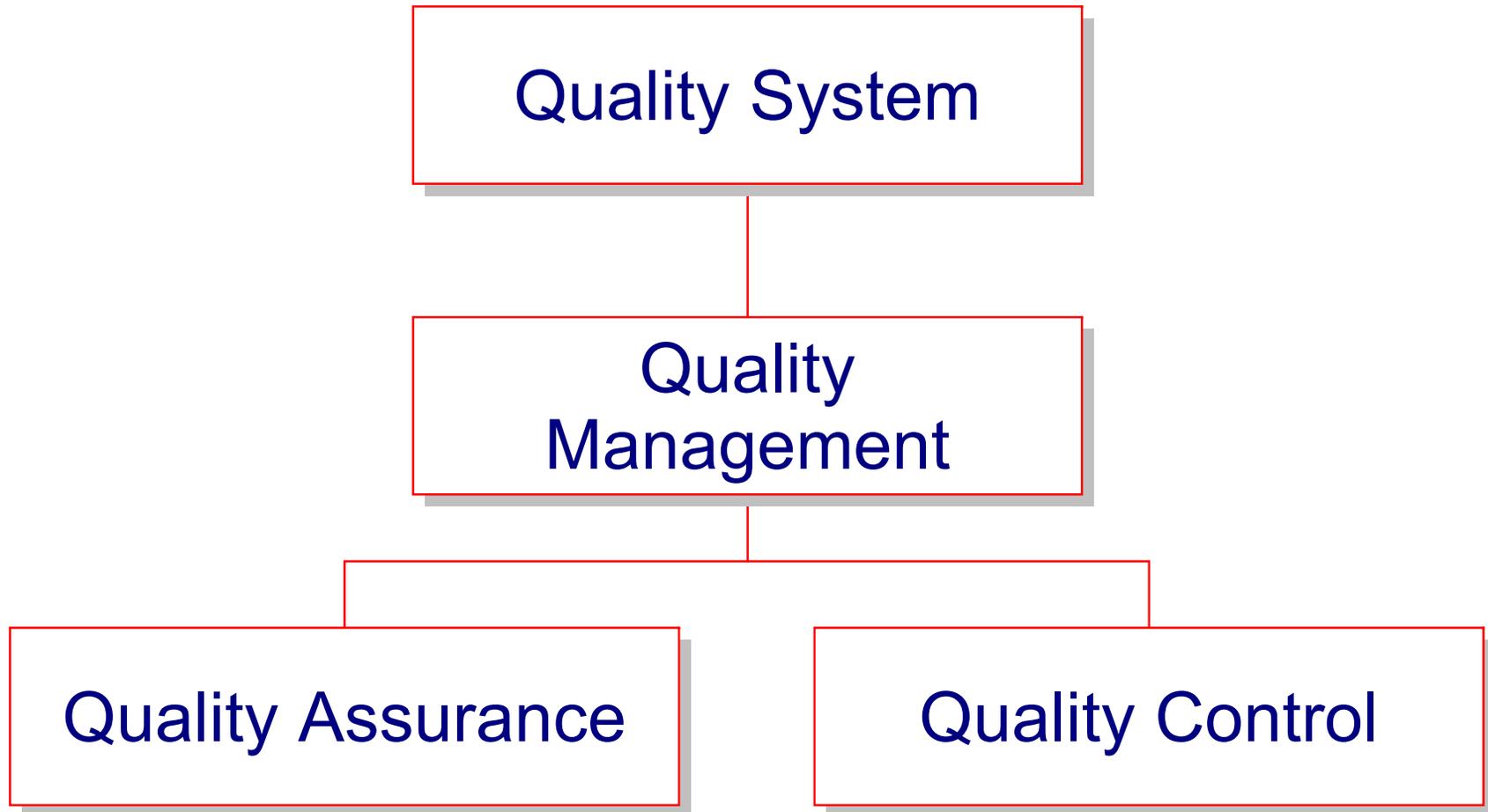

Introduction to EPA Quality System Requirements

Course Goals

At the completion of this course, you will:

- **Understand EPA's quality system requirements**
- **Understand the roles and responsibilities in implementing a quality system that meets EPA requirements**
- **Be familiar with the basic tools of the EPA Quality System**

What is a Quality System?



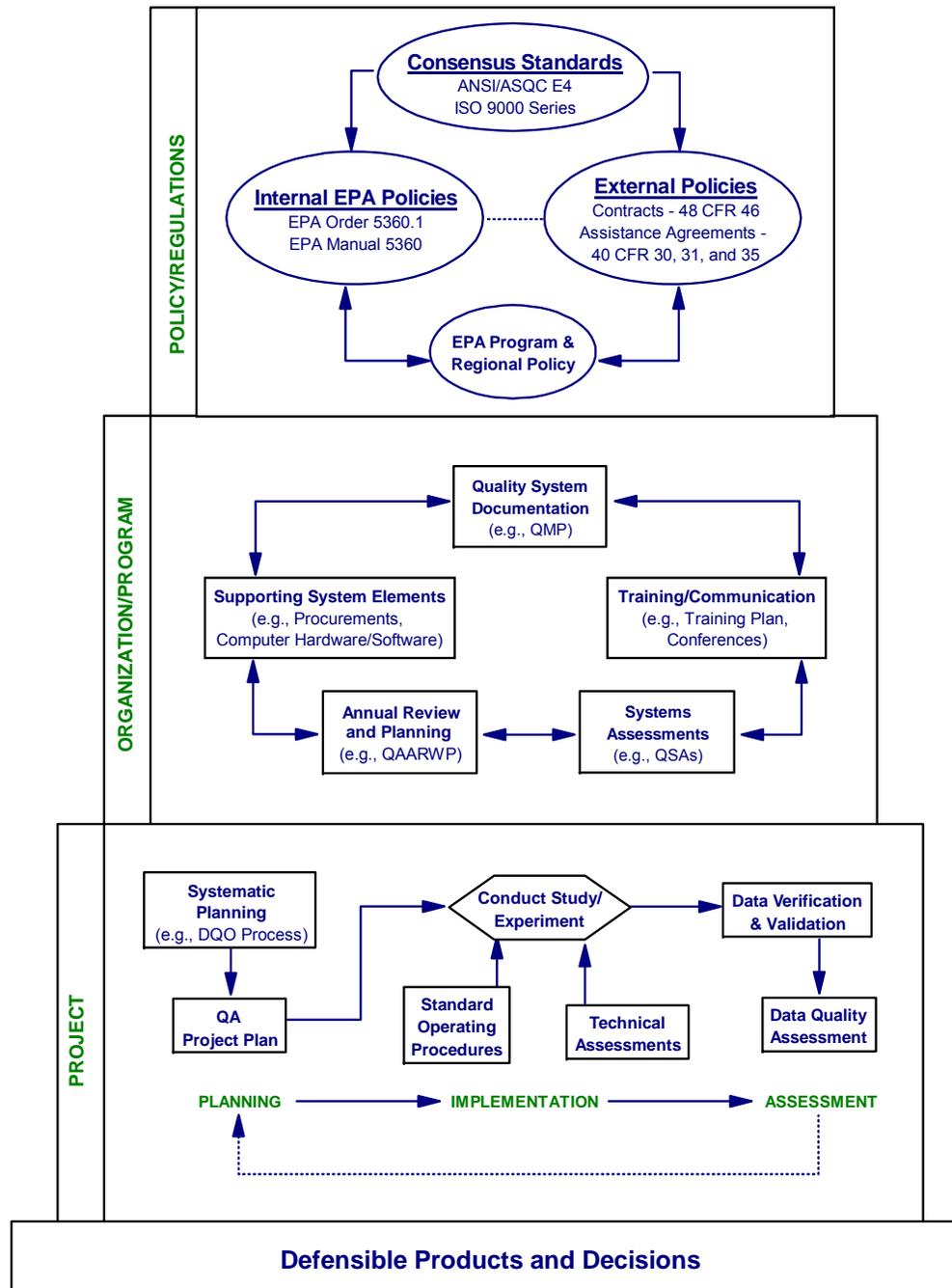
Participants in the Quality System

- **EPA Personnel**

- Executive Leads/Senior Managers for National Programs
- Regional Administrators and Senior Managers
- Quality Management Personnel
- Agency Managers and Staff
 - For contracts: Project Officer, Work Assignment Manager, Delivery Order Manager

- **Non-EPA Personnel**

- Contractors
- Assistance Agreement Partners
- Interagency Agreement Partners



Types of Quality Management Tasks

- **Exclusively EPA functions**
 - Performed by EPA officials such as QA Managers (QAMs) or other designated officials
- **Discretionary Functions**
 - Performed by either EPA personnel or non-EPA personnel

Exclusive Quality Management Tasks

- **Managing and coordinating the Quality System**
 - **Quality Management Plan (QMP)**
 - **QA Annual Report and Work Plan (QAARWP)**
- **Reviewing and approving procurement and financial assistance documents for QA requirements**
- **Reviewing and approving QA planning documents**
 - **Quality Assurance Project Plan (QAPP)**
- **Tracking and reporting Quality System deliverables**

Exclusive Quality Management Tasks

- **Developing guidelines and procedures to implement QA/QC**
- **Managing contractor support work assignments and delivery orders**
- **Planning and conducting management assessments**
- **Planning and conducting technical assessments**
- **Reviewing and approving final reports for quality documentation**

Discretionary Quality Management Tasks

Tasks integral to an effective quality system but not explicitly required by EPA Order 5360.1 include:

- Reviewing and assisting in the development and preparation of environmental data collection survey designs
- Preparing and presenting quality management information
 - In technical literature
 - At meetings and symposia
- Performing research relative to quality management issues

Goals of the EPA Quality System

- **Protect human health and the environment**
- **Make correct decisions**
- **Conserve/optimize resource use**
- **Ensure that environmental programs and decisions are supported by data of the type and quality needed for their intended use**

Graded Approach

QA and QC requirements commensurate with:

- **Importance of work**
- **Available resources**
- **Unique needs of organization**
- **Consequences of potential decision errors**

EPA Quality System Requirements

EPA and non-EPA Organization

- American National Standard, ANSI/ASQC E4

EPA Organizations

- EPA Order 5360.1
- EPA Order 5360 (Quality Manual)
- Contracts Management Manual (EPA Order 1900)

Non-EPA Organizations

- Federal Acquisition Regulations (for non-EPA Organizations)

EPA Order 5360.1

EPA Order 5360.1 Policy and Program Requirements for the Mandatory Agency-wide Quality System

- Defines Quality System requirements for EPA organizations**
- Requires participation by every EPA organization collecting and using environmental data for decision making**
- Requires that the EPA Quality System comply with ANSI/ASQC E4-1994**

American National Consensus Standard

ANSI/ASQC E4, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs

- American National Consensus Standard providing the basis for planning, implementing, documenting, and assessing a quality system
- Includes non-mandatory guidelines for going beyond minimum requirements
- Part A: Management Systems
- Part B: Environmental Data
- Part C: Environmental Technology

Internal EPA Quality System Requirements

An EPA Organizations must:

- Assign a Quality Assurance Manager (QAM) independent of the data generation line of management**
- Document the organization's quality system in a Quality Management Plan (QMP)**
- Provide sufficient resources to implement the quality system**
- Submit a QA Annual Report and Work Plan annually**
- Assess its quality system annually**

Internal EPA Quality System Requirements - Continued

An EPA Organization must:

- Ensure that corrective actions from assessments are implemented**
- Use a systematic planning approach for work**
- Approve QA Project Plans prior to start of work**
- Implement Quality System requirements in all EPA funded extramural agreements**
- Assess the quality of "secondary data"**
- Provide appropriate training for all management and staff**

EPA Quality Manual 5360

- **Defines procedures for satisfying the internal EPA Quality System Requirements**

EPA Contracts Management Manual

- **Requires QA Review Form for contracts, work assignments, delivery orders, and task orders**
- **QA Review Form signed by EPA QA Manager or authorized representative.**

Extramural Agreements

Extramural Agreements include:

- **Acquisitions including:**
 - **Contracts**
 - **Work assignments**
 - **Task orders**
 - **Technical directives**
- **Financial assistance including:**
 - **Cooperative agreements**
 - **Grants to state and local governments**
 - **Research grants**
 - **Grants to non-profit organizations**
- **Interagency agreements**

Authorizing Regulations for Quality Requirements

- 48 CFR Part 46, "Federal Acquisition Regulations"
- 40 CFR Part 30, "Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations"
- 40 CFR Part 31, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments"
- 40 CFR Part 35, "State and Local Assistance"
- EPA ICR #0866, OMB #2080-033, "QA Specifications and Requirements"

Quality System Requirements for Extramural Agreements

EPA requirements for extramural agreements include:

- Conformance to ANSI/ASQC E4-1994**
- Documentation of the organization's quality system (usually called a Quality Management Plan) which should be approved prior to initiating environmental work, and/or**
- Documentation of the application of quality assurance and quality control activities to activity-specific efforts (usually called a Quality Assurance Project Plan) which should be approved prior initiating environmental data collection.**

EPA Acquisitions 48 CFR Part 46

- **Proposal from offeror must include:**
 - **Quality Management Plan and/or**
 - **QA Project Plan and/or**
 - **Combination Quality Management Plan/QA Project Plan**
- **QA Project Plan is required for individual projects after award**

Financial Assistance- Non-Profit Group

40 CFR Part 30

- **Applications must include:**
 - **Quality Management Plan or**
 - **Combination Quality Management Plan and QA Project Plan**
- **QA Project Plan is required for individual projects after award**

Financial Assistance- State and Local Governments 40 CFR Parts 31 and 35

- **Pre-Award/Application**
 - **Quality Management Plan (or Joint Quality Management Plan/QA Project Plan) required**
 - **Plan Must demonstrate suitability and effectiveness of Quality System to Award Official**
 - **Plan Must demonstrate conformance to ANSI/ASQC E4**
- **Post-Award**
 - **QA Project Plans required for individual projects**

Financial Assistance- Research Grants

40 CFR Part 30

- **Applications must include:**
 - **Quality Management Plan or**
 - **Combination Quality Management Plan and QA Project Plan**
- **QA Project Plan is required for individual projects after award**

Interagency Agreements

- **EPA Quality System requirements cannot be unilaterally imposed (Office of General Counsel opinion)**
- **When EPA provides funding:**
 - **Add a special condition to invoke conformance with ANSI/ASQC E4**
- **When another Agency provides funding to EPA:**
 - **EPA Quality System requirements are applicable**

Aids for Implementing the Quality System-Documentation

- For EPA, requirements are given in EPA Quality Manual for Environmental Programs (EPA Order 5360)
- For holders of extramural agreements, requirements are given in EPA Requirements Documents (QA/R-Series) produced by the Quality Staff
- For everyone, non-mandatory guidelines are given in EPA Guidance Documents (QA/G-Series) produced by the Quality Staff
- Documents, regulations, and QA contacts are available at www.epa.gov/quality

Quality Management Tools at EPA

Planning:

Quality Management Plans
QA Project Plans
Data Quality Objectives Process

Implementation:

QA Project Plans
Standard Operating Procedures
QA Annual Report and Work Plans

Assessment:

Management Assessments
Technical Assessments
Data Quality Assessment
Data Validation and Verification

Quality Management Plans

Purpose: To document how an organization will plan, implement, and assess its Quality System

Responsibility: Senior Management

Documentation: EPA Users: *Chapter 3, EPA Quality Manual for Environmental Programs* (EPA Order 5360)

Extramural Users: *EPA Requirements for Quality Management Plans* (QA/R-2)

Quality Management Plan General Requirements

The Quality Management Plan must discuss:

- **Mission and quality policy of the organization**
- **Specific roles and responsibilities with respect to QA and QC activities**
- **Means and structure to assure effective communication**
- **Processes used to plan, implement and assess work and effectiveness for QA and QC activities**
- **Process for continual improvement of the Quality System**

Typical Characteristics of a Good QMP

- **Clearly documented responsibilities for QA Officer/Manager**
- **QA Officer/Manager reports directly, or has unrestricted access, to senior management official**
- **Specific commitment to performing the needed assessments, and a description of the process used**
- **Clearly defined responsibilities for personnel reviewing and approving QAPPs**

Typical Characteristics of a Good QMP (continued)

- **Clearly stated management commitment to QA and specific responsibilities documented**
- **Commitment to a specific process for systematic planning for new data collection activities**
- **Clear process for identifying resources to plan, implement, and assess the effectiveness of the quality system**
- **Process for identifying QA/QC training needs of staff**

QA Project Plans (QAPPs)

Purpose:

To document type and quality of data for environmental decisions; a blueprint for collecting and accessing data

Responsibility:

Organization performing activity

Documentation:

EPA Users: Chapter 5, EPA Quality Manual for Environmental Programs (EPA Order 5360)

Extramural Users: *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*

Everyone: *Guidance for Quality Assurance Project Plans (QA/G-5)*

QA Project Plans (QAPPs)

- Required planning documents that explain how environmental data collection activities are planned, implemented, documented, and assessed during the life cycle of a specific program, project, or task
- QA Project Plans are required when environmental data operations occur for:
 - Contracts, work assignments, delivery orders
 - Grants, cooperative agreements
 - Interagency agreements (when negotiated)
 - State-EPA agreements
 - Responses to statutory or regulatory requirements and to consent agreements

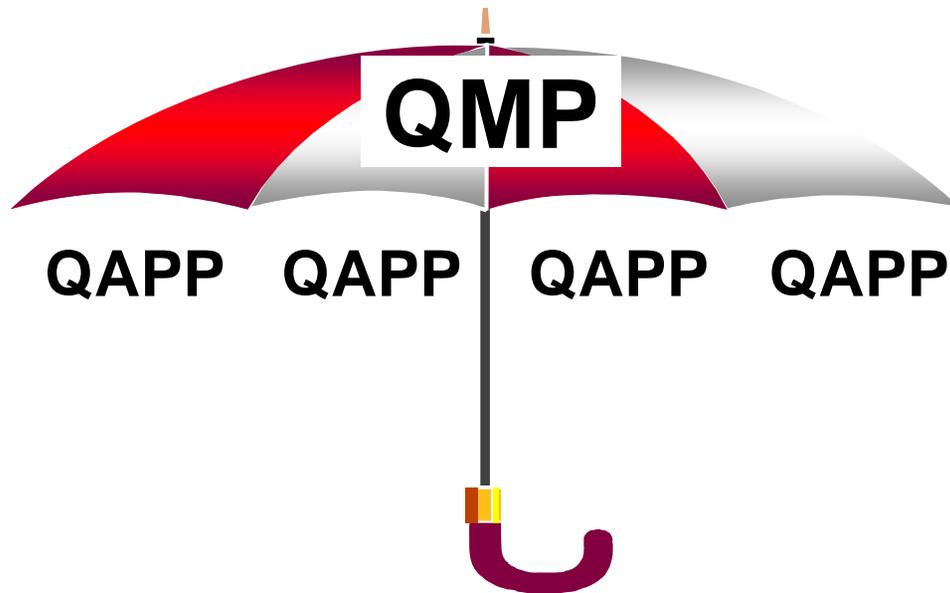
QAPP General Requirements

The QAPP must provide sufficient detail to show that:

- The project technical and quality objectives (e.g., DQOs) are identified
- The intended measurements or data acquisition methods are appropriate for achieving project objectives
- The assessment procedures are sufficient for confirming that data of the type and quality needed are obtained
- Data use limitations are defined

QMPs vs. QAPPs

- **Quality Management Plans reflect activities and policies common to all projects.**
- **Quality Assurance Project Plans reflect specific projects.**



Systematic Planning

- Planning is the key to successful programs
- EPA policy requires that all work be planned using a *Systematic Planning Process*
- Quality requirements should be based on a *Graded Approach*
- Effective planning must include all stakeholders (data users, data producers, decision makers) to ensure needs are defined at the outset
- Planning must be documented

Systematic Planning Approaches

- **Several systematic planning approaches are available, including:**
 - **Observational Method**
 - **DQO Process**

Common Elements in All Systematic Planning Approaches

- Questions to be answered:
 - Who is making the decision?
 - Why are data being collected?
 - What data are needed to make the decision?
 - Why does the decision maker need that type and quality of data?
 - How does the decision maker plan to use the data to make a defensible decision?
 - What are the "measures of success" for the project?
- Get only the type, quantity, and quality of data necessary

Data Quality Objectives (DQO) Process

- Purpose:** To define type and quality of data that a decision maker needs before carrying out data collection
- Saves time and money
 - Doing it right the first time
 - Obtaining data sufficient for analysis
- Responsibility:** Developed by project team of data users and data generators
- Guidance:** Guidance for the DQO Process (QA/G-4)
- Software:** DEFT Software for the DQO Process (QA/G-4D)

DQO Process

- **A statistics-based planning process for ensuring that environmental data are of the type, quantity, and quality needed for decision making**
- **Qualitative and quantitative statements derived from each step of the DQO Process define performance criteria**

Standard Operating Procedures (SOPs)

- Purpose:** To document routine technical and administrative activities to ensure consistency in the quality of the product
- Responsibility:** Appropriate technical personnel working with QA Manager
- Documentation:** *Guidance for the Preparation of Standard Operating Procedures (QA/G-6)*

Standard Operating Procedures (SOPs)

Written documents that give precise descriptions of routine procedures

- Detail stepwise process for sample collection operations, laboratory analyses, or equipment use
- Ensure consistency and conformance with organizational practices
- Serve as training aids on methods and instrument use
- Provide ready reference and documentation of proper procedures

Quality Assurance Annual Report and Work Plans (QAARWPs)

- Purpose:** To summarize the results of the implementation of an EPA organization's Quality System in the previous fiscal year and to describe QA activities planned for the upcoming year
- Responsibility:** Senior Management
- Documentation:** *EPA Quality Manual for Environmental Programs (EPA Order 5360)*

Quality Assurance Annual Report and Work Plans (QAARWPs)

QAARWPs are:

- **Management tools for documenting the past fiscal year's activity and for estimating the workload for the current year**
- **Required by EPA Order 5360.1**
- **Submitted annually (usually in November) to the Quality Staff, Office of Environmental Information**

QAARWP Specifications

QA Annual Report

- **Management Accomplishments**
 - **Innovations implemented**
 - **Technical assessments completed**
 - **Technical assistance given**
 - **Guidance developed or revised**
 - **Publications, presentations, awards completed**
- **Management Assessments of Approved Quality System**
 - **Assessment made by organization itself**
 - **Assessment made by others (i.e., third party)**

QAARWP Specifications

Work Plan

– Quality Management Resources

- FTE proposed to support quality management implementation
- Dollar amount proposed for QA/QC support
 - Proposed travel funds
 - Proposed training funds

–Activities

- Major QA/QC activities expected during the year in:
 - Training
 - Assistance
 - Assessments

Quality System Assessment

- **Management**
- **Technical**
- **Data Quality**

Management Assessments

- **Purpose:** To determine conformance with an approved QMP and to assess the suitability and effectiveness of its implementation
- **Responsibility:** EPA Managers of individual organizations

Quality System Audit

- **A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are appropriate and have been developed, documented, and effectively implemented in accordance and in conjunction with specified requirements.**
- **Such requirements may be defined by:**
 - **EPA Orders**
 - **Extramural Agreement Regulations**
 - **Approved Quality Management Plans**

Quality System Audit

- QSA uses quantitative approach to documented quality systems.
- Findings are based on objective evidence.
- QSA is a conformance/compliance audit:
 - Does the quality system conform to specifications?
 - Does the quality system comply with regulations?
 - Does the quality systems satisfy the QMP?
- QSA does not judge quality of individual data sets.

Management Systems Review

- **The qualitative assessment of QA and QC practices to establish if they conform to policies and requirements and are adequately implemented to satisfy needs and expectations.**
- **Such policies and requirements may be given by:**
 - **EPA Orders**
 - **Extramural Agreement Regulations**
 - **Approved Quality Management Plans**

Management Systems Review

- **Similar, but less quantitative than QSA.**
- **Applies best to situations where the quality system is not well-documented.**
- **Investigative in nature - - seeks to determine what is actually happening.**
- **Interview is primary data collection method.**
- **MSR does not judge the quality of individual data sets.**

Technical Assessments

Purpose: To evaluate the implementation of a project or activity against its defined technical or quality procedures or criteria

Responsibility: Project Managers with the assistance of the appropriate technical personnel, their EPA Manager, and QA Manager

Documentation: *Guidance on Technical Assessments for Environmental Data Operations (QA/G-7)*

Technical Assessments

- **Technical Assessments are self or independent evaluation processes used to measure the conformance, performance, or effectiveness of systems**
- **Technical Assessments include:**
 - **Technical Systems Audits**
 - **Readiness Reviews**
 - **Surveillances**
 - **Performance Evaluations**
 - **Audits of Data Quality**
 - **Peer Reviews**

Data Quality Assessment (DQA)

Purpose: To assess type, quantity, and quality of data

- Verifies DQOs
- Develops DQOs not fully developed
- Verifies QAPP components
- Verifies sample collection procedures

Responsibility: Appropriate technical personnel

Documentation: *Guidance for DQA: Practical Methods for Data Analysis (QA/G-9)*

Data Quality Evaluation Statistical Toolbox (DataQUEST) (QA/G-9D)

Data Quality Assessment (DQA)

- Determine if environmental data are of the type, quantity, and quality needed
- Scientific and statistical evaluation of data
- The DQA Process may be performed:
 - During a project to check the process of data collection
 - At the end of a project to check if objectives were met
- The DQA Process provides a tool for confirming that the systematic planning criteria were met

DQA Process - Prospective

- **What supplemental information is needed?**
- **Are further data really necessary?**
- **Should parts of the DQOs be changed?**
- **Where can the DQO Process be improved?**

DQA Process - Retrospective

- **Were the data quality objectives achieved?**
- **Were the data quality objectives meaningful?**
- **Were the assumptions viable?**
- **Were the statistical tests powerful enough?**

Summary

Authorities

- **Internal EPA Policies**

- **EPA Order 5360.1**
- **EPA Manual 5360**

- **External Policies**

- **48 CFR 46**
- **40 CFR 30, 31, 35**

Summary (continued)

Quality System Tools

- **Quality Management Plans**
- **QA Project Plans**
- **Standard Operating Procedures**
- **Systematic Planning and the Data Quality Objectives Process**
- **Assessments**
- **Quality Assurance Annual Report and Work Plan**

Summary (continued)

- **EPA Quality System Documents**
 - **EPA Requirements for Quality Management Plans (QA/R-2)**
 - **EPA Requirements for Quality Assurance Project Plans (QA/R-5)**
 - **Guidance for Quality Assurance Project Plans (QA/G-5)**
 - **Guidance for the Data Quality Objectives Process (QA/G-4)**
 - **Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)**