooperative agreements and

interagency agreement requirements. Oversight of contractor QA-related products is accomplished mainly by the efforts of the RQAM, QA Staff and/or other designated technical specialists (*e.g., risk assessor, hydrogeologists, etc.*) as requested by the Project Officer.

E.3 Documentation and Records Management

Maintaining important QA documents and records is a continuous process in the Region and LCD. This process serves as a vehicle for identifying quality-related documents and records requiring management control.

The Enterprise Content Management System (ECMS) is the official EPA email management program. ECMS integrates technologies, tools, and methods to capture, manage, store, preserve, and deliver content across an enterprise. ECMS allows the management of unstructured information including images, office documents, graphics, drawings, and print streams, as well as electronic objects such as Web pages and content, e-mail, video and rich media assets throughout the content's lifecycle. The Land and Chemicals Division also manages its record center where project related documents are captured in Versatile Express, an electronic database designed for file management. Processes and activities within LCD's records center conform to the Agency's Federal Records Center and the Region's Records Management policies.

LCD Project Officers are responsible for managing all project level quality-related documents and records (paper and electronic), including transmission, distribution, retention, access, preservation (including using established infrastructure to protect records from damage, loss, and deterioration), traceability, retrieval, removal of obsolete documents, and disposition. The Project Officer is also responsible for ensuring that records and documents accurately reflect completed work.

LCD is responsible for ensuring consistency and technical accuracy of its work products. It is the LCD Division Director's responsibility to establish procedures to ensure that disseminated information products are of adequate quality for their intended use and that they comply with [EPA/260R-02 008](#).

For more information on [documentation](#) and [records management](#) including applicable legislation, regulations, guidance and policies, see Section E.3 of the [Region III QMP](#) .

E.4 Computer Hardware and Software

EPA's ability to fulfill its mission is dependent upon a strong information technology infrastructure. OEI is responsible for managing the EPA's information technology infrastructure and components. In that role, OEI has established information technology standards to manage and ensure that information technology components integrate properly into the infrastructure. The Land and Chemicals Division has utilized these tools to facilitate collaboration and enhance communication through both the LCD Intranet and SharePoint.

E.4.a Roles and Responsibilities

The CSB in OPM is responsible for local area and wide area network support; managing and operating the regional computer center; providing data communications services; personal computer planning and operational support; information technology security; and management of Regional word processing support. CSB also participates in overall information management for the Region in cooperation with EAID and the ISB. CSB focuses on desktop applications when participating in information management activities.

Any computer hardware or software purchased by LCD exclusively for its use will be evaluated by the OPM LAN Systems Administrator and approved by the OPM PC site coordinator before purchase.

E.4.b LCD Data Systems

The RCRA Program maintains a national database about the status of generators and facilities in the RCRA universe, including facilities subject to the RCRA corrective action process. The database is called the national RCRA Information System Database, or "RCRAInfo." Information for this database is supplied by both the EPA Regional Offices and the authorized states. The system is set up so states input their data directly into RCRAInfo.

LCD has state cooperative agreements (grants) with the authorized states in the Region to document the terms and responsibilities associated with the operation and maintenance of RCRAInfo. These cooperative agreements create a shared responsibility between EPA and the states to (a) collaborate to develop management procedures to facilitate the flow of RCRA Program data into RCRAInfo, and assure the timely entry and accuracy of the data, (b) adhere to any operating procedures developed for the RCRAInfo data management, and (c) participate in the RCRAInfo User Conference, conference calls and training. According to these cooperative agreements, procedures are to be in place to check data for accuracy.

In addition, state grantees are required to have QAPP which address the generation and use of environmental data.

LCD's non-RCRA Enforcement programs maintain a database called FIFRA/TSCA Tracking System (FTTS). This database includes case development, information on asbestos (AHERA), FIFRA, PCB, Federal facilities, Section 12 exports, and good lab practice (GLP) audits. Information on inspections and enforcement actions performed by EPA or the States is entered into the FTTS by LCD.

The FTTS is used to generate a mid-year and end-of-year report for EPA headquarters and LCD management. Before this data is released outside of the Pesticide Branch, it is reviewed for accuracy by the Branch Chief.

The FIFRA Program maintains the FTTS. This database includes information on facilities regulated under FIFRA, including pesticide production information, which must be reported to EPA annually.

The FTTS is used to identify facilities for possible enforcement actions, by LCD to generate reports for State inspectors, and by EPA headquarters for tracking pesticide production. The Pesticide Branch Chief reviews this database for accuracy prior to its use in any enforcement action.

E.4.c Data Standards

All Federal agencies are required to adhere to Federally-mandated data standards and regulations. Within LCD, adherence to [data standards policy](#) is accomplished through the direction of OEI.

APPENDIX 1: Programs Covered by the LCD Quality System

- **Clean Air Act (CAA) – National Emissions Standards for Hazardous Air Pollutants (NESHAP)**
- **Asbestos enforcement grants Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**
 - **Pesticide cooperative agreement grants**
 - **Pesticide environmental stewardship grants**
- **Resource Conservation and Recovery Act (RCRA)**
 - **Corrective action (either through permits or administrative orders)**
 - **RCRA Hazardous Waste (Subtitle C) grants**
 - **RCRA Underground Storage Tank (Subtitle I) grants**
 - **RCRA compliance and enforcement (both Subtitle C and I) grants**
- **Toxic Substances Control Act (TSCA)**
 - **Delisting Toxic Substances Control Act (TSCA)**
 - **TSCA 404(g) lead grants**
 - **TSCA PCB enforcement**
 - **Asbestos worker protection**
 - **Other TSCA lead grants**
- **Asbestos hazard in schools – Asbestos Hazard Emergency Response Act (AHERA)**
- **Asbestos Schools Hazard Abatement Reauthorization Act (ASHARA)**

APPENDIX 2 Table E.1. Core Quality Assurance Training Courses

(excerpted from Region 3 Quality Management Plan)

<u>Course Title</u>	<u>Description</u>
Region III Quality System Awareness	A detailed overview of the Agency’s quality system requirements and how they are implemented in Region II
Systematic Planning for Environmental Data Operations	This course shall provide an overview of systematic planning. During this course, participants will learn the elements of a systematic planning approach based on the scientific method.
Quality Assurance Project Plans	This course shall provide an overview of the twenty-four QAPP elements found in QA/R-5 and the UFP-QAPP. During this course, the need for systematic planning and EPA's graded approach to project plan development shall be emphasized. Based on the training needs of the audience, the course may either focus on how to write or review a QAPrP/QAPP.
Field Operations	Under development
Data Evaluation	This course shall provide an overview of data validation and usability. Participants will acquire knowledge of 1) the importance of data validation; 2) Region III’s data validation procedures; and 3) the usability of data against project objectives.
Information Quality Guidelines	Participants will acquire: 1) knowledge of the origin and intent of the 2001 Data Quality Act; 2) information on the implementation of EPA’s Information Quality Guidelines (IQGs); 3) insight on managing IQG requests; and 4) appreciation of the impact of the IQGs on enhancing EPA’s Quality System.
QA Refresher (On-line – under development)	A briefing on updates/changes to the quality system; required for Region III staff every 2 years to maintain QA proficiency.

REFERENCES

EPA Quality System Documents

Region 3 Quality System Documents

Land and Chemicals QA/QC SharePoint site – This site is frequently updated and may contain additional documents not referenced in the list below.

Policy and Program Requirements for the Mandatory Agency-Wide Quality System; EPA Order CIO 21050.0; U.S. Environmental Protection Agency, Washington, D.C. 2000.

EPA Quality Manual for Environmental Programs; CIO 2105-P-01; U.S. Environmental Protection Agency, Washington, D.C. 2000.

EPA Requirements for Quality Management Plans (QA/R-2); EPA/240/B-01/002; U.S. Environmental Protection Agency, Washington, D.C. 2003.

Guidance on Assessing Quality Systems (QA/G-3); EPA/240/R-03/002; U.S. Environmental Agency, Washington, D.C. 2003.

EPA Requirements for Quality Assurance Project Plans (QA/R-5); EPA/240/B-01/003; U.S. Environmental Protection Agency, Washington, D.C. 2001.

Guidance on Systemic planning using the Data Quality Objectives Process (QA/G-4); EPA/240/B-06/001; U.S. Environmental Protection Agency, Washington, D.C. 2006.

Guidance on Quality Assurance Project Plans (QA/G-5); EPA/600/R-02/009; U.S. Environmental Protection Agency, Washington, D.C. 2002.

Guidance on Geospatial Data Quality Assurance Project Plans (QA/G-5G); EPA/240/R-03/003; U.S. Environmental Protection Agency, Washington, D.C. 2003.

Guidance for Preparing Standard Operating procedures (SOP) (QA/G-5G); EPA/240/R-03/003; U.S. Environmental Protection Agency, Washington, D.C. 2007.

Guidance on Technical Audits and Related Assessments for Environmental Data Operations (QA/G-7); EPA/600/R-99/080; U.S. Environmental Protection Agency, Washington, D.C. 2000.

Guidance on Environmental Data Verification and Data Validation (QA/G-8); EPA/240/R02/004; U.S. Environmental Protection Agency, Washington, D.C. 2002.

Data Quality Assessment: Statistical Methods for Practitioners (QA/G-9S); EPA/240/B-06/003; U.S. Environmental Protection Agency, Washington, D.C. 2006.

Guidance for Developing a Training Program for Quality Systems, (QA/G-10); EPA/240/B00/004; U.S. Environmental Protection Agency, Washington, D.C. 2000.

Guidance for Quality Assurance for Environmental Technology Design, Construction and Operation (QA/G-11); EPA/240/B-05/001; U.S. Environmental Protection Agency, Washington, D.C. 2005.

Information Management

[Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA, 260R-02-008, December 2002](#)

[Region 3 Quality Management Plan, September 21, 2015](#)

Program Documents

[Field Manual for Grid Sampling of PCB Spill Sites to Verify Cleanup, EPA-560/5-86-017, U.S. Environmental Protection Agency, Washington, D.C. May 1986](#)

[Safety, Health & Environmental Management Program Guidelines Asbestos Procedures and Programs for Employees, April 2005](#)

[Get The Lead Out – EPA Region III Guidance for Preparing Lead-Monitoring Project Plans](#)

[QAPP Guidance for FIFRA Programs, EC-G-2000-067](#)

[Uniform Federal Policy for Quality Assurance Project Plans, Parts 1 through 2C, March 2002-2012](#)

[Verification of PCB Spill Cleanup by Sampling and Analysis, EPA-560/5-85-026, U.S. Environmental Protection Agency, August, 1985](#)

[EPA Region 9 Guidance for Quality Assurance Program Plans – R9qa/03.2](#)

Quality Management Plans/Quality Manuals

[Region III Quality Assurance Project Plan Preparation Checklist, April, 2001](#)

[LCD Quality Assurance Checklist for Program Managers and Project Officers](#)

[Region III Quality Management Plan, September 2015](#)

Procurement and Financial Assistance

[Acquisition Handbook, Office of Acquisitions Management, U.S. Environmental Protection Agency](#)

[EPA Acquisition Guide \(EPAAG\)](#)

[Federal Acquisition Regulation \(FAR\), General Services Administration, Department of Defense, National Aeronautics and Space Administration](#)

[Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions, \(November 2015\), Chapter 46, Section 46.2.1 EPA Acquisition Guide \(EPAAG\)](#)

[Region III Quality Assurance Requirements for Grants and Cooperative Agreements, U.S. Environmental Protection Agency, November 7, 2000](#)

Miscellaneous

[USEPA Contract Laboratory Program National Functional Guidelines \(Series\), U.S. Environmental Protection Agency](#)

[EPA Region III Quality System Audit Checklist](#)

[Peer Review Handbook, 3rd Edition, EPA/100/B-06/002, U.S. Environmental Protection Agency, 2001.](#)

[Sample Submission Procedures for the Office of Analytical Services & Quality Assurance Laboratory Branch, EPA Region III](#)

[Standard Operating Procedures for Region III Enforcement and Compliance Assistance Branch \(ECAB\) in the Office of Enforcement, Compliance, and Environmental Justice \(OECEJ\)](#)