Commonwealth of Kentucky
Energy and Environment Cabinet
Department for Environmental Protection

QUALITY MANAGEMENT PLAN

January 19, 2016

Quality Management Plan Identification Form

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Plan Coverage:	This Quality Management Plan (QMP) outlines the policy, organizational structure, and commitment of the Kentucky Department for Environmental Protection (KDEP) to develop and implement a Quality Assurance program consistent with USEPA regulations, policy, and guidelines. The purpose of the plan is to ensure that all environmental data directly generated by its programs or through grants administrated by the Department for Environmental Protection is of known, discernible, and verifiable quality.

Quality Management Plan Approval

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1.0 INTRODUCTION

Policy Statement on Quality Assurance

The Kentucky Department for Environmental Protection (KDEP) is committed to identify, establish, implement and maintain a Quality Systems Program for the Department for Environmental Protection that 'sets the bar for quality data and processes' and meets the quality needs of the Department. The Quality Systems Program must: 1) complement the Department's Quality Management Plan; 2) provide direction for the Department's procedures and processes; 3) establish and maintain a defined level of data excellence and information; 4) be cost-effective; 5) and support the Department's mission statement.

Sound environmental decision-making relies on a '*known level of quality*' for all information (analytical data, geological data, field measurements, etc.) utilized in the process of protecting human health and the environment. Establishing and maintaining a *Standard of Quality* will provide a solid foundation necessary in the management of Kentucky's environmental programs.

KDEP is committed to maintaining a quality system for planning, implementing, and assessing its activities and for environmental data planning, collection and analysis. The department developed this Quality Management Plan to provide a framework for the KDEP Quality System and describe the elements of the agency's quality assurance and quality control program. This document also ensures compliance with the United States Environmental Protection Agency's (USEPA) Quality Assurance policy and program requirements. The Quality Management Plan commits department resources to the systematic development and implementation of a uniform Quality System to ensure that data is based on sound science, is legally defensible and technically valid. KDEP is committed to implementing the Quality System and each division has designated personnel to coordinate implementation in their respective divisions. The staff dedicated to quality assurance duties participate on work teams that address any issues that arise concerning quality processes and implement the elements of the KDEP quality system.

Department staff and management depend on data that has been collected and evaluated in a manner that provides for sound, consistent, appropriate and informed environmental decision-making. Utilizing SOPs and QAPPs helps to ensure these outcomes. Implementing this Quality Management Plan is necessary to ensure that the data that are collected by and for the agency are of sufficient quality to support the decisions of the department.

The USEPA's quality assurance policy requires a written Quality Management Plan (QMP) for all assistance awards that involve environmentally-related measurements of monitoring data. State agencies that receive assistance grants under the Clean Air Act (CAA), the Clean Water Act (CWA), the Safe Drinking Water Act (SDWA), the Resource Conservation and Recovery Act (RCRA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) are required to have a written Quality Management Plan. The policy extends to the recipients of "pass through" grants when the grant requires the recipient to gather environmentally-related data.

The Department for Environmental Protection collaborated with USEPA in the adoption of the Performance Partnership Grant (PPG) and the Performance Partnership Agreement (PPA) with the implementation of the FFY 2016 funding cycle. The department's PPG recipients follow all QA programmatic assurances referenced in the EPA awards documents. The agency has complied with the EPA Policy Directive Number FEM-2012-02 with the submittal of the "Demonstration of Quality Assurance Competency for the Kentucky Department for Environmental Protection," to USEPA Region 4 on February 6, 2015. All of the department's PPG grants comply with the quality assurance competency document.

The PPA Priorities and Commitments List captures all programmatic requirements in a consolidated QA section to ensure program compliance and assist EPA and the department staff identifying all necessary QA components.

This Quality Management Plan has been developed under the direction of EPA QA\R-2 *EPA Requirements for Quality Management Plans* 2001. Reissued 2006.

2.0 MANAGEMENT AND ORGANIZATION

KDEP's mission is to protect and enhance the environment. This mission is important because it has a direct impact on Kentucky's public health, citizen safety, and the quality of Kentucky's valuable natural resources - the environment.

The quality assurance (QA) management for the department consists of staff in the commissioner's office, the Divisions of Water, Air Quality, Waste Management, Environmental Program Support, Enforcement, and Compliance Assistance and Region 4 EPA quality assurance staff. These tiers of management provide multiple levels of review for all documents (this QMP, QAPPs, SOPs, etc.) and maintain sufficient and appropriate activities that support QA for all environmental collection and data review. Data are managed at a level that supports decisions based on principles of scientific validity and acceptable indicators of quality such as data quality objectives (the DQOs) as defined by EPA (2006).

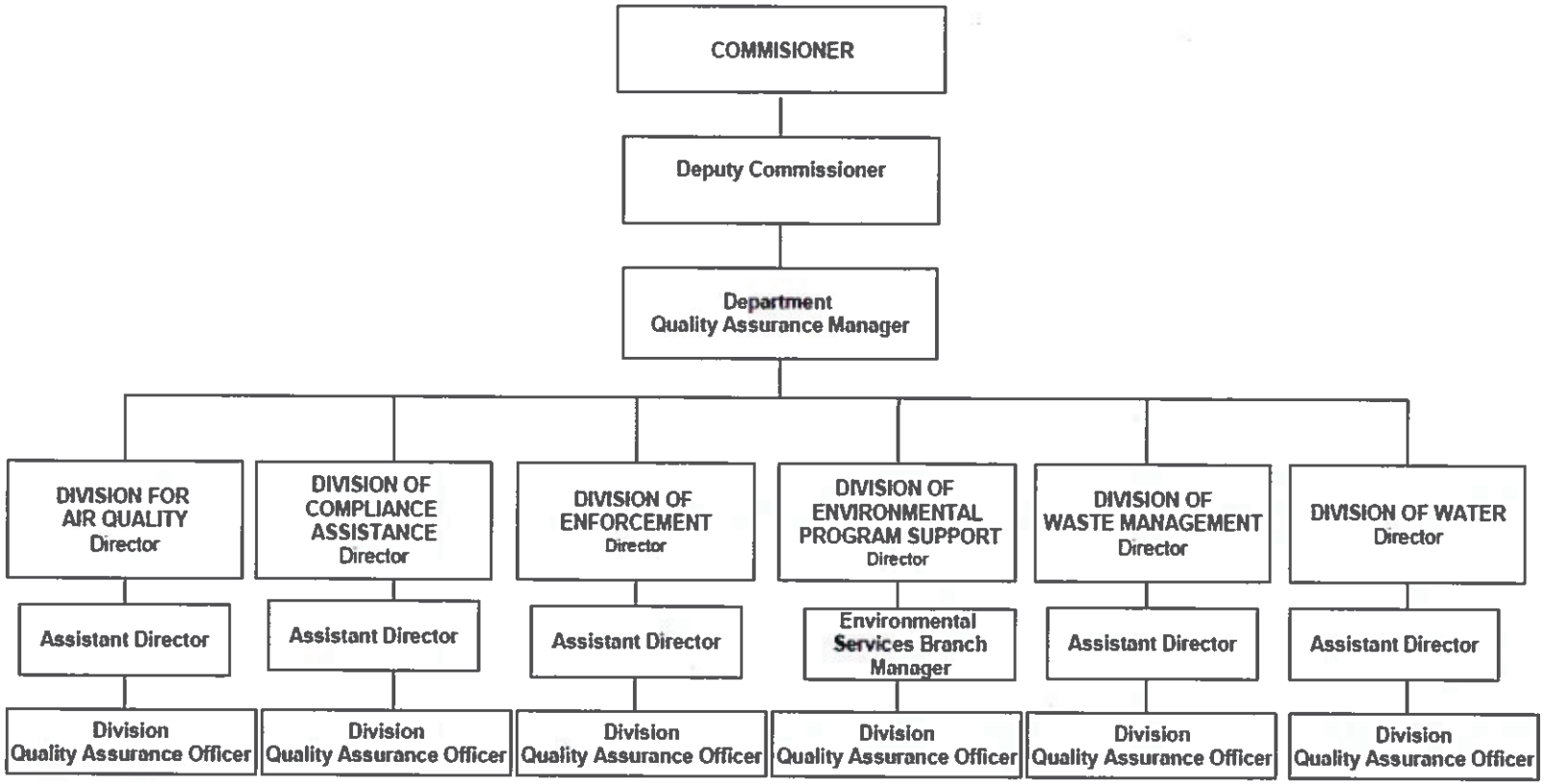
Agency management requires broad application of the KDEP quality system to all environmental programs and technical processes within the department. It is not feasible to list every environmental program and technical process within KDEP. KDEP management supports the universal application of QA management to the KDEP programs.

2.1 Organizational Charts

The following organization charts depict the levels of management in the QA system, as well as all personnel that may be involved in data collection, review or analysis. Titles of positions are represented rather than names of individuals, negating the need to update this QMP with every instance of a personnel change.

DEPARTMENT FOR ENVIRONMENTAL PROTECTION

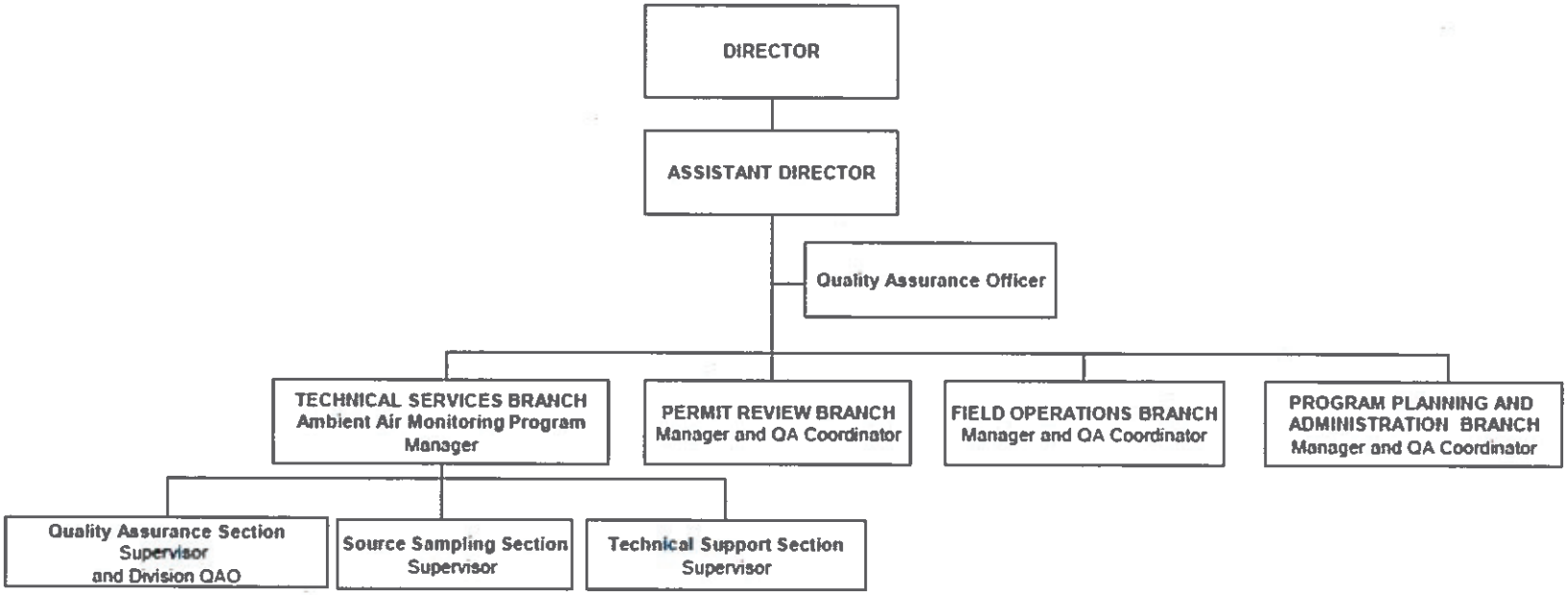
Quality Management Staff



Revised 9/15

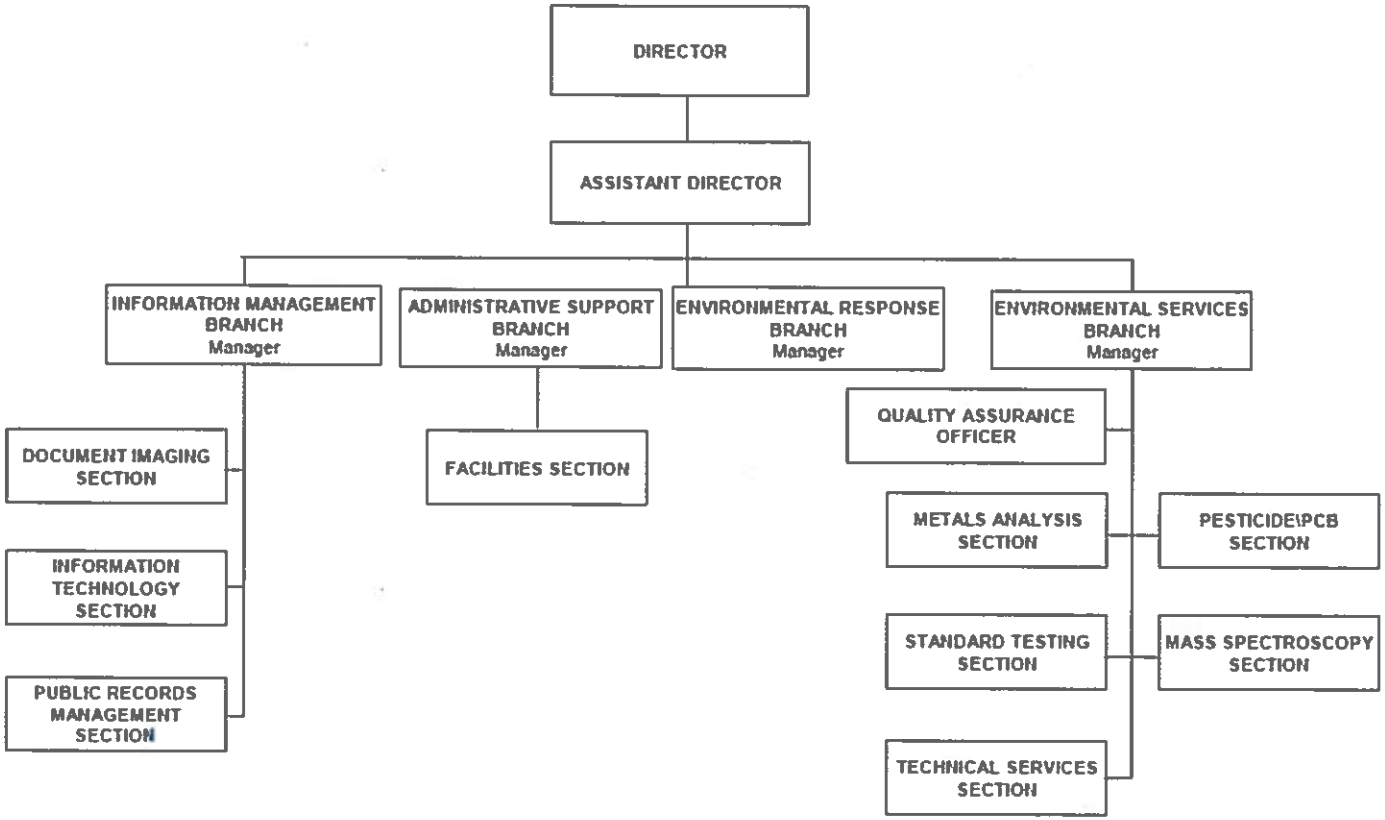
DIVISION FOR AIR QUALITY

Quality Management Staff



Revised 9/15

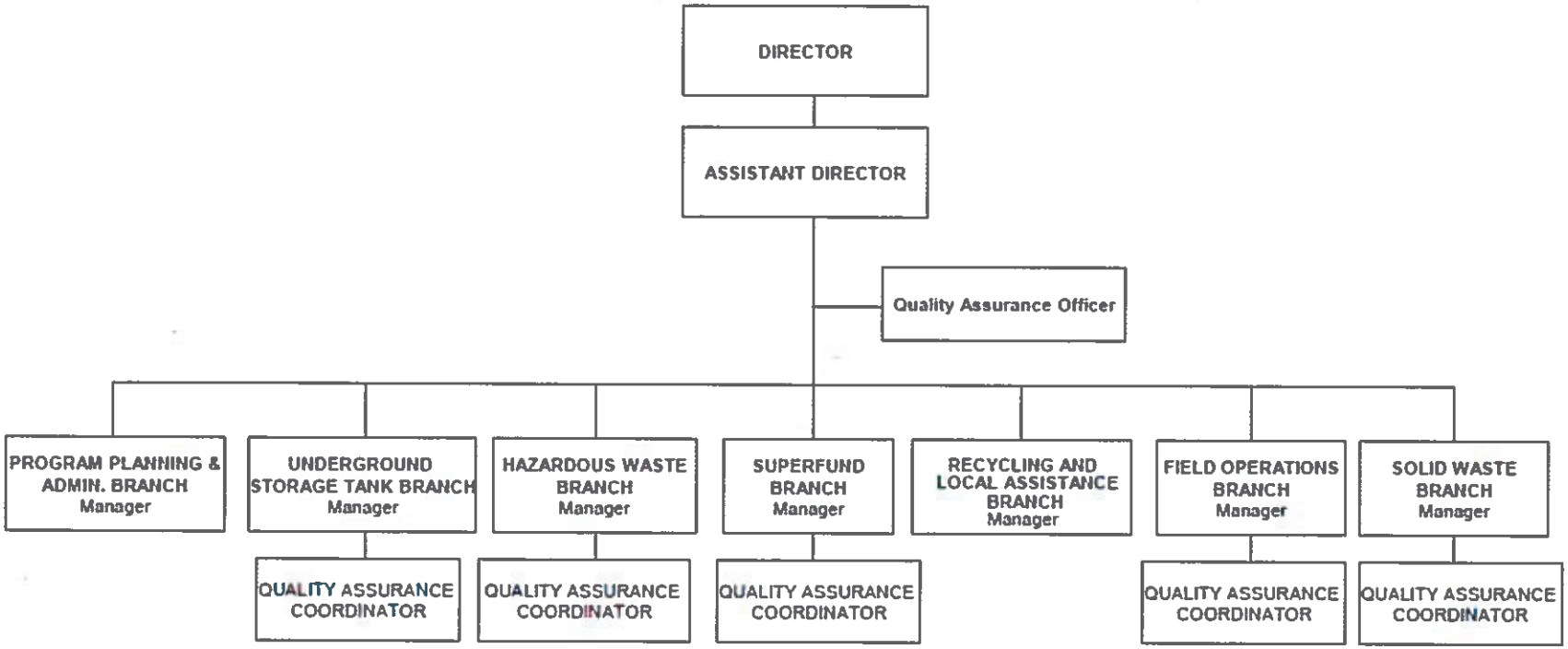
DIVISION OF ENVIRONMENTAL PROGRAM SUPPORT
Quality Management Staff



Revised 9/15

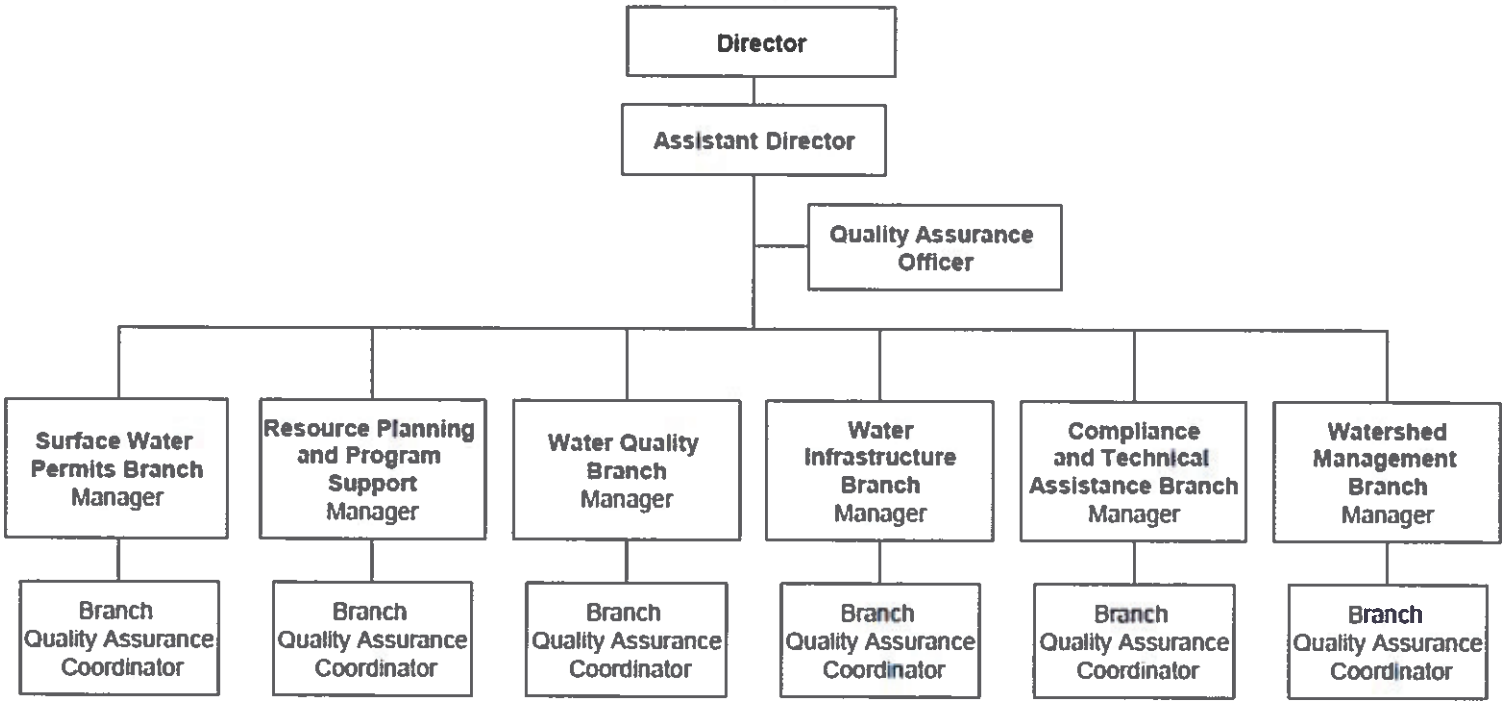
DIVISION OF WASTE MANAGEMENT

Quality Management Staff



Revised 9/15

DIVISION OF WATER
Quality Management Staff



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3.0 QUALITY SYSTEM DESCRIPTION

The Quality Management Plan (QMP) and quality systems apply to all environmental data collection and review programs administered by KDEP. This QMP serves as an umbrella document for all quality assurance activities of the department. It serves as the management tool for KDEP quality systems. The department-wide QMP will serve as the primary quality assurance document for the divisions (Division for Air Quality, Division of Water, Division of Waste Management, Division of Compliance Assistance and Division of Enforcement) and each division will develop program- and project-specific Quality Assurance Project Plans (QAPPs) and Standard Operating Procedures (SOPs) under the authority of the departmental QMP. The QMP is prepared by the Division QAOs and the QAM, and approved by all Division Directors within KDEP. The Environmental Services Branch ('the State laboratory') in the Division of Environmental Program Support (DEPS) operates under a separate Laboratory Operations and Quality Assurance Manual (LOQAM) and will maintain the plan as required by the department-wide QMP and EPA quality systems requirements. The DEPS laboratory Technical Services Section under the authority of the DEPS QAO develops the LOQAM for lab operations.

All KDEP division and branch environmental data collection activities require a project-specific Quality Assurance Project Plan (QAPP) and Standard Operating Procedures (SOPs) be submitted for approval by DEP quality assurance staff prior to commencement of field activities, except under circumstances requiring immediate action to protect human health and the environment. This procedure ensures compliance with the requirements, protocols, and policies specified in the quality system. Environmental data review programs must also have a quality assurance document that outlines methods and procedures for acceptance criteria.

Kentucky shall implement the Quality System by publishing the QMP on the KDEP internet and intranet websites and maintain copies of current project plans and standard operating procedures on division and departmental computer network drives. The divisions Quality Assurance Officers (QAOs) meet monthly or whenever necessary topics arise, to discuss and provide implementation guidance of the Quality System and assist program staff with quality assurance and quality control development. Quality assurance activities are coordinated across divisions and environmental programs by the Quality Systems Team in cooperation with KDEP management through department-wide, division, and program-specific training, consultation with program staff, and assistance with procedure and quality assurance document development. Members of the Quality Systems Team coordinate with corresponding management to implement the elements of the quality system at the division and departmental levels and report annually on quality system activities for the divisions and the department.

KDEP may utilize the services of a third party contractor to perform environmental sample collection and data handling, sample analysis, and/or preparation of a project-specific QAPP. If a third party consultant's services are utilized, KDEP contracting requirements apply to the bid process, format and content of bid packages, insurance and any other applicable requirement for outside contractors. The bid package issued by KDEP must either include the project-specific QAPP or a request for the preparation of a project-specific QAPP, which meets the requirements of the QMP. The bid package includes a requirement of submittal of a QA reporting package during the project. All work performed by the contractor shall be in compliance with the DEP quality system procedures and shall follow all QAPPs, SOPs, and sampling and analysis plans approved by the department.

Analysis of environmental samples collected by the Department for Environmental Protection is primarily done by the Environmental Services Branch of the Department for Environmental Protection ('the State lab'). Outside laboratories may be used based on the workload or analytical capabilities of the Environmental Services Branch laboratory, or by entities performing work on behalf of the agency under contract or grant. QAPPs are required for all environmental data generating projects, and laboratory documentation is required under the QAPP approval process. Documentation from labs include a copy of their quality assurance statements or manual, standard operating procedures for all analyses that are to be performed, and any other information that is identified throughout project planning. Laboratory audits may be conducted when data issues are identified. A detailed list of laboratories is available upon request from programs of the Department, but is not included within this QMP due to the changing nature of such a list.

In addition, all regulatory permits that submit data to KDEP from an outside analytical laboratory must be certified by Kentucky through a rigorous review process. Certification requirement information can be found on the Division of Water's web site at this address: http://water.ky.gov/permitting/Pages/labcert.aspx.

3.1 Deviation and Dispute Resolution Process

To ensure compliance with the Quality Systems procedures, any deviations from the Quality Management Plan, Quality Assurance Project Plans or Standard Operating Procedures shall be thoroughly discussed and documented by the project manager in consultation with the division QAOs. The quality systems documents will be revised, as needed, to reflect appropriate and necessary changes.

Disputes within the agency are resolved at the lowest organizational levels where possible, through informal discussions with Branch Managers, Quality Assurance Officers and the individuals involved. Formal discussions may include legal services to ensure that regulations are followed. Disputes between laboratories and the KDEP are conducted through formal field auditing procedures, which consist of laboratory

certification staff on-site at a lab facility to evaluate all lab operations and documentation. A field audit report is generated and distributed to all necessary parties. When disputes are not resolvable with corrective action, formal enforcement may occur through the Division of Enforcement, which may include cessation of services to the state until issues are resolved, fines are imposed, or other actions are taken.

3.2 Specific Roles, Authorities, and Responsibilities of Management and Staff

The following provides a list of management and staff and their specific roles, authorities and responsibilities as they pertain to KDEP's quality system:

Commissioner

The commissioner has the overall responsibility for directing the implementation of the Department's Quality Management Plan. The authority for implementation of the Quality Management Plan is delegated to the respective divisions. Each division is responsible for the appropriate quality systems related to its specific environmental monitoring or measurement programs.

Division Director

The division director establishes program policy, manages resources, and provides direction to implement the department's Quality Management Plan. In addition, the Director is responsible for ensuring that personnel are properly classified for the jobs they perform, thereby meeting the educational and/or experience requirements for each position. The Director will designate a Quality Assurance Officer (QAO) to ensure that programs implement a quality environmental measurement system. The division director reports to the commissioner.

Department Quality Assurance Manager (QAM)

The department QAM is responsible for assessing, monitoring, coordinating and documenting the implementation of the department's quality system. The department QAM is located in the commissioner's Office and works independently of the divisions and programs that generate, compile, and evaluate the environmental data. The department QAM works with the divisions to ensure that the Quality Management Plan is appropriately implemented. The department QAM reports to the commissioner, and works with division directors and division QAOs on quality assurance implementation, evaluation and assessment, coordinates necessary changes in the department's quality assurance program, and coordinates quality assurance training for department staff. The department QAM coordinates the preparation of QA reports that summarize major QA activities, identify deficiencies in the QA process and activities, and outline corrective

actions for improving data quality. The reports are submitted to DEP management for review and appropriate action.

The Quality Assurance Manager (QAM) is the upper level quality assurance person assigned to the Department for Environmental Protection. The QAM has the responsibility to review all quality assurance project plans and standard operating procedures. The QAM has the final authority to determine quality and usability of environmental data and in deciding on data review policy and implementation of corrective actions.

Branch Manager

The branch manager, under the direction of the division director, is responsible for the development, implementation, and operation of the branch. The branch manager supervises branch personnel, oversees program development, coordinates branch resources, and monitors the implementation of the programs and projects. The branch manager is responsible for ensuring that SOPs, consistent with the Quality Management Plan, are developed and updated for the branch's routine processes involved with the generation of environmental data. The branch manager also has the responsibility to ensure the review of QA data, and in conjunction with the QAO, to implement, monitor and review QC studies performed by the branch. QA responsibilities at the branch level may be delegated to a branch-specific Quality Assurance Coordinator, in consultation with the manager. The branch manager reports to the division director.

Division Quality Assurance Officer

The division QAO will serve as a technical resource to division programs for subjects pertaining to the division's quality system. The division QAO will also be responsible for assessing, monitoring, and documenting the implementation of the quality system. The division QAO will function independently from the testing or monitoring operations. The division QAO will coordinate internal assessments to document compliance with stated procedures and to perform critical evaluations of the effectiveness of the quality system in producing the desired outcomes. The division QAO will prepare reports that summarize major quality assurance activities, include the results of internal assessments, and document the corrective actions being implemented by division programs to ensure data quality. These may include, but are not limited to, the identification of quality assurance needs, resolution of quality assurance problems, and the participation in performance evaluation studies and audits. The division QAO reports to the director on quality assurance issues.

Branch Quality Assurance Coordinator

The branch coordinator (QAC) assists the branch manager in all QA/QC activities for branch operations, including: Standard Operational Procedures (SOP) preparation, Quality Assurance Project Plan (QAPP) development, and review of QA data.

Project Officer

The project officers have the primary responsibility for ensuring that the QMP requirements are integrated into the design of each project. In conjunction with the Division QAO, the project officers develop QAPPs, coordinate project resources, and monitor project implementation to ensure compliance with the requirements of the QAPP. The project officers ensure that the personnel administer the project in accordance with the QAPP and SOPs.

Technical Personnel

Technical personnel are responsible for complying with all quality assurance/quality control protocols that pertain to their duties. These may include, but are not limited to, the identification of quality assurance needs, resolution of quality assurance problems, and the participation in performance evaluation studies and audits.

4.0 QUALITY SYSTEM COMPONENTS

Environmental measurements provide the basis for many of the decisions made within KDEP. These measurements are used for environmental trend monitoring, assessing water quality standards and uses, developing pollutant/contaminant control strategies, determining compliance with permit limits and regulatory standards, and supporting enforcement actions.

The overall data quality objective for KDEP environmental programs has been identified by management as "environmental data of acceptable precision, accuracy representativeness, comparability, and completeness, and of the highest quality possible for its intended use." The department's overall data quality objective is the responsibility of all employees involved in job functions that directly affect the generation or review of environmental data. In order to ensure that these objectives are maintained, an assessment of quality objectives is performed at the conclusion of each environmental project or program.

Quality related definitions are described below.

4.1 Quality Definitions

Quality Assurance - The collection of management activities necessary to provide adequate confidence that environmental data meets defined or implied standards of quality. Quality assurance includes activities such as: planning, implementation, assessment, reporting, and quality improvement to ensure that the outcomes from each activity are of the type and quality needed by the department's programs.

Quality Assessment - The evaluation of the data and the data generation process to determine the level of quality achieved. Performance assessments and data quality assessments are quality assessment activities. Technical personnel and supervisors in accordance with Quality Assurance Project Plans and Standard Operating Procedures conduct data quality assessments. Performance assessments are conducted by project officers and technical staff and communicated to management and division QAOs.

Quality Control - The technical activities that measure the operation of a process against defined performance standards to ensure that the outcomes of the process meet the needs of the user. Quality control consists of specific tasks or actions that both assess and document the performance of a process as it relates to the quality of the data produced. Quality-control reports are provided to supervisors and managers, as necessary.

4.2 Quality System Structure

The following provides a list of KDEP's quality system basic components and a brief description of each:

Quality Management Plan - The Quality Management Plan identifies and describes the structure, policies, and procedures of the quality system. In addition, it details the responsibilities, authorities, and accountabilities of the personnel in the department. This QMP serves as the primary quality systems document for the department. Each division and program shall follow the procedures stated in the QMP. The Environmental Services Branch in the Division of Environmental Program Support (DEPS) operates under a separate Quality Management Plan and will maintain the plan as required by the department-wide QMP and EPA quality systems requirements and guidance.

Management Reviews - The qualitative assessment of data collection processes and/or organizations are reviewed to determine if the prevailing quality management structure, policies, practices and procedures are adequate to ensure that the type and quality of data being used is adequate to meet the needs of the department's programs. Deficiencies are identified and corrective actions are developed and implemented. Communications of necessary changes are made with technical personnel and others via a chain-of-command

through branch managers and supervisors. The division QAOs and department QAM will conduct an annual review of quality assurance procedures and planning documents and produce a Quality Assurance Annual Report.

Project Plans – QAPPs describe and document the specific activities for a major initiative, including: project scope, project management, measurement and data acquisition, assessment, and data validation. QAPPs are developed on a project basis, and submitted to the Division QAO for review and comment. KDEP's approval process includes internal review and approval by the branch manager, division QAO, division director, and the department QAO. For projects which involve a grant and/or assistance agreements funded by EPA, the final draft of a project specific QAPP will be submitted to EPA Region 4 for review and/or approval.

Standard Operating Procedures - Standard Operating Procedures (SOPs) are written documents that detail the steps to be followed in conducting routine procedures used by a division. SOPs are approved by management as the selected method for performing certain routine or repetitive procedures.

Technical Assessments - Technical Assessments examine processes, methodology, and equipment to ensure appropriateness and the proper following of implementation of the QAPP requirements.

Data Quality Assessments - Data quality assessments are evaluations of a collection of data to determine if the data is of adequate quality to meet the needs of project goals and objectives. Data Quality Assessments must determine if the data is acceptable for incorporation into the Department's decision-making processes.

Feedback/Corrective Actions – As part of the post-project closure procedure, data quality assessment findings shall be reviewed by the division QAO and the project manager. A final report shall be issued which identifies any deficiencies in the environmental data collection as compared to the project specific QAPP, the project's data quality objectives and KDEP's QMP. The final report shall be issued from the project manager and division QAO and sent to: the specific branch manager and the division director.

Third-Party Consultants – Consultants or contractors must either provide a copy of their quality system documents as they pertain to environmental sample/data collection for KDEP review and approval, or accept responsibility for following KDEP's project-specific QAPP and SOPs. The requirement that a third-party consultant utilize these quality systems documents to conduct field activities ensures that the environmental data produced from a specific project meets the requirements of KDEP's QMP and the specific project's QAPP and data quality objectives.

4.3 Evaluation of Quality Objectives

Data quality objectives will be established using EPA's Guidance for the Data Quality Objectives Process; EPA QA/G-4 (2006). The basic elements of the process are shown below:

1. State the Problem
    a. Identify the planning team members
    b. Describe the problem
    c. Determine resources

2. Identify the Decision
    a. Identify the principal study questions
    b. Define alternative actions
    c. Develop a decision statement
    d. Organize multiple decisions

3. Identify the Inputs to the Decision
    a. Identify information needed
    b. Identify sources of information
    c. Determine the basis for establishing the action level
    d. Determine the best sampling and analytical methods

4. Define the Boundaries of the Study
    a. Define target population of interest
    b. Specify the boundaries the data will represent
    c. Determine the time frame for data collection and decision making
    d. Determine practical constraints on collecting data
    e. Determine a timeline for the decision process

5. Develop the Analytic Approach
    a. Specify an appropriate population parameter
    b. Confirm the action levels, detection limits, reporting limits
    c. Develop a decision rule

6. Specify Tolerable Limits on Decision Errors
    a. Determine the range of the parameter of interest
    b. Choose a null hypothesis
    c. Examine consequences of making an incorrect decision
    d. Specify a range of values where consequences are minor
    e. Assign probability values to data above action limits, but within tolerance

7. Optimize the Design for Obtaining Data
    a. Review the DQO outputs

b. Develop the data collection design options
c. Formulate each design
d. Select the ideal population size that satisfies the DQOs
e. Decide on the most resource-effective design
f. Document the details in the QAPP

5.0 PERSONNEL QUALIFICATION AND TRAINING

The KDEP is committed to maintaining a professional qualified staff. To that end, each division implements a training program. Requests for training are coordinated by each division. Additionally, each division coordinates training activities with cabinet administrative personnel. Training is conducted in each division for all personnel that have quality assurance-related duties. Records of internal and external training are maintained by the division. The training officer receives a copy of all training documents. The effectiveness of training is assessed initially through evaluations completed after training is conducted. Comments are evaluated and discussed for further action on the part of the quality systems team at the department level. QA products are also examined for thoroughness and acceptability (QAPPs and SOPs). If products are deemed incomplete or unacceptable, additional program specific training may be developed and implemented. Annual system audits may be conducted that also allow for identification of program weaknesses and strengths in QA.

Effectiveness of training for the individual employee is assessed during the performance evaluation process by the employee's supervisor. Each employee is evaluated through an annual performance evaluation and at three interim evaluations. Additional training or retraining may be identified during the evaluation process. Each division maintains documentation of its employees' training.

5.1 Orientation

All new KDEP employees attend an orientation class where they receive an introduction to the department's organization, policy, and procedures. Additional orientation activities are conducted at the various organizational levels of each division and program. All personnel working on projects that involve procurement, data collection, or data evaluation are properly trained and are responsible for implementing the relevant parts of the QAPPs and attendant SOPs.

5.2 General Training

KDEP employees are routinely provided training opportunities to enhance their administrative, management, and computer skills. The Government Services Center (GSC) provides training for employees to improve their communication and management

skills. Departmental policy requires that all managers complete a minimum series of management courses from GSC. Managers are encouraged to pursue the Certificate of Supervisory Essentials (CSE) program. Other internal training opportunities are conducted within individual divisions and branches, and cross training is encouraged between programs. Personnel are also encouraged to seek out training opportunities offered from outside sources.

5.3 Technical Training

KDEP strives to maintain personnel who are technically knowledgeable. Personnel are encouraged and may be required to participate in technical training programs. Technical training is commonly obtained through external sources. Additionally, significant technical training in program requirements and standard operating procedures occurs internally. This in-house training may include other branches or agencies to share new information, technologies, or policies using expertise within the agency or otherwise contracted by the agency. These training sessions are performed by designated qualified personnel.

5.4 Quality Systems Training

The department shall ensure that KDEP personnel are trained on quality systems activities. Personnel that are responsible for developing, implementing, and using quality systems documents shall be identified by the QAO. Training shall be provided biannually for KDEP personnel that provides an overview of quality systems and implementation of quality in the department. Training shall be conducted by the Quality Systems Team or obtained from external sources including the U.S. Environmental Protection Agency. Training for individual divisions, programs, and projects may also be provided to supplement the biannual departmental Quality Systems training. Each training session shall be documented by the QAO and include an evaluation of the training for the QAO and management. The Quality Systems Team evaluates training needs and documents the effectiveness of the training in the annual Quality Assurance Management Review submitted to KDEP management.

5.5 Certifications

The department encourages staff to obtain certifications and actively seeks to hire certified individuals for specific job duties. In addition to professional certification, all personnel involved in projects that require data collection and data assessment are trained, and certified by the project manager and supervisor that the employee is properly trained and familiar with the QAPP and SOPs. All employees must pass the minimum requirements to perform QA procedures and know how to use all instrumentation needed to collect and analyze data. KDEP's programs utilize a variety of certified professional staff including: Professional Engineers, Registered Geologists, and Registered Land

Surveyors. Regulatory mandates and the standards of professional associations may dictate specific certifications for employees. The specific positions requiring certification or license are identified on the class specifications maintained by the Kentucky Personnel Cabinet. Certified or registered individuals are usually employed in the Environmental Engineer I, II, Consultant, Supervisor, or Branch Manager classifications, or Geologist Registered or Geologist Supervisor – Registered classification. Those positions that require certification or license are generally involved with permit review and issuance, project and plan design, and groundwater hydrology.

5.6 Roles and Responsibilities of QA Personnel

Department Quality Assurance Manager

1. Is organizationally separate from the groups generating, compiling and evaluating environmental data
2. Oversees the KDEP quality system
3. Coordinates regular Quality Systems Team meetings comprised of QA staff
4. Plans and coordinates department-level Quality Systems training
5. Conducts annual review of the Quality Management Plan and coordinates revisions
6. Reviews project-specific QAPPs

Division Quality Assurance Officer

1. Acts as a conduit for Quality Assurance information to staff
2. Assists in developing QA policies and procedures
3. Coordinates the input of QA reports
4. Assists in solving QA related problems
5. Ensures that updated QAPPs are in place for all environmental data operations associated with the program
6. Ensures that technical system audits, data quality audits and data quality assessments are performed
7. Tracks and verifies timely implementation of corrective actions
8. Ensures that technical personnel follow the appropriate QAPP
9. Reviews quality assurance / quality control of environmental data

6.0 PROCUREMENT OF ITEMS AND SERVICES

All items and services procured by KDEP's programs that are used in the generation of environmental data must meet the requirements of this QMP. To accomplish this goal KDEP's programs will ensure that:

- Technical specifications for the procurement of an item or service includes specifications that ensure acceptable quality in the item or service;

- The process of selecting a supplier includes an assessment of the supplier's quality system and the supplier's ability to supply items or services that meet quality specifications;
- Items and services provided by a supplier may be evaluated to determine compliance with quality specifications prior to use by the Department's programs; and
- Programs may conduct appropriate audits of the supplier's quality systems as part of project implementation and work with that supplier to correct identified problems as soon as possible.

The branch managers of the administrative branches within the Division of Environmental Program Support, Division for Air Quality, Division of Waste Management, and Division of Water are responsible for overseeing procurement of items and services for their respective divisions and ensuring that the items and services meet the quality needs of the department. In consultation with the QAOs, they shall ensure that contracts with third parties include provisions that the contractor will follow DEP quality assurance procedures.

6.1 Specifications for Items and Services

The project manager will typically develop specifications for the procurement of items and services. The division QAO will participate, as appropriate, to ensure that items and services conform to the requirements of this QMP, the project specific QAPP and the project's data quality objectives. The procurement of items or services must begin with the development of qualitative and quantitative specifications for the item or service. These specifications must include appropriate quality specifications to demonstrate that the item or service is acceptable for use by the department's programs. Examples of these quality specifications for items are technical specification sheets, quality certifications held by suppliers, and certifications of item quality. Examples of quality specifications for services are requirements for certifications held by individuals and suppliers, regulatory mandated requirements for specific test procedures and methodologies, regulatory requirements for quality systems, and program-specific quality control tests or methods. The Division Director or designee will approve all procurement specifications.

6.2 Selection of Suppliers

The selection of suppliers of items and services must include an assessment of the supplier's ability to provide an item or service of adequate quality to be accepted and used by KDEP's programs. When required by KDEP, suppliers of services must have an acceptable quality management plan or project plan that complies with the requirements of this QMP. KDEP may require a supplier to provide statements or documentation on how the quality requirements of the technical specifications will be met during the

duration of any service agreement. If it is determined by KDEP that a supplier's quality system, QMP or QAPP does not meet the requirements of KDEP's QMP and project specific QAPP, then the supplier shall either: 1) modify their existing quality system documentation to meet the requirements of KDEP; or 2) agree to utilize KDEP quality system documents (QMP and project specific QAPP) for the duration of the contract. Certain program-specific QA/QC requirements are written directly into the contract specifications, and must be accepted for the contract to proceed.

6.3 Acceptance of Items and Services

KDEP's programs must determine that items and services are of useable quality prior to their use by the programs. Services provided to KDEP must conform to KDEP's QMP and follow QAPP and SOP templates, or meet these requirements using their own technical program. Each item or service is assessed to determine conformance with the technical specifications for the item. Any quality control information accompanying an item or service is evaluated against the requirements of the technical specifications. Items and services not meeting the technical or quality specifications are audited and may be returned to the supplier.

6.4 Audits of Suppliers

Determining the quality of some items and services can be difficult. At times, the quality of an item or service is established by the supplier's adherence to specific procedures, conducting process quality checks, and documenting process activities. In such cases, KDEP's programs may conduct audits of the supplier's processes to determine compliance with the technical specifications. Audits of suppliers may be conducted when:

1. Such audits are part of the technical specifications for the procurement of the item or service;
2. When suppliers fail to provide usable items or services to the extent that the program believes a quality problem exists; and
3. When a supplier makes substantial changes in their processes or quality system to correct deficiencies.

7.0 DOCUMENTS AND RECORDS

KDEP's programs, in addition to records required by statute, make and preserve records containing adequate and proper documentation of their organization, function, policies, decisions, procedures, and essential transactions. These records serve as the agency's memory and are of critical importance in ensuring that the department continues to function effectively and efficiently. All KDEP personnel are engaged in creating, maintaining, and using records. Therefore, it is important that everyone understands their record management responsibilities.

The process for approval, issuing, revision, using and authentication of quality assurance documents follows a chain of command of quality system personnel. The following table provides a summary of task-specific quality system requirements, their internal controls, and positions within KDEP responsible for those tasks.

Quality Document Type	Activity	Responsible Position	Internal Control	Notes
Quality Management Plan	Preparation	Department QAM	Controlled Document	
	Review / Approval	Branch Managers Division Directors Commissioners Office	Review and approval are documented in internal coordination routing slip. Signature of management documented on the document approval page.	
	Maintenance	Department QAM		
Project Specific QAPP	Preparation	Project Manager	Controlled Document	
	Review/Approval	Branch Manager Branch QAC Division QAO Division Director Department Manager	Review and approval are documented in internal coordination routing slip. Signature of management documented on the document approval page.	QAPPs are retained by each division (e.g. hardcopy, database, server-based)
	Maintenance	Division QAO		
Standard Operating Procedures	Preparation	Project-level Personnel	Controlled Document	
	Review/Approval	Branch Manager Branch QAC Division QAO Division Director Department	Review and approval are documented on internal coordination	

Quality Document Type	Activity	Responsible Position	Internal Control	Notes
		Manager	routing slip. Signature of management documented on the document approval page.	
	Maintenance	Project-level Personnel Division QAO		

Data Quality Objectives	Preparation	Project Manager	Uncontrolled Document	
	Review / Approval	Branch Manager Division QAO Division Director	Review and approval are documented in internal coordination routing slip	DQOs are retained by each division (e.g. hardcopy, database, server based)
	Maintenance	Division QAO		

These central documents (QMPs, QAPPs, and SOPs) developed for the quality system must go through internal review and approval, and upon signature, be controlled to maintain the integrity of the document and the version shall be identified on the documentation control. All QMPs, QAPPs and SOPs are controlled by document number, revision number and unique identification. All persons signing QA documents, from the author to the division director, assume responsibility for understanding the most recent version. The QA Officer has the responsibility to ensure that the most recent version of QA documents is published and available for division or department personnel.

Other documents may be designated for document control by the division QAO, department QAM, or management based on the characteristics of the document or the role it plays in the quality system or the department. Project- or facility-related documents, once approved, are maintained in the department's TEMPO data management system and are locked when completed to maintain document integrity. The date of the document when locked is maintained in TEMPO.

Once internal review is complete, the departmental QMP is submitted to the U.S. EPA Region 4 Quality Assurance staff for review and approval. QAPPs, and SOPs are submitted for external review as required by contract, and signature space is maintained for EPA personnel on those documents.

Identification of necessary revisions may occur at the data collection level, and are communicated immediately to the project manager. QAPPs and SOPs are then amended to include necessary changes, and circulated for review, approval, and signature through the division QAO and management-level personnel. Revised documents with amended document control are distributed to all personnel involved in the monitoring activity, and if necessary, training is provided in any new or amended sampling or documentation methods. Project-level managers are responsible for ensuring that quality documents reflect on-going and completed work, in coordination with branch and/or division QAOs. Current versions of the documents shall be maintained by the division QAO in hard copy and electronically in the central quality assurance document repository located on the network drive for the department. Traceability of KDEP records is maintained through revision numbers on the documents. Historic documents are stored electronically on network drives, and are available for review as needed. The server undergoes daily backup to ensure data integrity. Staff in the resource planning section of each division are responsible for compliance with regulatory and statutory requirements. Project managers and QA officers are responsible that completed work is reported and implemented as stated.

Chain-of-custody (COC) documentation is described and included in every QAPP and SOP that is developed. This COC process is followed throughout the life of the data and/or sample, according to the quality document parameters. If the COC cycle is broken or ill maintained, the samples may be discarded and/or flagged as compromised. Project-level personnel and project managers are responsible for following COC procedures and maintaining custody records that meet appropriate requirements. Chain-of-custody records are maintained in either print or electronic copies, stored in project files or on department networks. Laboratories verify COCs upon receipt, and are returned to KDEP programs when samples are completely analyzed. Legal documents are maintained by the legal office within each division, and are secured and available through legal personnel.

Records will be managed as a department asset throughout their life cycle. Record management consists of three basic stages: creation, active use, and disposition. The record's life cycle is initiated by the creation, collection, or receipt in the form of data or documents in the course of carrying out the department's administrative and programmatic responsibilities. The life cycle continues through processing and active use of the information in the record, until the record is determined to be inactive. The final step is disposition, which frequently includes transfer to inactive storage, followed by transfer to the archives or destruction. Records, including quality assurance records, will be retained in accordance with the Kentucky Department for Environmental

Protection Document Retention Schedule. This document identifies the records requiring retention, the retention time for the document, and the format and location for retention. Branch managers are responsible for ensuring that all documents pertaining to environmental measurement processes are retained in accordance with this schedule. Administrative personnel are responsible for grant management, and ensure that all administrative records are maintained and updated according to regulation, statute, or cooperative agreement. The department's document retention schedule adheres to the document retention policies and procedures of the Kentucky Department for Libraries and Archives (http://www.kdla.ky.gov/recmanagement.htm). The policy includes maintaining the computer hardware and software for re-creating electronic records during the period of retention.

8.0 COMPUTER HARDWARE AND SOFTWARE

Information technology continues to be an indispensable tool for the generation and processing of environmental data. Accordingly, it is very important that the department's information technology is adequate and capable of supporting all of the information technology needs of the department.

The department has multiple levels of IT staff that operate on division-level and project-level teams. Department staff test and maintain overarching data management systems (like the main database for permitting activities, a.k.a. TEMPO and a main database for water quality and biological data storage in Division of Water, a.k.a. KWADE) for all divisions in KDEP through the use of small test groups that perform system checks for general operability. Once test groups are satisfied that a piece of hardware or software will meet the needs of a user, then all users receive the components.

If current computer equipment is determined to not meet the needs of the Department or Divisions, alternate processes must be developed to meet all internal and EPA data reporting requirements. If alternate processes are not available, then the situation would be reported to users and decisions would have to be made at the management level.

8.1 Computer Hardware Assessment and Selection

KDEP depends upon information technology to support its program activities. One of the important components of any information technology is the hardware system(s) that serves as the platform from which applications process, manage, and store information. Hardware includes PCs, servers, mainframe computers, printers, scanners, and local-area and enterprise networks. The evaluation and selection of hardware is based upon the findings of an assessment process that considers the needs of the users, the cost of hardware procurement, installation and maintenance, the compatibility of the hardware

with existing information technology infrastructures, and the training requirements for both users and system administrators.

Several examples of EPA or equivalent databases are:

The department's primary database for the storage of permit, compliance, inspection and project related information is TEMPO. TEMPO includes multiple audits that have been programmed into the system. Depending on the type of audit conducted by TEMPO, emails will be sent at the time the error is created, on a nightly-basis, or on a weekly basis either to the staff responsible for the error or to management. Within TEMPO there are mandatory fields that prevent staff from leaving the page if data is not entered. Masterfile data is restricted to trained staff, and information management staff perform audits of Masterfile to ensure trained staff are not making mistakes. Individual programs have SOPs to note how their data should be properly entered within the program-specific modules. Scanned documents are quality assured and undergo a second quality check to ensure legibility and accuracy of indexing.

The Division for Air Quality houses its monitoring data in a certified EPA database. This AQS system operates by using three SOPs with hands-on training. The SOPs (TS-17-10 Data Quality Assessment, TS-17-14 Data Handling, TS-17-14A Data Processing) that detail the acquisition of ambient air monitoring data from sites in the field, the QA and annual certification of said data, and the submittal of quality assured data to EPA's AQS database are used daily by trained staff and reviewed by supervisors.

The Division of Water is implementing an environmental monitoring database which houses biological and water chemistry data (KWADE). Within the database structure, there are checks and balances on the data whereby a project cannot be completed or used in decisions until two separate people sign off on the content. There are built-in features that address out-of-range values for data. Database entry QA occurs with every entered project, and is done at a 100% level.

The Division of Water also utilizes the EPA database ADB, which is used for assessment reporting for the 305(b) and 303(d) reports. Individual assessments are manually checked for correct entry at a 100% level. Electronic reports are run every 6 months (or whenever requested) to determine errors, and correct as needed.

Individual computers located at user's work stations and laptop units are purchased based on warranty information of the systems, and the cost benefit of providing new components versus upgrading older units. The newest technology available is assured through this process. Contracts for new systems are maintained at the cabinet level, and

are not decided on by KDEP personnel. If components do not meet individual personnel or program needs, then exceptions to the general contracting can be obtained. Examples include additional monitors for more efficient working conditions and additional memory cards for advanced statistics and GIS applications. A petition to cabinet personnel must be accomplished to receive special hardware or software, with program-level personnel providing the justification and rationale for the special need.

8.2 Computer Hardware Upgrades

The number of information-technology processes used by the department's programs continues to grow in size and complexity while the ability of the department's hardware infrastructure to accommodate this growth is an ongoing challenge. The decision to upgrade hardware is based upon the findings of an assessment process that considers the needs of the users, the cost of upgrade procurement, installation and maintenance, the compatibility of the upgraded hardware with existing information technology infrastructures, and the training requirements for both users and system administrators.

8.3 Computer Software Assessment and Selection

Software utilized by the department's programs can be placed into three categories: 1) the cabinet's standardized software for word processing, spreadsheets and desktop publishing; 2) specialized commercial applications such as local area network software, GIS or environmental modeling; and 3) custom software designed and created specifically for the Department's programs. The processes used in the selection of software vary depending upon the software category. The selection of software is based upon the findings of an assessment process that considers how well a specific application can meet the needs of the users, the cost of the application and associated hardware, compatibility with existing information technology infrastructures, and the training requirements for both users and system administrators.

Electronic data submitted for inclusion into KDEP database systems must meet the specified format that is described in the program's Standard Operating Procedure (SOP). The SOP is provided to internal and third-party electronic data producers. Project-specific QAPPs identify the extent of quality control verification of hard copy and electronic data results.

8.4 Personnel

Personnel in the Commonwealth of Technology office (COT) with assistance from the IT sections of KDEP manage main computer databases. Development of databases includes quality assurance fields and required inputs that ensure both appropriate data is entered, and complete data sets are obtained. Each division and each program also has a point of

contact for databases in use for special programs. That person is usually responsible for day-to-day operations and general query creation that meets the needs of many users.

Everyone that enters data into program databases must perform a percentage of data verification compared to the hard copy print outs of environmental data. If errors are made during the transcription process, a third-party is involved to check entry and resolve discrepancies.

Program users of the data are responsible for the completeness and accuracy of the data within program databases. Quality control checks are implemented by every database program, and individuals that are not directly involved in data collection may perform the QC checks upon a percentage of the entered data. Newly developed databases are incorporating certain QC checks on an automated basis, assuring that data values are within acceptable parameters, with commenting fields available for rationale and additional description. Oversight of all electronic storage and management is performed by IT staff within the Department, in cooperation with quality assurance managers.

9.0 PLANNING

KDEP implements planning processes that result in the creation of documents that outline environmental monitoring projects. These documents define processes that maintain a quality environmental measurement system. All staff required to meet project objectives are included in project planning. Procedures for evaluating the effectiveness of the planning process include the success of the project demonstrated through annual reports, the applicability of the project outputs through periodic reporting and review of projects and QA activities though annual reporting to the commissioner of the department.

9.1 Project Plans

Project plans are developed for all major environmental data collection activities conducted by or on the behalf of the department's programs.

The development of project plans is the responsibility of the project supervisor, and the plans are developed in cooperation with specialists in the appropriate planning branch of the division. At a minimum, and depending on the type of project, initial planning meetings occur with geologists, hydrologists, biologists and other scientists within the divisions, QA representatives, and branch-level management. Certain projects may involve local stakeholders and officials. The state laboratory is involved in analysis, and discussions occur with lab personnel when any special analysis is necessary to accomplish the project goals.

Roles and responsibilities for each member of the QAPP team are outlined in the QAPP itself in the appropriate section. Detail is included on development, review and

implementation roles. QAPPs developed outside of the agency also follow the same guidance for roles and responsibilities, and included are KDEP management and reviewers, as necessary.

The type and quality of data is partially pre-determined by strategic and operational planning within the department. Desired outcomes for data quality are outlined within QAPP documents, and types of data are determined by EPA-directed grants and state-funded projects. Individual QAPPs specify the data quality objectives, which may exceed the assertion that all data will meet the quality standards outlined in the QMP.

Management is involved in initial prioritization of planning, and the branch managers and QA officers present projects to division-level staff as appropriate. The division directors and department QA manager review and approve all project plans, and therefore have input prior to the beginning of all monitoring projects.

The division QAO reviews each project plan to ensure that it includes all quality components as outlined by this Quality Management Plan. All project plans require approval by the branch manager, branch QA coordinator (if applicable), division QAO, and division director or designee, and the department QAM. This review chain includes all internally and externally generated QAPPs and SOPs.

Each project plan will include the following minimum components:

Project Management

1. Title and Approval Sheet
2. Table of Contents
3. Distribution List
4. Project/Task Organization
5. Problem Definition and Background
6. Project/Task Description
7. Quality Objectives and Criteria
8. Special Training/Certifications
9. Documentation and Records

Measurement and Data Acquisition

1. Sampling Process Design (Experimental Design)
2. Sampling Methods
3. Sample Handling and Custody
4. Analytical Methods
5. Quality Control
6. Instrument/Equipment Testing, Inspection, and Maintenance
7. Instrument/Equipment Calibration and Frequency
8. Inspection/Acceptance of Supplies and Consumables

9. Non-direct Measurements
10. Data Management

Assessment and Oversight

1. Assessments and Response Actions
2. Reports to Management

Data Validation and Usability

1. Data Review, Verification, and Validation
2. Verification and Validation Methods
3. Reconciliation with User Requirements

9.2 Sampling/Study Plans

Project plans should be used in conjunction with sampling plans, or elements of the sampling plan may be incorporated into the project plan itself. The project officer prepares a sampling/study plan for each activity. Only those activities conducted in response to emergencies and unexpected events that occur in the field are not required to have a study plan prepared prior to the event. However, the emergency arm of the department should have a pre-prepared SOP to cover activities commonly encountered. Also, after the emergency has been resolved, the process followed is clearly documented and procedures are reviewed for effectiveness and quality assurance. Typically, sampling/study plans are no more than 1-2 pages in length. Sampling/study plans clearly state the purpose of the measurement event and outline the investigative approach to be followed. Sampling/study plans identify who will be involved in the activity, what the activity will include, reference to a specific SOP, when the event will occur, and how the environmental monitoring data will be stored and utilized. Sampling/study plans also serve as a communication tool that coordinates activities between programs such as sample collectors and the laboratory.

9.3 Standard Operating Procedures

It is the responsibility of the branch manager to ensure that SOPs are developed and updated for routine program processes involved with the generation of environmental data and administrative program elements. The programs responsible for implementing the process will develop the SOPs. If there is an activity that is standard across divisions or programs, divisions and programs may work together to create a joint SOP for those activities. The QAO, branch manager and division director approve all SOPs.

9.4 Environmental Data Operations Planning

The following outlines the process adopted by KDEP for planning environmental data operations:

1. Identify roles and responsibilities of management and staff – Division directors have overall responsibility for managing the divisions. The direct responsibility for assuring data quality is with management. Ultimately, the director is responsible for establishing QA policy and for resolving QA issues identified through the QA program.

2. Identify how technical expertise in sampling, statistics, analytical services, and QA/QC is provided – Adequate education and training are integral to any program that strives for reliable and comparable data. Personnel assigned to these tasks will meet the education, work experience, responsibility, personal attributes, and training requirements for their positions.

3. Use of data quality objectives in planning process – Data Quality Objectives are used to establish the link between specific end use(s) of the data with the data collection process and data quality needed to meet a program's goals. The DQO process is a multi-step process based on scientific methods to ensure that the data collected meets the needs of the data user(s) and the decision makers in terms of information to be collected. The DQO process will be used during the development of program / project specific QAPPs.

4. Process for preparing, reviewing and approving QAPP – Program/project-specific QAPPs are initiated by the project manager which must include all of the necessary technical aspects of the program / project. The QAPP is then reviewed by the division director and the division QAO.

5. Process for preparing, reviewing, and approving QAPPs for/by contractors – Program/project-specific QAPPs that are submitted by third-party contractors must be reviewed and approved prior to commencement of work activities. The contractor's QAPP should be reviewed by the responsible KDEP program, or project manager, the division director and the division QAO.

9.5 Review Process and Approval of Outside Contractors Work Processes

Contractors providing data that are proposed for use in KDEP programs are required to prepare and implement a quality system. Adopting the KDEP quality system and documents is an option, or outside entities can develop their own system and submit for

review by KDEP quality assurance staff. All QAPPs and SOPs that are prepared by outside agencies must be reviewed and accepted by KDEP, following the same procedures as internal documents. Data reporting is also required to be submitted for review prior to project completion.

10.0 IMPLEMENTATION OF WORK PROCESSES

The QMP is reviewed annually by Division QAOs and the QAM. The QMP is revised when significant revisions are required. The QMP must be updated and resubmitted to EPA on a five year schedule; edits are performed by the QAOs and QAM.

Each division's QAO shall ensure that QAPPs are reviewed on an annual basis. The project manager is responsible for development of the Quality Assurance Project Plan and evaluating the Standard Operating Procedures and sampling/study plans for the project on an annual basis. The project manager shall distribute the planning documents to individuals on the distribution sheet in the planning documents for review, modification, and approval. Upon approval of the individuals on the distribution list, the final planning documents shall be stored electronically as a PDF on a shared network drive and an approved copy transmitted to the appropriate program office when required by grant, Memorandum of Agreement, or other funding mechanism. The approved planning documents shall be made available to project personnel and stakeholders for implementation submitted through the mail, email, or from the Department or Division's web sites. All revisions to these documents will be tracked on the 'Revision History' section in the QAPPs and SOPs, and distributed to all involved parties through the previously-mentioned avenues.

All sampling, analyses, and data management related to environmental measurement will be conducted in a manner consistent with the requirements of an approved project plan and sampling/study plan. The project manager is responsible for ensuring that audits of project and sampling/study plans are conducted in a timely manner, and for determining that environmental data generation processes conform to project specifications. In addition, the project manager ensures that deficiencies or deviations from the approved plans are identified and corrective actions are implemented, and that reports on the implementation of project and sampling plans are made to management. The planning documents shall be revised as needed in response to the corrective actions.

The implementation of project and sampling/study plans is documented by the reports prepared by the project manager. Strategy and sampling plan activities may need to be modified prior to or during implementation of the planning documents. Changes in the design or implementation of project plans must be documented as attachments to the project plan. The project manager must approve each attachment.

Management reviews of programs are conducted to assess the performance of the environmental data generation processes. An important outcome from these reviews is the identification of processes benefiting from the development of Standard Operating Procedures. Based upon recommendations from management reviews, the division director or designee will instruct the appropriate branch manager to develop or modify specific Standard Operating Procedures.

Project progress is tracked by the branch manager and section supervisor to ensure that the projects are following the required timeline. The manager and supervisor may adjust the timeline and reassign staff to reflect priorities and department and division commitments.

Administrative work processes in the Department for Environmental Protection are conducted in compliance with business rules developed for the TEMPO database (Tools for Environmental Management and Protection Organizations) and other approved databases to ensure consistency and assure data quality and document storage and availability.

11.0 ASSESSMENT AND RESPONSE

All programs conducting environmental measurement processes conduct systematic assessments of the performance of these programs. These assessments are performed to determine how successful each process is in accomplishing the goals of the quality system. The division director is responsible for:

1. Assembling individuals with the level of competence, experience, and training necessary to conduct the assessment;
2. Authorizing the individuals access to programs, managers, staff, documents and records;
3. Receiving and approving the assessment report containing the findings and recommendations from the assessment; and
4. Approving and implementing changes and/or corrective actions.

The division quality assurance officer shall coordinate the quality assessment and response process. Disputes that originate in the quality system between quality assurance procedures and recommendations shall be addressed by the branch manager in consultation with the division QAO. The division director shall have final authority in resolving any disputes or inconsistencies that result from or are identified by the assessment. If a resolution is in question after consultation with division directors, the QAM will then have final authority on conducting or accepting the audits and assessments.

11.1 Assessments

Management Reviews

Management reviews are conducted annually by executive management to examine the quality management structure, policies, practices, and procedures and ensure that they are adequate for producing the necessary data and quality. Division management reviews are conducted annually by the division. The division QAO will coordinate the annual quality management review. The department will report on quality assurance activities for the fiscal year by developing a Quality Assurance Annual Review.

Technical Assessments

Regular technical assessments that are based on objective evaluations and identify effective corrective actions are an important part of a progressive QA program. Program personnel periodically perform technical assessments of the departmental procedures. These assessments consider methods, QA/QC procedures, documentation, and records. Assessments that focus on performance, standard traceability, and documentation of testing activities are also performed on a regular basis by program personnel as necessary to track performance trends and identify performance problems or issues.

Data Quality Assessments

Data quality assessments are performed to ensure that the data meets the desired quality. These assessments are conducted by program personnel when receiving data for analysis and use. Each division determines the quality of data needed in a particular situation as part of the planning process. Because the level of data quality is dependent upon the requirements of the user, criteria are not specified in this document. It is important to stress cooperation between the user and laboratory when determining data quality needs.

The general criteria used for assessing data quality include: precision, accuracy, representativeness, comparability, and completeness. Objective evaluation of data quality requires that both the data user and the laboratory agree upon specific criteria with respect to the analytical needs of the user and the analytical capabilities of the laboratory.

Reconciling DQOs from the QAPPs is a part of the data usability analysis, and decisions are made based on whether data meets or exceeds the established thresholds of acceptability that are stated in the QAPP. The evaluation of sampling designs, error determination and basis for assumptions are all addressed by project planning teams and assessed in periodic and final reporting. Based on the findings in assessment reporting determines the action taken by management concerning the data collected by each project. Management signs off on project plans, and therefore has the opportunity to comment and address deficiencies that may arise during project operations.

11.2. Assessment Response

Following the completion of an assessment, the assessor will submit a report to the division director. The assessment report will include:

1. A determination of whether tasks were performed in accordance with established criteria (SOP & directives);
2. An identification of any deviations from approved procedures;
3. Proposed recommendations for resolving quality problems; and
4. An evaluation of whether the process produces an outcome that is consistent with quality system objectives.

The division director will review the report and forward it to appropriate management. Management is responsible for reviewing the report with the program staff. In the event that the report identifies a concern, management will initiate corrective action. The division director shall have final authority in resolving any disputes or inconsistencies that result from or are identified by the assessment within each division. The implementation of corrective actions identified during program assessments will be tracked by the division QAO. The division QAO will maintain documentation of corrective actions. Written response to the assessment and audit findings will be prepared. The QAM receives notification of all such actions, and is consulted as necessary. Monthly meetings between all QAOs and the QAM discuss all procedures related to audits or assessments conducted for division programs.

12.0 QUALITY IMPROVEMENT

KDEP is committed to a proactive approach that provides continuing improvement in the quality of its technical activities and administrative services. Planning, documentation, implementation, and assessment are critical components to ensuring quality programs. The Quality Management Plan provides an important input to the department's strategic planning process to ensure the quality of the department's environmental data generation processes are maintained and improved.

Improvement will be accomplished through regular annual reviews of departmental quality procedures, project plans, standard operational procedures, review and update of the Quality Management Plan, Quality Assurance Annual Report, and biannual quality assurance training. The Quality Systems team meets monthly to review implementation of the Quality Management Plan.

Quality improvement is an ongoing process and personnel at each level have responsibilities for improvement in the department's quality system. Program staff should follow quality processes, participate in quality assessment and corrective action activities, and provide recommendations to the project manager on opportunities to improve the process or activities, and participate in developing standard operating

procedures. The project manager ensures compliance with quality processes and identifies procedures during assessment for improvement. Quality Assurance coordinators and officers for programs and divisions coordinate implementation of the quality system and serve as points of contact for program staff on implementation and improvement of the quality system. The departmental QAM and management are responsible for regular reviews of the KDEP Quality System and identification of opportunities for improvement.

If processes are discovered that contradict or fall outside of the KDEP quality processes, they shall be identified and addressed at the lowest management level, if possible, in consultation with the division QAO. If there are disputes regarding resolution of processes, the division director has final authority for dispute resolution.

Corrective action reviews are part of the QAPP narrative. Templates for corrective action are developed at the division level. The template documents corrective action procedures, and provides for action taken during such reviews. Management then examines results from corrective action reviews and provides input and decisions on next steps in the process.

Formal corrective action, including compliance deadlines, is documented, tracked and verified using the department-wide database (TEMPO), available to all staff. The Division of Enforcement has procedures for maintaining formal corrective action documentation.

13.0 REFERENCES

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14.0 TERMS AND DEFINITIONS

Accuracy - The degree of agreement between an observed value and an accepted reference value; a data quality indicator.

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

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

Comparability - The degree to which different methods, data sets, and/or decisions agree or can be represented as similar; a data quality indicator.

Completeness - The amount of valid data obtained compared to the planned amount, and usually expressed as a percentage; a data quality indicator.

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

Data Quality Objectives (DQO) - Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Design – specification, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

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

Environmental data – any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology.

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

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

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

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

Historical data - Previously collected information from one or more projects which may or may not be useful for a new purpose. This is also known as existing data or secondary data.

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

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

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

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

Management systems review – the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure,

policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

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

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

Precision – The degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves; a data quality indicator.

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

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

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

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

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

Quality Assurance Project Plan (QAPP) – a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be

implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Quality improvement – a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

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

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

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

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

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

Representativeness – The degree to which data accurately and precisely represent the frequency distribution of a specific variable in the population; a data quality indicator.

Secondary data – Preexisting or acquired information collected by others for other purposes commonly used during a project's preliminary assessment; for geographic data this may include aerial photographs or information generated for or by external, independent parties, which are then transmitted to the current user. See also historical data.

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

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

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

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

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

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

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

APPENDICES

Appendix A. Quality Assurance Project Plans

Quality Assurance Project Plan

(QAPP)

Title of Project

Kentucky Energy and Environment Cabinet
Department for Environmental Protection
DIVISION
BRANCH

Revision Number: 1.0
Effective Date:

General QAPP Requirements - Contents

Project Management

1. Title and Approval Sheet
2. Table of Contents
3. Distribution List
4. Project / Task Organization
5. Project Definition / Background
6. Project Task Description
7. Data Quality Objectives for Measurement Data
8. Special Training Requirements / Certification
9. Documentation and Records

Measurement / Data Acquisition

1. Sampling Process Design
2. Sampling Methods Requirements
3. Sample Handling and Custody Requirements
4. Analytical Methods Requirements
5. Quality Control Requirements
6. Instrument / Equipment Testing, Inspecting and Maintenance Requirements
7. Instrument Calibration and Frequency
8. Inspection / Acceptance Requirements (for supplies and consumables)
9. Non-direct Measurements
10. Data Management
    Data Submission Format(s) and Minimum Requirements
    A. Laboratory Hardcopy
    B. Electronic Data Submission
    Data Handling and Storage
    A. File Library
    B. Retention Policy

Assessment / Oversight

1. Assessments and Response Actions
2. Reports to Management

Data Validation and Usability

1. Data Review, Verification, and Validation Requirements
2. Validation and Verification Methods
3. Reconciliation with Data Quality Objectives

Appendix B. General QAPP – Additional Information

The following supporting information may be included in a QAPP, as applicable. Depending on the QAPP, it could be included in the body of the QAPP or included as an appendix.

1. Organizational Chart
2. List of Acronyms
3. Glossary of Quality Assurance and Related Terms
    a. Glossary of Quality Control Terms
    b. Glossary of Field Sampling Terms
    c. Validation Activities Glossary of Terms
4. Checklists Useful in Quality Assurance Review
5. Example Standard Operating Procedure – Administrative Format
6. Example Standard Operating Procedure – Technical Format
7. References Cited

Appendix C. Standard Operating Procedures

Example Cover Sheet

Short Title/ID# _____
Rev. # _____
Date: ____/____/____
Page 1 of ____

[TITLE]

STANDARD OPERATING PROCEDURE

_____
(Show Name Here)

Prepared by: _____ Date: _____
(Show Title Here)

Reviewed by: _____ Date: _____
(Show Title Here)

Approved by: _____ Date: _____
(Show Title Here)

Kentucky Department for Environmental Protection
DIVISION
BRANCH

Standard Operating Procedure –Format

1. Title Page
2. Table of Contents
3. Procedures
    a. Scope & Applicability
    b. Summary of Method
    c. Definitions
    d. Health & Safety Warnings
    e. Cautions
    f. Interferences
    g. Personnel Qualifications
    h. Equipment and Supplies
    i. Procedure
    j. Data and Records Management
4. Quality Control and Quality Assurance Section
5. Reference Section (including any referenced or related SOPs)

More details on developing Standard Operating Procedures may be found in "Guidance for Preparing Standard Operating Procedures (SOPs)" EPA QA/G-6 (http://www.epa.gov/quality/qs-docs/g6-final.pdf). The SOP should follow the review and approval procedures described in the Quality Management Plan and should include SOP Document Control to allow for tracking of changes to the SOP.

Appendix D. List of Department Acronyms

106	Overall Water Pollution Control Program Grant, Clean Water Act
401	Water Quality Certification under Section 401 of Clean Water Act
402	Point Source Discharge permits under Section 402 of CWA (NPDES)
404	Dredge and Fill permit under Section 404 of Clean Water Act
104(b)(3)	EPA Special Studies in Water Quality Grant
106(g)	33 USC 1256 Groundwater Pollution Control Program Grant; 33 USC 1256(g)
303(d)	A listing of waters that do not meet water quality criteria.
305(b)	A report to Congress on water quality conditions in Kentucky
319(h)	Section of the Clean Water Act that pertains to nonpoint source pollution
7Q10	A stream flow that statistically occurs for 7 days once every 10 years
ASIWPCA	Association of State and Interstate Water Pollution Control Administrators
ASTM	American Society for testing of Materials
ATSDR	Agency for Toxic Substances and Disease Registry
BACT	Best Available Control Technology
BMP	Best Management Practice(s)
BOD	Biochemical Oxygen Demand
CAA	Clean Air Act
CAS	Chemical Abstract Service
CDBG	Community Development Block Grant
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act (1980)
CFR	Code of Federal Regulations
cfs	cubic feet per second
CLP	Contract Laboratory Program
COC	Chain of Custody
CSO	Combined Sewer Overflow
CWA	Clean Water Act
DAQ	Division for Air Quality
DEP	Department for Environmental Protection
DMR	Discharge Monitoring Report
DNR	Department for Natural Resources
DOE	Department of Energy
DOW	Division of Water
DQA	Data Quality Assessment
DQI	Data Quality Indicator

DQO	Data Quality Objective
DWM	Division of Waste Management
DWS	Drinking Water Standard
DWSRF	Drinking Water State Revolving Fund
EEC	Energy and Environment Cabinet
EF	Emission Factor
EI	Emissions Inventory
EIS	Environmental Impact Statement
EPA	Environmental Protection Agency
fps	feet per second
FR	Federal Register
GIS	Geographic Information System
GLP	Good Laboratory Practices
gpd	gallons per day
gpm	gallons per minute
GPS	Global Positioning System
IARC	International Agency for Research on Cancer
ICP	Inductively Coupled Plasma
IDLH	Immediately Dangerous to Life and Health
ISO	International Organization for Standardization
KAR	Kentucky Administrative Regulation
KDEP (or KYDEP)	Kentucky Department for Environmental Protection
KGS	Kentucky Geological Survey
KIA	Kentucky Infrastructure Authority
KPDES	Kentucky Pollution Discharge Elimination System
KRS	Kentucky Revised Statute
LC	Lethal Concentration. Liquid Chromatography
LCA	Life Cycle Assessment
LDAR	Leak Detection and Repair
LIDAR	Light Detection and Ranging
LNAPL	Light Non-Aqueous Phase Liquid
LOAEL	Lowest-Observed-Adverse-Effect-Level
MACT	Maximum Achievable Control Technology
MCL	Maximum contaminant level
MCLG	Maximum contaminant level goal
MDL	Method Detection Limit
MEI	Maximally (or most) Exposed Individual

mg/L	Milligrams per liter
MGD	Million gallons per day
MOA	Memorandum of Agreement
MSL	mean sea level
MSW	Municipal Solid Waste
NAAQS	National Ambient Air Quality Standards
NAPL	Non-Aqueous Phase Liquid
NAS	National Academy of Sciences
NEPA	National Environmental Policy Act
NESHAP	National Emission Standard for Hazardous Air Pollutants
NIEHS	National Institute for Environmental Health Sciences
NIOSH	National Institute of Occupational Safety and Health
NIST	National Institute of Standards and Technology
NOAEL	No Observable Adverse Effect Level
NOEL	No Observable Effect Level
NOx	Nitrogen Oxides
NPDES	National Pollutant Discharge Elimination System
NPS	Nonpoint Source
NSF	National Sanitation Foundation
NSR	New Source Review
NTU	Nephelometric turbidity unit
O_3	Ozone
OAQPS	Office of Air Quality Planning and Standards
OSHA	Occupational Safety and Health Administration
PAH	Polynuclear Aromatic Hydrocarbons or Polycyclic Aromatic Hydrocarbons
PARCC	Precision, Accuracy, Representativeness, Comparability, and Completeness
PM	Particulate Matter
PM10	Particulate Matter (10μm and less)
PM2.5	Particulate Matter Smaller than 2.5 μmeters
POTW	Publicly Owned Treatment Works
ppb	Parts per billion
PPE	Personal Protective Equipment
PPG	Performance Partnership Grant
ppm	Parts per million
PRP	Potentially Responsible Party
PSD	Prevention of Significant Deterioration
PTE	Potential to Emit

PWS	Public Water System
QA	Quality Assurance
QA/QC	Quality Assistance/ Quality Control
QAC	Quality Assurance Coordinator
QAM	Quality Assurance Manager
QAO	Quality Assurance Officer
QAPP	Quality Assurance Project Plan
QC	Quality Control
RCRA	Resource Conservation and Recovery Act
RI/FS	Remedial Investigation/ Feasibility Study
RQ	Reportable Quantity
SCFM	Standard Cubic Feet Per Minute
SCR	Selective Catalytic Reduction
SDWA	Safe Drinking Water Act
SDWIS	State Drinking Water Information System
SEP	Supplementary Environmental Project
SIC	Standard Industrial Classification
SIP	State Implementation Plan
SOP	Standard Operating Procedure
SPAP	Special Appropriations Grant
SRF	State Revolving Loan Fund
SWMU	Solid Waste Management Unit
TC	Total coliform(s)
TDS	Total Dissolved Solids
TIC	Tentatively Identified Compounds
TMDL	Total Maximum Daily Load
TSCA	Toxic Substances Control Act
TSS	Total Suspended Solids (non-filterable)
ug/L	Micrograms per Liter
USEPA	United States Environmental Protection Agency
USGS	United States Geological Survey
VOC	Volatile Organic Compound
WQS	Water Quality Standard
WWTP	Wastewater Treatment Plant

Appendix E. Revisions

Revisions in #3.0 from Revision # 2.2 (December 9, 2010)

Title Page and Page Headers	Revised Content for date and version number
Entire Document	Re-organized sections for better flow, i.e., organizational charts.
Entire Document	Re-numbered sections to reflect new organizational flow.
Section 1.0	Added assistance grant award language to include all relevant laws to the quality system framework.
Section 2.0	Added all divisions in the department.
Section 3.0	Added statement about Kentucky's laboratory certification program.
Section 5.2	Amended statement on training agency and available training programs.

Revisions in #3.1 from Revision # 3.0 (September 30, 2015)

Section	**Revised Content**
Title Page and Page Headers	Updated date and version number
Section 1.0	Added language describing allocation of resources for quality assurance activities. Revised language regarding KDEP's submission of the quality assurance competency document.
Section 2.0	Clarified KDEP programs and processes that require quality management controls.
Section 3.0	Clarified roles and responsibilities for QMP preparation, review and approval. Revise language regarding DEPS LOQAM development and operations.
Section 3.2	Clarified that the DEP QAM has final authority to determine quality and usability of environmental data.
Section 4.3	Corrected item 5 under elements of a the Data Quality Objectives process.
Section 6.0 and Section 9.5	Added language regarding conformance with and use of KDEP QMP, SOPs and

	QAPP by 3rd party contractors and suppliers.
Section 8.0	Additional language to describe IT equipment and software needs and reporting requirements and response to changes in IT needs. Additional language to describe QA process for determining completeness and accuracy of data in KDEP primary databases.
Section 10.0	Revised language regarding annual review and revision process for KDEP QMP, QAPPs and SOPs. Clarified that final, approved copies of these documents shall be stored electronically as PDFs.
Section 11.0	Clarified the roles of staff performing internal audits and assessments.