



Quality Management Plan

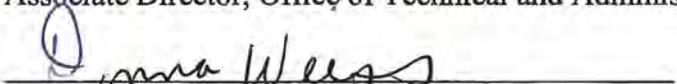
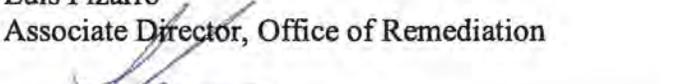
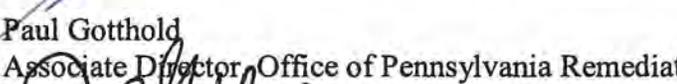
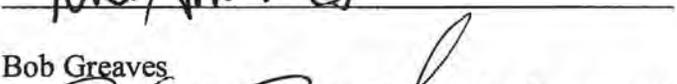
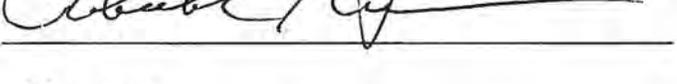
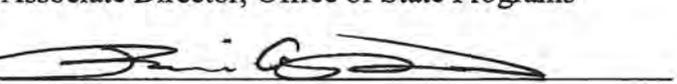
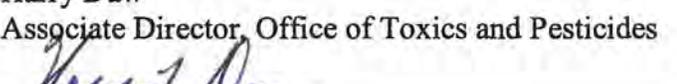
June 2011

*US Environmental Protection Agency
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QUALITY MANAGEMENT PLAN
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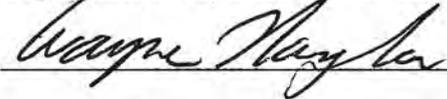
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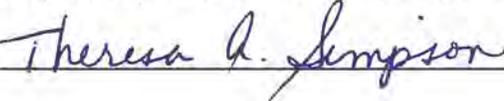
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TABLE OF CONTENTS**LIST OF ABBREVIATIONS**

SECTION A: QUALITY SYSTEM FOUNDATION	1
A.1 INTRODUCTION	1
A.1.a Mission, Policy and Scope	1
A.1.b Programs Covered by the LCD Quality System	2
A.2 LCD ORGANIZATIONAL STRUCTURE	3
A.3 QUALITY SYSTEM ROLES AND RESPONSIBILITIES	3
A.3.a LCD Director	4
A.3.b LCD Quality Assurance Coordinator	4
A.3.c LCD Project Officers	5
A.3.d Regional Quality Assurance Manager	6
A.3.e OASQA Quality Assurance Team	7
A.4 COMMUNICATION	7
A.5 DISPUTE RESOLUTION	8
A.6 RESOURCES FOR THE LCD QUALITY SYSTEM	8
A.7 PRINCIPAL COMPONENTS OF THE LCD QUALITY SYSTEM	8
A.8 QUALITY MANAGEMENT PLANS	9
A.8.a LCD Quality Management Plan	9
A.8.b Quality Management Plans for Extramural Projects	9
SECTION B: PLANNING	11
B.1 PROGRAM-SPECIFIC PLANNING	11
B.2 PROJECT-LEVEL PLANNING	11
B.2.a Systematic Planning Process	11
B.2.b Quality Assurance Project Plans	12
B.2.c Generic or Program Quality Assurance Project Plans	14
B.2.d Secondary Use of Environmental Information or Data	15
B.3 INFORMATION QUALITY GUIDELINES	15
SECTION C: IMPLEMENTATION OF WORK PROCESSES	17
C.1 PROGRAM IMPLEMENTATION	17
C.2 PROJECT IMPLEMENTATION	18
C.2.a Quality Assurance Project Plans	18
C.2.b Standard Operating Procedures	18
C.2.c Inspection and Oversight of Facilities and Work Processes	19
SECTION D: EVALUATION	20
D.1 ASSESSMENT TOOLS	20
D.1.a Internal Quality System Assessments	20
D.1.b External Quality System Assessments	21
D.2 TECHNICAL SYSTEMS AUDITS	21

D.3 DATA VERIFICATION AND VALIDATION	22
D.4 DATA QUALITY ASSESSMENT	23
D.5 PEER REVIEW	24
D.6 QUALITY IMPROVEMENT	24
SECTION E: INFRASTRUCTURE	25
E.1 QUALIFICATIONS AND TRAINING	25
E.1.a LCD QA Training Requirements	25
E.1.b Courses	25
E.1.c Documentation of Training	26
E.1.d Training Requirements	26
E.2. PROCUREMENT AND FINANCIAL ASSISTANCE	28
E.2.a Procurement - Contracts	28
E.2.a.1 Small Purchases	29
E.2.b Financial Assistance	29
E.2.b.1 Grants and Cooperative Agreements	29
E.2.b.2 Interagency Agreements	30
E.2.c Evaluation of Deliverables	31
E.3 DOCUMENTATION AND RECORDS MANAGEMENT	32
E.4 COMPUTER HARDWARE AND SOFTWARE	33
E.4.a Roles and Responsibilities	33
E.4.b LCD Information Management Systems	33
E.4.c Data Standards	34
FIGURES	
Figure 1: Region III Land and Chemicals Division Organizational Chart	36
REFERENCES	38

LIST OF ABBREVIATIONS

AHERA	Asbestos Hazard Emergency Response Act
ASHAA	Asbestos School Hazard Abatement Act
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
COR	Contracting Officer's Representative
CSB	Computer Services Branch
DQOs	Data Quality Objectives
EAID	Environmental Assessment and Innovation Division
ECMS	Enterprise Content Management System
EPA	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
OPM	Office of Policy and 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
QAT	Quality Assurance Team
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Assessment
RCRA	Resource Conservation and Recovery Act
RPM	RCRA Project Manager
RQAA	Regional Quality Assurance Assessment
RQAM	Regional Quality Assurance Manager
RQAO	Regional Quality Assurance Officer

RQC	Regional Quality Council
SAP	Sampling and Analysis Plan
SOP	Standard Operating Procedure
SSTS	Section 7 Tracking System
TSA	Technical Systems Audit
TSCA	Toxic Substances Control Act
USACE	United States Army Corps of Engineers
WAM	Work Assignment Manager

SECTION A: QUALITY SYSTEM FOUNDATION

A.1 INTRODUCTION

A.1.a Mission, Policy and Scope

EPA's overarching mission is to protect human health and the environment. To accomplish this mission, EPA utilizes environmental information from a variety of sources. The Land and Chemicals Division (LCD) Quality Management Plan (QMP) describes the policies,

procedures and management system within the organization that govern quality control activities of environmental information collection and/or use. Activities involving environmental information and/or data that are covered by the LCD Quality System include, but are not limited to:

Environmental information or data is defined as any measurements or information that describe environmental processes, location, or conditions; or the ecological or health effects and consequences; or the performance of environmental technology. For LCD, environmental information also includes data produced from models, and compiled from other sources such as databases or literature.

- 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 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. In order for this data to be used with a high degree of certainty by the intended user(s), its quality must be known and documented. This goal will be achieved by ensuring that appropriate resources are made available and proper procedures are followed throughout each environmental project's planning, implementation and evaluation phase.

LCD subscribes to the Region III Quality Policy which is reproduced below:

Region III Quality Policy

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.

This QMP established the foundation for implementing an effective quality system within LCD. The QMP applies to all LCD programs, activities, grants, contracts and interagency agreements that collect and/or evaluate environmental data which is used to make decisions or support actions related to our defined missions and responsibilities. Listed below are specific examples of environmental programs, grants and activities within LCD which are covered by the LCD Quality System.

A.1.b Programs Covered by the LCD Quality System

Asbestos

- Clean Air Act – National Emissions Standards for Hazardous Air Pollutants (NESHAPs)
- Asbestos enforcement
- Asbestos hazard in schools - Asbestos Hazard Emergency Response Act (AHERA)
- Asbestos School Hazard Abatement Act (ASHAA)
- 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)
- Delisting

Toxic Substances Control Act (TSCA)

- TSCA 404(g) lead grants
- PCB enforcement
- Other TSCA lead grants

A.2 LCD ORGANIZATIONAL STRUCTURE

LCD is one of five divisions and six program offices in Region III that reports to the Regional Administrator. The Division is composed of the Immediate Office of the Director and Deputy Director and seven program offices. The program offices are the Office of Technical and Administrative Support, Office of Remediation, Office of Pennsylvania Remediation, Office of Materials Management, Office of State Programs, Office of Toxics and Pesticides and Office of Land Enforcement. The Office of Toxics and Pesticides is further divided into two branches which are the Toxics Programs Branch and Pesticides and Asbestos Programs Branch. A copy of the current LCD organizational chart can be found in Figure 1.

Because the Region employs a decentralized approach in the implementation of its Quality Management System, each division or program office which collects or evaluates environmental data assigns a Quality Assurance Coordinator (QAC) to the Regional Quality Council (RQC). On issues related to the Division's Quality System, the LCD QAC reports directly to the LCD Division Director.

A.3 QUALITY SYSTEM ROLES AND RESPONSIBILITIES

In accordance with EPA Order CIO 2105.0, *Policy and Program Requirements for the Mandatory Agency-Wide Quality System*, overall responsibility for the quality assurance program in Region III rests with the Regional Administrator. This document is available at:

<http://www.epa.gov/irmpoli8/policies/21050.pdf>. The responsibility for developing and documenting Regional Quality Assurance (QA) policies, procedures and guidance;

All individuals in the Region who are directly or indirectly involved with environmental data operations have some responsibility for ensuring data quality.

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) Director. Each Division and Program Office within the Region that collects and/or evaluates environmental data assigns a Quality Assurance Coordinator (QAC) to 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.

Anyone in LCD who is directly or indirectly involved with environmental data collection activities has responsibility for ensuring data quality. This will include staff, supervisors, program managers and senior managers.

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 intermural 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 are 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;
- 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. The LCD QAC reports to the Director of LCD and works closely with the Regional Quality Assurance Manager (RQAM), the Regional Quality Assurance Officer (RQAO) and the Office of Analytical Services and Quality Assurance (OASQA) Quality Assurance Team (QAT) in EAID. 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 Quality Council (RQC);
- Identifying LCD QA and QC needs, and responding to LCD QA and QC problems or questions with the assistance of the RQAM, the RQAO and the OASQA QAT;
- Reviewing, in addition to other qualified reviewers, generic or project-specific Quality Assurance Project Plans (QAPPs) developed for the acquisition of environmental data by LCD grantees;
- Identifying LCD QA training needs in cooperation with the RQC and the RQAM. The assessment of LCD training needs, and the arrangement and development of training courses will be done, where appropriate, in coordination with the RQC, the RQAM, and the LCD Office of Solid Waste and Emergency Response (OSWER) Training Coordinator;
- 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 3 QA Annual Report and Work Plan.

A.3.c LCD Project Officers

LCD Project Officers, RCRA Project Managers (RPMs) and Work Assignment Managers (WAMs) have the primary responsibility for ensuring that environmental data generated for projects which they administer or oversee is 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 who generate environmental data indirectly through the administration of permits or orders or who administer projects supported by EPA through contracts, grants or interagency agreements (IAs). LCD Project Officers fulfill this responsibility in cooperation with the LCD QAC and other Division staff, as appropriate.

For the purposes of this document, LCD uses the terms Project Officer (Technical and Administrative), RCRA Project Manager and Work Assignment Manager interchangeably.

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 QAPP is reviewed and approved.

QAPPs can exist in two basic forms: (1) a project-specific QAPP prepared for a particular data collection activity, or (2) a generic QAPP (modified, as needed, by the user for a specific data collection project).

Many of the LCD continuing environmental grant programs (*i.e.*, state program grants in RCRA Subtitle C and Subtitle I or the TSCA lead program) require only a generic QAPP from the grantee. This generic QAPP is reviewed for completeness, and sent to the OASQA (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. Other LCD grant programs may involve project-specific QAPPs (*i.e.*, grants to universities and citizens groups). These project-specific QAPPs will be processed as described above for generic QAPPs, except that the grant Project Officers may also perform a technical review of the QAPP, in addition to the other qualified reviewers.

Other LCD programs (*i.e.*, RCRA corrective action) require project-specific QAPPs from facilities doing site investigations or remedial activities. These site-specific 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, as appropriate.

LCD 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 environmental data collection. In these situations, the generic QAPP and Standard Operating Procedures (SOPs) of the ECAB are used for data collection activities. Any environmental data collection activities conducted using contracts or IAs will only be done with a generic or 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 generic or site-specific QAPP has been approved prior to the data collection activity.

Regardless of who reviews the generic or site-specific QAPP for a particular grant of direct data collection activity, 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 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 for extramural agreements;

- 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, RQAO 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.e OASQA Quality Assurance Team

The OASQA QAT is located within EAID, and its functions consist exclusively of QA. 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.

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 communications.

This QMP will be distributed or otherwise 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 distributed to all affected Division personnel, as applicable. The LCD QMP will be posted on the Region's internet and intranet sites and/or shared directories, as applicable. When the QMP is revised, the new version will be posted and older versions archived.

The LCD QAC is the representative of the Division on the RQC. This council functions as the primary Regional group for 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 sends 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 Division QAC or Division 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 THE LCD 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 taken 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.

A.7 PRINCIPAL COMPONENTS OF THE LCD QUALITY SYSTEM

The Region III Quality Management Plan mandates that a total Quality Management System be created and implemented by each division. This section of the LCD QMP describes the tools that are used to ensure uniform implementation of QA requirements for all environmental data collection activities. A variety of tools and procedures are employed for planning, implementation and evaluating the LCD Quality System.

This QMP describes an integrated system of responsibilities for implementing QA requirements. This system includes LCD management, the LCD QAC, Project Officers, the RQAM and the OASQA QAT.

Successful implementation of the LCD Quality System requires a consistent and graded approach, with QA practices implemented in a manner that is appropriate to the complexity of the environmental data collection activity and the intended use of the data.

A variety of tools and procedures are employed for planning, implementing and evaluating the Division's Quality System. The principle components of the LCD Quality System exist at the program and project level, and are listed below:

Program Level	Project Level
Quality Management Plans	Data Quality Objectives
QA Annual Report and Work Plan	Quality Assurance Project Plans
Quality System Assessments	Standard Operating Procedures
Training Plans	Data Quality Assessments
Information Quality Guidelines	Pre-Dissemination Reviews

A.8 QUALITY MANAGEMENT PLANS

A.8.a LCD Quality Management Plan

The LCD RQC has prepared this plan to describe the Division’s QA requirements, objectives and internal policies. This document is consistent with the requirements found in the *EPA Quality Manual for Environmental Programs* (CIO 2105-P-01-0), May, 2000, available at:

The LCD QMP contains the policies and procedures being implemented to ensure that environmental data generated, collected, compiled, analyzed and/or utilized by and for the Division are of adequate quality for its intended use.

<http://www.epa.gov/irmpoli8/policies/2105P010.pdf>, and EPA Order *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* (CIO 2105.0), which was previously cited. This 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 RQAM. The LCD QMP shall be reviewed and updated by the LCD QAC, as necessary, on an annual basis. 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. When 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.8.b Quality Management Plans for Extramural Projects

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 QMP, or

LCD Policy

Recipients of LCD financial assistance (i.e., grants, cooperative agreements, contracts and interagency agreements) that involve the generation, collection, compilation and/or use of environmental data must develop and implement QA policies and practices that are sufficient to produce data of adequate quality to meet program objectives.

equivalent document. The QMP for grants, cooperative agreements and contracts shall be prepared in accordance with the most recent version of EPA QA/R-2, *EPA Requirements for Quality Management Plans*, May 2000, available at <http://www.epa.gov/quality1/qs-docs/r2-final.pdf>. The content of the QMP, or equivalent document for IAs, shall be negotiated by both parties. These QMPs shall be reviewed and update annually, or as needed. The extramural project QMP is reviewed by the RQAM, or designee.

Should there be multiple programs involved in a grant, cooperative agreement, IA or contract, the recipient may submit a single QMP covering all the programs in the grant, cooperative agreement, IA or contract, or a separate QMP for each program receiving such funds, per the *Region III Quality Assurance Requirements for Grants and Cooperative Agreements*, November 7, 2000, available at http://www.epa.gov/region03/esc/qa/pdf/grant_conditions.pdf.

The recipient's QMP shall be approved internally by its Quality Assurance Manager, or equivalent, and the organization's senior management. Financial assistance recipients at all levels must submit their QMP or combined QMP/QAPP to the LCD Project Officer prior to the initiation of environmental data operations, as required by the latest revision of the *Region III Quality Requirements for Grants and Cooperative Agreements* document, cited in the paragraph above. The QMP or combined QMP/QAPP shall be forwarded to the RQAM, or designee, for review. The QMP or combined QMP/QAPP must be approved by the RQAM prior to conducting environmental data operations. EPA approval is valid up to five years. The recipient shall review its QMP annually and report minor organizational and/or policy changes in its annual report to the Agency, as applicable. When there are substantial organizational and/or policy changes that impact the recipient's quality system, the recipient shall update and resubmit its QMP for the RQAM's review and approval.

For smaller or single program/project organizations, there may be situations when a single document is more applicable. By applying a graded approach to these situations, the RQAM and/or LCD QAC may identify more appropriate quality system documentation required from the organization receiving financial assistance. Each situation will be determined on a case-by-case basis by the RQAM and/or LCD QAC, as applicable. In general, organizations receiving financial assistance may be granted an exception or modification to the QMP requirement if they meet criteria which may include, but not be limited to, the following:

- One-time, short-term, and special projects or projects of limited scope;
- Organizations generating, collecting, compiling and/or using environmental data for public education purposes.

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**" 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.

A major goal of our Quality System is to promote effective planning for the collection, analysis and processing of environmental information and data. Quality planning must occur

at both the program-specific and project levels in order to ensure that data meets programmatic and quality goals.

B.1 PROGRAM-SPECIFIC PLANNING

LCD develops an annual action plan which is tied to the Region III Strategic Plan and budget distribution process, together with the priorities established by applicable National Program Offices.

LCD administers several programs in Region III (*e.g.*, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and Resource Conservation and Recovery Act (RCRA)). All LCD environmental data operations conducted in support of these programs are covered by this QMP, though not all require the same level of QA. When initiating a new program or incorporating major statutory changes, the program shall establish the minimum quality system components required to achieve program compliance.

B.2 PROJECT-LEVEL PLANNING

B.2.a Systematic Planning Process

LCD Policy

A systematic planning process shall be used for all environmental data operations conducted by or on behalf of the Division.

The 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, available at <http://www.epa.gov/quality/qs-docs/g4-final.pdf>, 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), which was previously cited.

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 of 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 the laboratory), evaluated (*i.e.*, QA review, validation, verification), and assessed against its intended use and the 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 participates in the planning process.

B.2.b Quality Assurance Project Plans

The systematic planning process described above results in the development of a sampling network design, generation of appropriate data quality indicators, selection of measurement and analytical methodologies, standard operating procedures, etc. 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 conducted under police powers.

LCD Policy

All projects and tasks involving environmental data operations that are conducted by or for the Division shall have an approved QAPP in place prior to the start of data generation or use.

The Division has embraced the “graded approach,” as defined in Section 2.4.2 of *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5, March 2001, available at: <http://www.epa.gov/quality1/qs-docs/r5-final.pdf>. The level of detail found in the QAPP shall be appropriate for the nature of the work being performed and the intended use of the data.

The QAPP shall be prepared in accordance with the *EPA Requirements for Quality Assurance Project Plans* document cited above. EPA’s Office of Solid Waste and Emergency Response (OSWER) has issued OSWER Directive 9272.0-17, stating that the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP), available at: http://www.epa.gov/fedfac/pdf/ufp_v2_final.pdf, is designated for use in Federal facility projects where environmental data are collected (e.g., Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), RCRA, Brownfields). LCD endorses this policy and encourages the use of the UFP-QAPP for Federal facility and other hazardous waste projects. QAPP requirements apply to all environmental data operations conducted by Division staff or through grants, cooperative agreements, contracts, IAs and compliance orders.

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 review by a qualified person (such as the designated staff of the OASQA QAT, the Project Officer (if applicable) and, as appropriate, the LCD QAC.

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

All individuals assigned responsibility for QAPP reviews shall be knowledgeable of the documents *EPA Requirements for Quality Assurance Project Plans* (previously cited), and/or 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. The current LCD QAC has been qualified as having sufficient knowledge and expertise to review QAPPs. The RQAM or designee may determine that additional individuals within the Division are capable of performing QAPP review if they demonstrate that they meet the above requirements. The *Region III Quality Assurance Project Plan Preparation Checklist*, developed by the OASQA Quality Assurance Staff, may be used for this review. A link to this document can be found at: <http://www.epa.gov/region03/esc/qa/qapp.htm>, in the “Preparing Quality Assurance Project Plans” section.

Regardless of who reviews the QAPP, the Project Officer is responsible for its approval. Once the QAPP has been reviewed and all critical issues have been addressed, the Project Officer shall indicate QAPP approval via signature or approval memorandum; ensure it is implemented as written; and include a copy in the project file. For continuous projects, the QAPP must be reviewed annually by the authoring organization. Annual review shall be documented in the organization's annual report to LCD. Additionally, the QAPP must be revised and submitted to EPA for review every three to five years, based upon 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 an addendum. Sometimes the scope of a project can change which may have the potential to affect the quality of the data. If these changes are significant (as determined by the Project Officer) and affect the scope and objectives of the project, data use, or data quality; 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.

B.2.c Generic or Program Quality Assurance Project Plans

For continuing environmental grants and assistance contracts or IAs, a generic or program QAPP may be prepared. A generic or program QAPP shall adhere to the QAPP requirements specified in Section B.2.b of this plan. The generic or program QAPP shall include the elements which remain constant in the grant, contract or IA. Most generic or program QAPPs 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 generic or program QAPP shall include the procedures being used for the preparation, review and approval of the site-specific or project-specific plan. If the site-specific or project-specific plan contains analytical and/or sampling procedures that are not found in the generic or program QAPP, the site-specific or project-specific plan must be reviewed in accordance with the procedures in Section B.2.b of this plan.

The Project Officer is responsible for the approval of the generic or program QAPP. The decision to approve or reject a generic or program QAPP is based on the Project Officer's technical expertise and the comments received from a qualified QAPP reviewer.

The appropriateness of a generic or program QAPP is determined on a case-by-case basis by the Project Officer in cooperation with the RQAM, LCD QAC or Quality Assurance Staff. The Project Officer shall ensure that the approved generic or program QAPP 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.

LCD compliance and enforcement programs may use generic QAPPs for their environmental data collection activities. These QAPPs are frequently prepared by other

agencies supporting the Division's compliance and enforcement activities or occasionally by outside contractors. LCD has approved a generic QAPP for the Philadelphia, Baltimore, Norfolk and Huntington Districts of the U.S. Army Corps of Engineers (USACE) which will be used when the USACE is tasked for environmental data collection in support of compliance and enforcement activities.

B.2.d Secondary Use of Environmental Information or Data

Secondary use data is defined as data that is collected for other purposes or from other sources, such as literature, industry surveys, compilations from computerized databases and the results from computerized or mathematical models of environmental process and conditions.

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;
- Define the acceptance criteria for the use of 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 no direct 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 generation project. Assistance with determining the appropriate elements for a QAPP for projects involving secondary use data may be provided by the RQAM or the OASQA QAT, upon request. The Project Officer is responsible for ensuring a QAPP is prepared for these types of environmental data projects.

B.3 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 (IQGs), contain EPA's policies and procedural

"Information" generally includes any communication or representation of knowledge, position or policy such as facts or data, in any medium or form. This includes "preliminary" information endorsed or adopted by EPA, and also conclusions or facts drawn from or based upon other existing information.

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 guidance is available at: http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf. This QMP incorporates by reference all definitions, principles, policies and procedures found in EPA's IQGs.

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 this QMP, the EPA Order *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* (CIO 2105.0) and the *EPA Quality Manual for Environmental Programs* (CIO 2105-P-01-0). These documents were previously cited in Section A of this plan. These procedures are currently being implemented at the program and project level.



C.1 PROGRAM IMPLEMENTATION

The LCD QMP will be reviewed annually by the Division 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 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 their 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, in accordance with the procedures specified in Section A.8.b. 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 (QAARWP). This 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 PROJECT IMPLEMENTATION

C.2.a Quality Assurance Project Plans

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

A Standard Operating Procedure is a set of written instructions that document a routine or repetitive activity that shall be followed.

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 SOPs that pertain to their program operations are implemented. It is the responsibility of Project Officers to ensure that SOPs referenced in specific QAPPs are implemented. The implementation of QA-related SOPs for LCD activities is a responsibility of the LCD QAC. Implementation of SOPs will be assessed through internal quality system audits (QSAs) and technical systems audits (TSAs) as described in Section D of this plan.

Currently, LCD has no formal SOPs for sampling and analysis. SOPs for field sampling are those of the OECEJ. In the event that the Division needs to create its own SOPs, the EPA document, *Guidance for Preparing Standard Operating Procedures (SOPs)*, EPA QA/G-6, April 2007, available at <http://www.epa.gov/quality1/qs-docs/g6->

[final.pdf](#), may be used to provide guidance on the development and use of SOPs. 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 generic QAPP and sampling SOP.

Sampling is conducted under the TSCA PCB enforcement program. This program relies on the OECEJ Field Inspection Program. The SOPs that they use for soil, tanks, drums and waste piles in the RCRA Subtitle C program are also used in the TSCA PCB program. In addition, OECEJ uses two EPA manuals "*Verification of PCB Spill Cleanup by Sampling and Analysis*" (EPA-560/5-85-026, August 1985), available at: <http://www.epa.gov/osw/hazard/tsd/pcbs/pubs/sampling.pdf> and "*Field Manual for Grid Sampling of PCB Spill Sites to Verify Cleanup*" (EPA-560/5-86-017, May, 1986), available at: <http://www.epa.gov/osw/hazard/tsd/pcbs/pubs/gridsampling.pdf>. They also follow the latest revision of the *Sample Submission Procedures for the Office of Analytical Services & Quality Assurance Laboratory Branch*, available at: http://www.epa.gov/region3/esc/pdf/sample_sub_procedures_rev12.pdf. 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, *Health and Safety Guidelines for EPA Asbestos Inspectors*, March 1991, (weblink not available), which is issued by EPA's Office of Administration, Safety, Health, 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 when problems are discovered through other, informal processes.

*LCD uses the terms **audit, review, assess, and evaluate** interchangeably.*

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 (QSAs). It is the goal of LCD to conduct an internal QSAs 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, previously cited, 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, available at: <http://www.epa.gov/quality1/qs-docs/g3-final.pdf>, 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 III Quality Management Plan, October 2008, available at: <http://www.epa.gov/region03/esc/qa/eqmp/qmp.html>, 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 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 OIE 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. TSAs may also be used as an investigative tool when problems are suspected. It is usually project-specific, and is

A technical systems audit is a systematic and objective examination of the facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management and analysis, and reporting aspects of an environmental measurement system.

usually conducted in the field or laboratory. Grantees with approved QMPs may conduct TSAs of their own environmental data operations.

At a minimum, each QAPP shall include the scope and frequency of TSAs 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 TSAs is documented in the QAPP. The Project Officer is responsible for ensuring the specified TSAs 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, practices 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, available at: <http://www.epa.gov/quality1/qs-docs/g7-final.pdf>, 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 TSAs is included in all QMPs and that all QMPs include the title(s) of the individual(s) responsible for conducting TSAs.

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 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, 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- 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 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, available at: <http://www.epa.gov/quality1/qs-docs/g8-final.pdf>, and *USEPA Contract Laboratory Program National Functional Guidelines*, available at: <http://www.epa.gov/superfund/programs/clp/guidance.htm>, may be used to conduct the data verification and validation processes.

D.4 DATA QUALITY ASSESSMENT

A Data Quality Assessment is the scientific evaluation of data to determine if they meet the planning objectives of the project, and thus are of the right type, quality, and quantity to support their intended use.

The scope of the Data Quality Assessment (DQA) should be appropriate for the project objectives and intended use of the data. EPA's guidance documents *Data quality Assessment: A Reviewer's Guide*, EPA QA/G-9R, February 2006, available at:

<http://www.epa.gov/quality1/qs-docs/g9r-final.pdf>, and *Data Quality Assessment: Statistical Methods for Practitioners*, EPA

QA/G-9S, February 2006, available at: <http://www.epa.gov/quality1/qs-docs/g9s-final.pdf>, 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, available at: http://www.epa.gov/peerreview/pdfs/peer_review_handbook_2006.pdf.

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.

LCD Policy

It is LCD's policy to provide the training necessary to ensure that all persons involved in handling environmental data understand the LCD Quality System.

E.1.a LCD QA Training Requirements

In order to ensure that 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 who are active participants in the LCD Quality System must be knowledgeable of the basic elements of the EPA 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 Project Plans;
- Data Evaluation;
- Information Quality Guidelines;
- QA Refresher.

These courses are listed and described in Table E.1 Core Quality Assurance Courses of the Region III Quality Management Plan, October 2008, available at: <http://www.epa.gov/region03/esc/qa/eqmp/qmp.html>.

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 the 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. For this reason, attendance at all courses is recorded. The Region's Office of Personnel and 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 manager 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.1.d Training Requirements

The following table outlines the minimum QA training requirements for the various groups of personnel, as specified in the Region III Quality Management Plan.

Training Requirements by Functional Role/Title

	Region III Quality System Awareness	Systematic Planning for Environmental Data Operations	Quality Assurance Project Plans	Data Evaluation	Quality System Assessments	Information Quality Guidelines	Refresher
Regional Administrator & Senior Leadership	X (briefing only)					X (briefing only)	
Program Managers (Associate Directors / Branch Chiefs / Team Leaders)	X					X	X
Project Officers / Work Assignment Managers / Technical Support Staff	X	X	X	X		X	X
Quality Assurance Coordinator	X	X	X	X	X	X	X

E.2 PROCUREMENT AND FINANCIAL ASSISTANCE

E.2.a Procurement – Contracts

The Contracts Branch within the Office of Policy and Management is responsible for developing and keeping current Regional purchasing policies and procedures. Quality assurance requirements for contracts are set forth in the *EPA Contracts Management Manual (Section 7.3.5.3 and Chapter 46)*, available at: <http://oamintra.epa.gov/?q=node/245>, and the *Federal Acquisition Regulation (FAR) 46.202-4 and 52.246-01*, available at: <https://www.acquisition.gov/Far>. All procurements originating in Region III must meet established administrative and quality assurance requirements in the latest editions of the:

- *Federal Acquisition Regulations, Part 13*;
- *Acquisition Handbook*, available at: [http://oamintra.epa.gov/files/OAM/ah\(new\)_0_0.pdf](http://oamintra.epa.gov/files/OAM/ah(new)_0_0.pdf);
- *EPA Contracts Management Manual*.

In order to assure that contractually procured environmental data operations are scientifically valid, defensible, and of known precision and accuracy, Contract Project Officers, Contracting Officer Representatives, and Contracting Officers are responsible for adhering to EPA's *Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions*, Procurement Policy Notice 01-02, April 7, 2004, available as Chapter 46 of the *EPA Contracts Management Manual* at: <http://oamintra.epa.gov/?q=node/245>. Requirements include completing the Region III QA Review Form. The QA Review Form shall be completed and signed by the Project Officer. The Project Officer's signature indicates that the agreement clearly describes the item or service needed and that associated technical and quality requirements are defined. The RQAM reviews and signs the QA Review Form to assure that all environmental data operations contractually funded by EPA are in compliance with *EPA Order CIO 2105.0*, previously cited. Where QA requirements apply, the Contracting Officer will assure that quality assurance terms and conditions are included in contract statements of work. The quality assurance term and condition requires contractors to document its quality system in a Quality Management Plan, as described in Section A.8.b of this document, and submit QAPPs or appropriate planning documents that meet EPA program-specific project goals and objectives, as described in Section B.2.b of this document. The EPA Project Officer will assure that the contractor complies with the conditions and deliverables.

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 measurements or data generation which qualify for small purchases must meet established administrative and QA requirements of the Federal Acquisition Regulations (FAR), previously cited, and all other regulations, delegations, policies and orders listed in Section E.2.a.1 of the Region III Quality Management Plan, October, 2008, previously cited. Bankcard, blanket purchase orders, and federal supply schedule procurements involving environmental data operations will adhere to these above requirements.

LCD Policy

Procurement of environmentally-related measurements or data generation which qualify as small purchases under the Federal Acquisition Regulations (FAR) is subject to QA 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.

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Public Law 99-519, "Asbestos Hazard Emergency Response Act of 1986," referred to as AHERA, requires that the National Institute of Standards and Technology (formerly the National Bureau of Standards) develop an accreditation program for laboratories conducting analyses of bulk samples of asbestos-containing material.

The purpose of this Bulk Asbestos Program is to accredit testing laboratories 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

LCD Policy

All applicants for grants or cooperative agreements involving environmental data operations shall submit a QMP prepared in accordance with the specifications provided in the most current version of the EPA Requirements for Quality Management Plans, EPA QA/R-2.

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 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 term and condition on the Funding Recommendation per the *Region III Quality Assurance Requirements for Grants and Cooperative Agreements*, November 7, 2000, available at: http://www.epa.gov/region03/esc/qa/pdf/grant_conditions.pdf. The term and condition 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 Office of Policy and Management (OPM) Grant Specialist requiring that the grantee submit a QAPP for review and approval by the LCD Project Officer prior to the initiation of projects involving environmental data operations. The LCD Project Officer will ensure that this condition is being met. The QAPP shall be prepared in accordance with the specifications provided in the most current version of the *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5, previously cited; which describes the quality assurance and quality control activities to be implemented for the work involving environmental data operations.

For grants consisting of a single project or task, a combined QMP/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/QAPP can only be made by the Project Officer and the RQAM or designee. The RQAM or designee will identify the QA elements that must be addressed in the combined QMP/QAPP. The combined QMP/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*

Requirements for Quality Management Plans, EPA QA/R-2, March 2001, previously cited in this document, or the *Intergovernmental Data Quality Task Force: Uniform Federal Policy for Implementing Environmental Quality Systems*, EPA-505-F-03-001, March 2005, available at: http://www.epa.gov/fedfac/pdf/ufp_v2_final.pdf, 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 Interagency Agreements (IAs). Before any environmental data operations can be performed, the external organization must have an approved QMP and QAPP (or equivalent documents)

LCD Policy

All IAs with environmental data operations in which LCD funds or participates shall require an approved QMP or equivalent document.

or successfully negotiated and acceptable to both parties. These QA requirements are in accordance with the specifications provided in *EPA Requirements for Quality Assurance Project Plans*, EPA QA/R-5, March 2001, previously cited, or the *Intergovernmental Data Quality Task Force: Uniform Federal Policy for Quality Assurance Project Plans*, EPA-505-B-04-900A, March 2005, previously cited above, as appropriate.

In order to document compliance with the above policy, the LCD Project Officer shall indicate in the IA Program Decision Memorandum (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 QAPP to the LCD Project Officer and that EPA will review and concur on the QA documents (*e.g.*, QAPPs, SAPs 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.

E.2.c 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 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 assessors, hydrogeologists, etc.) as requested by the Project Officer.

E.3 DOCUMENTATION AND RECORDS MANAGEMENT

Records include all books, papers, maps, photographs, machine readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the United States Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, function, policies, decision, procedures, operations, or other activities of the Government or because of the informational value in them. (44 U.S.C. Chapter 33, Sec. 3391).

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 content management

program. Enterprise content management integrates technologies, tools, and methods in order 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.

LCD Project Officers are responsible for managing all project level quality-related documents and records (paper and electronic), including transmittal, distribution, retention, access, preservation (including protection 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 ensure that established procedures to ensure that disseminated information products are of adequate quality for their intended use and that they comply with EPA's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*, EPA/260R-02 008, October 2002, previously cited, and EPA Region III's *Information Quality Guidelines Pre-Dissemination Review*, PDR Version 1.1, July 2007, available at: http://www.epa.gov/region03/esc/qa/document/forms/IQG_review_checklist.pdf.

For more information on documentation and records management including applicable legislation, regulations, guidance and policies, see Section E.3 of the Region III Quality Management Plan dated October 2008, previously cited.

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.

E.4.a Roles and Responsibilities

The Computer Services Branch (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 Information Services Branch (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 P.C. Site Coordinator before purchase.

E.4.b LCD Information Management Systems

The RCRA Program maintains a national database of information 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 that 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 creates 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 the RCRAInfo data management, and (b) 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 QAPPs which address the generation and use of environmental data.

LCD's non-RCRA Enforcement programs maintain a database called the FIFRA/TSCA Tracking System (FTTS). This database includes information on asbestos

(AHERA), FIFRA, lead, PCBs, Federal facilities, Section 12 exports, and good laboratory practice (GLP) audits. Information on inspections and enforcement actions performed by EPA or the States is entered into the FTTS by LCD.

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

The FIFRA Program maintains a database called the Section 7 Tracking System (SSTS). This database includes information on facilities regulated under FIFRA, along with information on pesticide production. Pesticide production information must be reported to EPA on an annual basis.

The SSTS database is used by LCD to identify facilities for possible enforcement actions, by LCD to generate reports for State inspectors, and by EPA headquarters for tracking pesticide production. Before this data is used in an enforcement action, it is reviewed for accuracy by the Pesticides and Asbestos Programs Branch Chief.

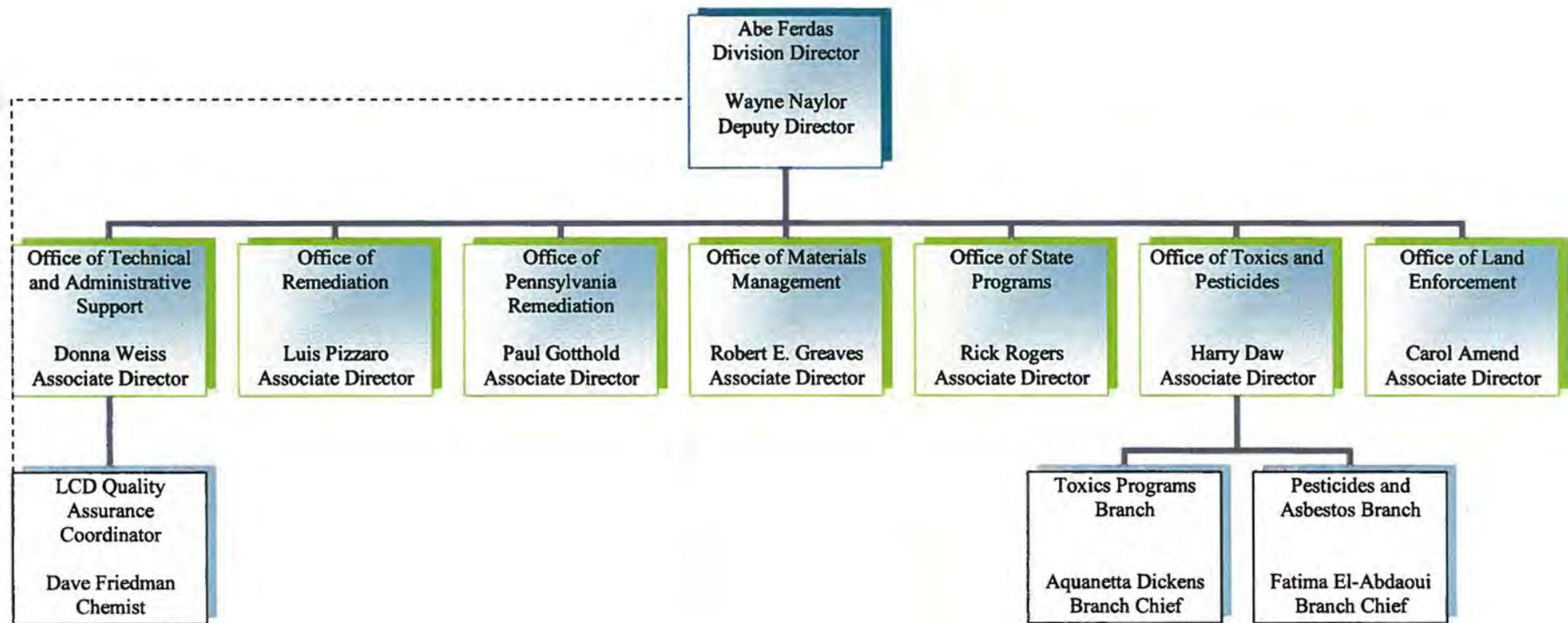
E.4.c Data Standards

All Federal agencies are required to adhere to Federally-mandated data standards and regulations. For more information on the Region III data standards policy, see Section E.4.c of the Region III Quality Management Plan dated October 2008, previously cited.

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Figure 1: Region III Land and Chemicals Organizational Chart

Land and Chemicals Division



— Lines of Authority

- - - - Lines of Communication

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