

POLICY AND PROGRAM REQUIREMENTS
FOR THE MANDATORY AGENCY-WIDE QUALITY SYSTEM

1. PURPOSE. This Order re-affirms the policy defined by EPA Order 5360.1, April 1984, and expands that policy to accommodate the current and evolving needs of the Agency. The Order establishes policy and program requirements for the preparation and implementation of organizational or programmatic management systems pertaining to quality and contains the minimum requirements for the mandatory Agency-wide Quality System.

2. BASIS, AUTHORITY, AND REQUIREMENTS.

a. Since 1979, Agency policy has required participation in an Agency-wide Quality System by all EPA organizations (office, region, national center or laboratory) supporting environmental programs and by non-EPA organizations performing work in behalf of EPA through extramural agreements. This policy was affirmed in EPA Order 5360.1 in April 1984 and is reaffirmed in this Order.

b. It is EPA policy that all environmental programs performed by EPA or directly for EPA through EPA-funded extramural agreements shall be supported by individual quality systems that comply fully with the American National Standard ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, incorporated herein by reference. ANSI/ASQC E4-1994 is a national consensus standard authorized by the American National Standards Institute (ANSI) and developed by the American Society for Quality Control (ASQC) that will provide a basis for the planning, implementation, documentation, and assessment of the Agency-wide Quality System. Adoption of this standard is consistent with the statutory authority of the *National Technology Transfer and Advancement Act of 1995* and the implementation authority of Office of Management and Budget (OMB) Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*.

c. Under Delegation of Authority-I-41, "Mandatory Quality Assurance Program," the Office of Research and Development (ORD) is the focal point in the Agency for Quality System policy. ORD is responsible for developing quality assurance and quality control (QA/QC) requirements and for overseeing implementation of the Agency-wide Quality System. The Assistant Administrator for Research and Development (AA/ORD) is designated as the Agency Senior Management Official for Quality. The Quality Assurance Division (QAD) is designated by the AA/ORD to serve as the central management authority for this program.

d. Each EPA Headquarters Office, National Program Office, Region, and components thereof, that conducts activities described by ANSI/ASQC E4-1994 shall develop and implement a quality system that complies with the requirements of this Order.

3. BACKGROUND.

a. The Agency-wide Quality System is a management system that provides the necessary elements to plan, implement, document, and assess the effectiveness of QA/QC activities applied to environmental programs conducted by or for EPA. This system embraces many functions including:

- establishing quality management policies and guidelines for the development of organization- and project-specific quality plans;
- establishing criteria and guidelines for planning, implementing, documenting, and assessing activities to obtain sufficient and adequate data quality;
- providing an information focal point on QA/QC concepts and practices;
- performing management and technical assessments to ascertain effectiveness of QA/QC implementation; and
- identifying and developing training programs related to QA/QC implementation.

In addition, this Order expands the applicability of QA/QC to the design, construction, and operation by EPA organizations of environmental technology such as pollution control and abatement systems; treatment, storage, and disposal systems; and remediation systems.

b. A consistent, Agency-wide Quality System will provide, when implemented, the needed management and technical practices to assure that environmental data used to support Agency decisions are of adequate quality and usability for their intended purpose. Since most EPA decisions rest on environmental data, a management system is needed that provides for: (1) identification of environmental programs for which QA/QC is needed, (2) specification of the quality of the data required from environmental programs, and (3) provision of sufficient resources to assure that an adequate level of QA/QC is performed.

4. REFERENCES. The following documents contain provisions which, through reference in this text, constitute provisions of this Order. At the time of the issuance of this Order, the editions were valid. Since policy documents and standards are subject to periodic revision, users of this Order should apply the most recent editions of the documents indicated below.

a. 40 CFR Part 30, "Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."

- b. 40 CFR Part 31, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."
- c. 40 CFR Part 35, "State and Local Assistance."
- d. 48 CFR Chapter 15, Subpart 1546.2, "Contract Quality Requirements."
- e. ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American National Standard, January 1995.
- f. Circular A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*, Office of Management and Budget, February 1998.
- g. Delegation of Authority I-41, "Mandatory Quality Assurance Program," U.S. Environmental Protection Agency, Washington, DC, April 1981.
- h. *EPA Order 5360, EPA Quality Manual for Environmental Programs*, 1998.
- i. *National Technology Transfer and Advancement Act of 1995*, PL104-113, March 1996.

5. SCOPE AND FIELD OF APPLICATION.

a. Scope. This Order defines the minimum requirements for quality systems supporting EPA environmental programs that encompass:

- (1) the collection, evaluation, and use of environmental data by or for EPA, and
- (2) the design, construction, and operation of environmental technology by EPA.

b. Applicability to Environmental Programs. This Order applies to (but is not limited to) the following environmental programs:

- (1) the characterization of environmental or ecological systems and the health of human populations;
- (2) the direct measurement of environmental conditions or releases, including sample collection, analysis, evaluation, and reporting of environmental data;

(3) the use of environmental data collected for other purposes or from other sources (also termed “secondary data”), including literature, industry surveys, compilations from computerized data bases and information systems, results from computerized or mathematical models of environmental processes and conditions; and

(4) the collection and use of environmental data pertaining to the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical dosimetry, radiation dosimetry).

c. Applicability to Other EPA Programs. This order applies to the collection and use of medical testing data from Government and non-Government personnel in EPA facilities for determination of substance abuse.

d. Organizational Applicability.

(1) EPA Organizations. The Agency-wide Quality System requirements defined by this Order apply to all EPA organizations, and components thereof, in which the environmental programs conducted involve the scope of activities described in Section 5.a above. The authority of this Order applies only to EPA organizations except as addressed by Section 5.d(2) below.

(2) Extramural Agreements. Agency-wide Quality System requirements may also apply to non-EPA organizations. These requirements are defined in the applicable regulations governing extramural agreements. Agency-wide Quality System requirements may also be invoked as part of negotiated agreements such as memoranda of understanding. Non-EPA organizations that may be subject to quality system requirements include:

(a) Any organization or individual under direct contract to EPA to furnish services or items or perform work (i.e., a contractor) under the authority of 48 CFR Chapter 15, Part 1546, (including applicable work assignments, delivery orders, and task orders);

(b) Institutions of higher education, hospitals, and other non-profit recipients of financial assistance (e.g., Grants and Cooperative Agreements) under the authority of 40 CFR Part 30;

(c) State, local, and Tribal governments receiving financial assistance under the authority of 40 CFR Part 31 and 35; and

(d) Other Government Agencies receiving assistance from EPA through interagency agreements.

6. QUALITY SYSTEM REQUIREMENTS AND IMPLEMENTATION.

a. Quality System Requirements. EPA organizations covered by the scope of this Order shall develop, implement, and maintain a quality system that demonstrates conformance to the minimum specifications of ANSI/ASQC E4-1994 and that additionally provides for the following:

(1) A quality assurance manager (QAM), or person assigned to an equivalent position, who functions independently of direct environmental data generation, model development, or technology development responsibility; who reports on quality issues to the senior manager having executive leadership authority for the organization; and who has sufficient technical and management expertise and authority to conduct independent oversight of and assure the implementation of the organization's quality system in the environmental programs of the organization.

(2) A Quality Management Plan (QMP), which documents the organization's quality policy, describes its quality system, identifies the environmental programs to which the quality system applies, and which is implemented following approval by the organization's executive leadership and the AA/ORD.

(3) Sufficient resources to implement the quality system defined in the approved QMP.

(4) Assessments of the effectiveness of the quality system at least annually.

(5) Submittal to the AA/ORD of the Quality Assurance Annual Report and Work Plan (QAARWP) for the organization that summarizes the previous year's QA/QC activities and outlines the work proposed for the current year.

(6) Use of a systematic planning approach to develop acceptance or performance criteria for all work covered by this Order. (See Section 3.3.8 of the EPA Quality Manual for Environmental Programs, 1998.)

(7) Approved Quality Assurance Project Plans (QAPPs), or equivalent documents defined by the QMP, for all applicable projects and tasks involving environmental data with review and approval having been made by the EPA QAM (or authorized representative defined in the QMP). QAPPs must be approved prior to any data gathering work or use, except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

(8) Assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use.

(9) Implementation of Agency-wide Quality System requirements in all applicable EPA-funded extramural agreements (see Section 5.d(2)).

(10) Implementation of corrective actions based on assessment results.

(11) Appropriate training, for all levels of management and staff, to assure that QA/QC responsibilities and requirements are understood at every stage of project implementation.

b. Quality System Implementation.

(1) EPA Organizations. Mandatory requirements for implementing this Order are contained in the *EPA Quality Manual for Environmental Programs*, hereafter referred to as the *EPA Quality Manual*. Additional non-mandatory guidance for implementing the requirements are provided in EPA Guidance Documents which may be applied to intramural environmental programs, as appropriate.

(2) Extramural Agreements.

(a) Mandatory requirements for implementing this Order are defined in applicable EPA regulations. EPA Requirements Documents provide specifications for satisfying the requirements of these regulations. The EPA Requirements Documents provide the equivalent information to the *EPA Quality Manual*, except they have been written especially for the extramural user. Non-mandatory guidance for implementing the requirements are provided in EPA Guidance Documents which may be applied to extramural environmental programs, as appropriate.

(b) Extramural organizations that provide objective evidence (such as a QMP or quality manual) of conforming to the specifications of the American National Standard ANSI/ASQC E4-1994 are in compliance with this Order.

7. GENERAL REQUIREMENTS FOR MANAGERS AND STAFF.

a. Assistant Administrator for Research and Development and ORD Senior Managers.

(1) The AA/ORD, as the Agency Senior Management Official for Quality, shall:

(a) Establish, document, and periodically revise Agency policies and procedures for planning, implementing, and assessing the effectiveness of the mandatory, Agency-wide Quality System.

(b) Review and approve QMPs from Agency components conducting environmental programs for implementation for up to five years.

(c) Perform periodic management assessments of all EPA organizations conducting environmental programs to determine the effectiveness of their mandatory quality systems and recommend corrective actions.

(d) Develop generic training programs, for all levels of EPA management and staff, so that quality management responsibilities and requirements are understood at every stage of project implementation.

(2) The AA/ORD and ORD senior managers shall:

(a) Designate a representative for quality management and QA/QC to advise and assist the AA in the planning, implementation, documentation, and assessment of the quality systems for organizations under the AA's responsibility.

(b) Ensure that all ORD components and applicable programs comply fully with the requirements of this Order.

(c) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in approved QMPs.

(d) Ensure that all ORD-funded environmental programs implemented through extramural agreements comply fully with applicable QA/QC requirements.

(e) Ensure that environmental data from research and development programs are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions.

(f) Perform periodic assessments of ORD organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.

(g) Ensure that deficiencies highlighted in the assessments of ORD organizations are appropriately addressed.

(h) Identify program-specific QA/QC training needs for all levels of management and staff and provide for this training.

(i) Ensure that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) that are commensurate with the quality management responsibilities assigned by this Order and the organization's QMP.

b. National Program Office Assistant Administrators and Senior Managers.

(1) Each National Program Office (NPO) Assistant Administrator shall designate a representative for quality management and QA/QC to advise and assist the AA in the planning, implementation, documentation, and assessment of the quality systems for organizations under the AA's responsibility.

(2) The National Program Office (NPO) Assistant Administrators and senior managers shall:

(a) Ensure that all NPO components and applicable programs comply fully with the requirements of this Order.

(b) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the organization's approved QMP.

(c) Ensure that all environmental programs implemented through extramural agreements comply fully with applicable QA/QC requirements.

(d) Ensure that environmental data from the parts of National Programs implemented by the Regions or delegated to State, local, and Tribal governments are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions.

(e) Ensure that all proposed and final regulations needing environmental data during their development or implementation include the application of sufficient and adequate QA/QC during the collection and use of such data.

(f) Perform periodic assessments of NPO organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.

(g) Ensure that deficiencies highlighted in the assessments are appropriately addressed.

(h) Identify program-specific QA/QC training needs for all levels of management and staff and provide for this training.

(i) Ensure that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) that are commensurate with the quality management responsibilities assigned by this Order and the organization's QMP.

c. Regional Administrators and Senior Managers. Regional Administrators and senior managers shall:

(1) Ensure that all Regional components and programs comply fully with the requirements of this Order.

(2) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program goals and is implemented as prescribed in the organization's approved QMP.

(3) Ensure that all environmental programs implemented through extramural agreements comply fully with applicable QA/QC requirements.

(4) Ensure that the environmental data from environmental programs delegated to State, local, and Tribal governments are of sufficient quantity and adequate quality for their intended use and are used consistent with such intentions.

(5) Ensure that training is available for State, local, and Tribal governments performing environmental programs for EPA in the fundamental concepts and practices of quality management and QA/QC that they may be expected by EPA to perform.

(6) Perform periodic assessments of Regional organizations conducting environmental programs to determine the conformance of their mandatory quality systems to their approved QMPs and the effectiveness of their implementation.

(7) Ensure that deficiencies highlighted in the assessments are appropriately addressed.

(8) Identify QA/QC training needs for all levels of management and staff and provide for this training.

(9) Ensure that performance plans for supervisors, senior managers, and appropriate staff contain critical element(s) that are commensurate with the quality management responsibilities assigned by this Order and the organization's QMP.

d. Quality Management Personnel. Quality management personnel, including the QAM, refers to individuals within the organization who are assigned specific quality management duties and are delegated authority for quality management as defined in the organization's QMP. The functions of the quality management personnel may be totally related to quality system activities or be in conjunction with other functions and responsibilities within the organization. If these personnel have other functions to perform, there should be no conflict of interest. Specific duties and responsibilities of all quality management personnel shall be documented in the organization's QMP. Specific responsibilities shall include:

(1) facilitating QMP development and approval by the organization and preparing updates to the approved QMP;

(2) representing the organization to QAD and other groups on matters pertaining to quality management and QA/QC;

(3) providing expert assistance to the staff in the organization on QA/QC policies, requirements, and procedures applicable to procurement and technical activities;

(4) reviewing and approving QMPs and QAPPs submitted by intramural programs and by holders of extramural agreements as defined in the organization's QMP;

(5) identifying QA/QC training needs for the organization;

(6) providing oversight of QA/QC implementation in the environmental programs conducted by or for the organization; and

(7) performing assessments of environmental programs and confirming the effectiveness of corrective actions.

e. Agency Managers and Staff.

(1) Managers at all levels shall:

(a) Ensure that quality management is an identified activity with associated resources adequate to accomplish its program quality goals.

(b) Ensure that all organizational components and programs comply fully with the requirements of this Order.

(c) Ensure that all applicable environmental programs for which management is responsible comply fully with the requirements of this Order.

(d) Perform all other quality management roles and responsibilities assigned to them in their organization's QMPs.

(2) Managers and staff shall:

(a) Ensure that all applicable intramural programs and activities comply fully with the requirements of this Order.

(b) Ensure that all applicable extramural environmental programs for which the manager or staff member is responsible comply fully with the requirements of this Order.

(c) Assure that the results of environmental programs are of sufficient quantity and adequate quality for their intended use.

(d) Perform all other quality management roles and responsibilities assigned to them in their organization's QMPs.

8. DEFINITIONS. The following terms have special meanings in relation to this Order.

a. 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 review, peer review, inspection, or surveillance.

b. environmental data - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the

performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

c. 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.

d. 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 applies to hardware-based systems; however, it also applies 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.

e. extramural agreement - a legal agreement between EPA and an organization outside EPA for items or services to be provided. Such agreements include contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements.

f. 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.

g. 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. In the context of this Order, an EPA organization is an office, region, national center or laboratory.

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

i. 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.

j. 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 customer.

k. quality assurance manager (QAM) - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.

l. quality assurance project plan (QAPP) - a 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.

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

n. 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.

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

p. 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/QC.

q. user - an organization, group, or individual that utilizes the results or products from environmental programs or the customer for whom the results or products were collected or created.

9. SUPERSESSION. This Order replaces EPA Order 5360.1, dated April 1984, in its entirety.

/s/

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and Organizational Services