

Directive No: CIO 2105.1

Issued by the EPA Chief Information Officer, Pursuant to Delegation 1-19, dated 07/07/2005

Environmental Information Quality Policy

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1. PURPOSE

This Policy:

- establishes policy and program requirements for the preparation and implementation of the Environmental Protection Agency's (EPA) Quality Program;
- is consistent with the principles in the American Society for Quality
 (ASQ)/American National Standards Institute (ANSI) E4:2014, Quality
 management systems for environmental information and technology programs—
 Requirements with guidance for use;
- recognizes existing quality policies, procedures, standards, and guidance as the foundation of the EPA Quality Program; and
- provides a structure to ensure and enhance the effectiveness of the Quality Program and its application to environmental information and technology programs.

This Policy affirms:

- EPA's commitment to applying quality principles and practices to environmental information and technology programs;
- EPA's commitment to utilizing environmental information that is of known and documented quality and is scientifically and legally defensible;
- the Office of Mission Support (OMS), Deputy Assistant Administrator (DAA) for Environmental Information (EI) and Chief Information Officer's (CIO) responsibility, as the designated federal official for quality at EPA, to lead, coordinate, and maintain an effective Quality Program throughout EPA;
- the DAA/CIO and the CIO Strategic Advisory Committee's (SAC) leadership of EPA's Quality Program in assuring the quality of environmental information and technology programs; and
- the roles of other key Agency managers and organizations that are implementing quality policies and practices for collection, production, evaluation, or use of environmental information across Agency programs.

2. SCOPE

This Policy defines the minimum requirements for the Quality Program supporting EPA environmental programs that encompass the collection, production, evaluation, or use of environmental information by or for EPA and the design, construction, and operation of environmental technology. Collectively these activities are referred to as environmental information operations.



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3. AUDIENCE

The audience for this Policy is all Agency employees responsible for environmental information operations. This includes Headquarters and Program Offices, Regions, and their sub-organizations. When cited in extramural agreements, this Policy also applies to non-EPA organizations (e.g., states, tribes, localities, regulated parties, volunteer organizations, contractors, cooperative agreement holders, grantees, other federal governmental agencies, intergovernmental organizations, educational institutions, and other environmental information providers) performing work in support of EPA's mission or national program priorities as defined by and in accordance with federal laws, regulations, extramural agreements, or performing work on a voluntary basis under agreement with EPA.

4. BACKGROUND

Since 1979, it has been an Agency requirement for all EPA organizations supporting environmental programs and non-EPA organizations performing work on behalf of EPA to participate in an Agency-wide Quality Program. Documentation of this policy, with a scope of primary environmental data collection, was first written in April 1984, in EPA Order 5360.1, *Policy and Program Requirements for the Mandatory Agency-Wide Quality Management System.*

On May 5, 2000, this Order was reissued and in 2008, renumbered as CIO 2105.0, and was written with the intent for the Agency's Quality Program to be applicable to only environmental data collection, evaluation, or use. On October 20, 2008, CIO 2106, *Quality Policy* and CIO 2106-P-01.0, *Procedure for Quality Policy* were published and addressed all Agency products and services; however, a notice to rescind CIO 2105 and CIO 2105-P-01-0 did not occur. As a result, there were two existing Quality Policies with an undefined relationship, which caused uncertainty with Agency managers and Quality Assurance (QA) personnel as to which policy was applicable.

A clarification memorandum issued on December 12, 2010 by the Assistant Administrator (AA)/CIO, restricted applicability of CIO 2106 to only environmental data collection, production, and use. The memorandum also directed that the Agency use the Federal Managers Financial Integrity Act (FMFIA) process for administrative and financial quality-related issues; and indicated use of the Information Quality Guidelines (IQG) process for all other quality-related issues.

On August 1, 2017, the CIO's SAC made the decision to rescind CIO 2106 and update CIO 2105 to be consistent with ASQ/ANSI E4 (2014) and current Agency directives that have quality components.

5. AUTHORITY

These citations are valid at the time of issuance of this Policy. Since these documents are subject to periodic review, users of this Policy should refer to the most recent version.

National Technology Transfer and Advancement Act (NTTA), (PL 104-113)



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- Clinger-Cohen Act of 1996 (PL 104-106)
- Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources
- Information Quality Act (IQA), Section 515 of Treasury and Government Appropriations Act, 2001 (PL 106-554, 31 USC 3516)
- 2 CFR 1500.11: Uniform Administration Requirements, Cost Principles and Audit Requirements for Federal Awards, Quality Assurance
- 40 CFR Part 40: Research and Demonstration Grants (EPA's Quality System-Related Regulations)7
- 40 CFR Part 35: State and Local Assistance
- 48 CFR Part 46: Quality Assurance

POLICY 6.

This Policy outlines EPA's Quality Program requirements to support EPA's mission to protect human health and the environment and to ensure environmental information and technology products are of known and documented quality for their intended use(s). It defines the DAA/CIO's role in leading the Agency Quality Program and recognizes and builds upon existing environmental information operations quality-related policies, procedures, and activities implemented across the Agency. This Policy ensures a comprehensive and coordinated approach for consistent implementation of continual improvement in the quality of EPA's environmental information and technology operations. Also, all environmental information operations performed for the Agency must comply with this Policy as defined in extramural agreements.

This Policy requires organizations to develop, implement, and maintain a Quality Program. Each organization listed in Section 3, Audience, and covered by the scope of this Policy must:

- A. Assign a Quality Assurance Manager (QAM). The title of this position may vary by organizational structure [e.g., Director of Quality Assurance (DQA) and Regional Quality Assurance Manager (RQAM)]. For this Policy, this position will be referred to as the QAM. This person will function independently of direct environmental information generation, model development, or technology development. The QAM will have Quality Management expertise, and the authority to conduct independent oversight of the organization's Quality Program. They will report on quality issues to senior managers having executive leadership authority for the organization.
- B. Develop a Quality Management Plan. Describe and document their Quality Program in a Quality Management Plan (QMP) consistent with the most current version of CIO 2105-P-01, Environmental Information Quality Procedure. The QMP describes the organization's Quality Program. It documents how the organization structures its Quality Program and describes its quality policies and procedures; criteria for and areas of application; and roles, responsibilities, and authorities. It also describes an organization's policies and procedures for implementing and assessing the effectiveness of the Quality Program. The QMP must document all technical activities to be performed under the Quality Program and how the program will integrate QA and quality control (QC) procedures and



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plans into all its environmental information operations activities. Approval of an EPA organization's QMP requires signatures by their executive leadership and the DAA/CIO or the Office of Enterprise Information Programs (OEIP) Director. C. Provide for Resources. Ensure resources are available to implement the Quality Program as defined in their QMP, including QA resources required for extramural activities in support of EPA. D. Conduct Systematic Planning. Document the processes for systematic planning and use them to develop acceptance or performance criteria and to perform

- E. Prepare Quality Assurance Project or Program Plan Documentation.
- Document the output of systematic planning in Quality Assurance Project or Program Plans (QAPPs) or equivalent document (in this Policy referred to as QAPPs) and approve them for use. Document the plan for environmental information operations in a QAPP consistent with the current version of EPA CIO 2105-P-01.1, *Environmental Information Quality Procedure*, as required for each environmental information project. EPA QAMs, as defined by the organization's QMP, review and approve QAPPs for all applicable environmental information operations projects 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. QAPPs must describe the project and data quality objectives (DQOs), applicable QA procedures, QC specifications, and implementation of other activities to ensure the expected quality of the project results.

design, construction, and operations for all environmental information operations.

- F. **Develop Directives.** Develop, maintain, and implement for their organization appropriate Quality Program related policies, procedures, standards, and guidance pertaining to all environmental information operations work.
- G. Execute Assessments and Audits. Plan, conduct, and document assessments and audits annually to provide information on the effectiveness of the Quality Program in accordance with the procedures described in their QMP and supporting QAPPs.
- H. **Identify Corrective Actions and Improvements.** Perform and document corrective actions and improvements.
- Hold Quality Program Management Reviews. Plan, conduct, and document management reviews of the Quality Program in accordance with the procedures described in the organization's QMP to assess its effectiveness and institute improvements. Performance of these reviews and timely action on the results demonstrates senior management commitment to implementation of the Quality Program.
- J. **Conduct Reporting.** Report annually QA/QC activities for each fiscal year (FY) and those activities planned for the upcoming FY to the CIO. Provide this information as described in the annual reporting data call from the CIO. This



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reporting of QA activities provides EPA managers access to information covering key QA/QC activities.

K. Evaluate Information using the Information Quality Guidelines (Pre-Dissemination Review). Plan for and assess all environmental information (primary and existing) prior to use in supporting Agency actions or decisions to verify the information is of sufficient quality, objectivity, utility and integrity for their intended use and purpose.

Ensure information disseminated by or for EPA conforms with the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency*¹, referred to as the Information Quality Guidelines (IQG) criteria for quality, objectivity, utility, integrity.

- L. Document Quality Program Requirements for Intra and Extramural Agreements. All EPA organizations shall identify projects, whether intramural or extramural, that may be subject to the Quality Program Policy and Procedure and document this determination. For those that are, identify and document approval of Quality Program documentation and strategies needed to support the project objectives.
- M. Address Environmental Information Quality Issues. Implement the CIO notification process described in the current version of CIO 2105-P-03.0, CIO Notification Procedure for Environmental Data Quality Issues².
- N. Address Field Activities. Implement the requirements as described in the current version of CIO 2105-P-02.0 EPA QA Field Activities Procedure³.
- O. **Conduct Training.** Require appropriate training for all personnel to assure that QA and QC responsibilities and requirements of the Quality Program are understood.

7. ROLES AND RESPONSIBILITIES

EPA Administrator: Promotes and ensures quality is an integral part of the Agency's mission by assuring that environmental information operations supporting EPA's programs and activities are scientifically and legally defensible and meet our customer and stakeholder needs and expectations. The Administrator may re-delegate the responsibilities for this Policy to Assistant Administrators (AA) and Regional Administrators (RAs).

^{1 &}lt;u>https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information</u>

² The current version of this document is available at https://www.epa.gov/sites/production/files/2020-08/documents/cio notification for environmental data quality issues procedure.pdf

The current version of this document is available at https://www.epa.gov/sites/production/files/2015-03/documents/2105-p-02.pdf



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Assistant Administrators (AA) and Regional Administrators (RA): Each AA and RA is responsible for the following QA activities:

- Implementing this Policy in the context of the organization's specific mission;
- Ensuring that adequate resources are devoted to QA activities to ensure compliance with EPA's QA directives, to support the organization's mission and to fully implement the organization's approved QMP;
- Ensuring that the organization's QMP includes activities that will help assure the quality of the information the organization collects, manages, or uses in carrying out its mission;
- Certifying annually to the DAA/CIO that the organization is implementing EPA's
 QA directives and that the quality of data produced and utilized by the
 organization is appropriate for its intended uses, including the use of data for
 programmatic decision-making and regulatory development. Provide this
 certification along with the organization's QA annual report to EQMD; and
- Promoting continual improvement in QA activities across the organization.

Office of Mission Support (OMS), Deputy Assistant Administrator (DAA) for Environmental Information (EI)/Chief Information Officer (CIO): Acts as the EPA Senior Management Official for quality management and leads Agency-wide implementation of this Policy and EPA's Quality Program. Informs AAs, RAs, and the SAC of any issues related to the quality of Agency environmental information and environmental information operations encompassed by this Policy.

Chief Information Officer's (CIO's) Strategic Advisory Committee (SAC): Comprised of Senior Information Officials (SIOs) and other senior managers. Advises and reports to the DAA/CIO on Agency-wide environmental information operations. The SAC serves as a forum to discuss coordination of cross-cutting Agency quality-related issues.

Senior Information Officials (SIOs): Oversee effective implementation, coordination, and management of the organization's Quality Program for environmental information operations. Located in each Program Office and Region, SIOs report to the Agency DAA/CIO on quality-related issues.

Mission Support Division Directors (MSDDs): Manage issues related to information technology and information management (IT/IM). Support the Region's Quality Program and coordinate with Laboratory Services and Applied Science Division Directors (LSASDDs).

Laboratory Services and Applied Science Division Directors (LSASDDs): Support the Agency's Quality Program and provide technical assistance and expertise within the Agency and with external partners.

Science and Technology Policy Council (STPC): Serves as a mechanism for addressing EPA's science policy issues that go beyond regional and program boundaries, with a goal of integrating policies that guide Agency decision-makers on their use of scientific and technical information.



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The STPC is an executive-level council that is chaired by the Agency's Science Advisor, and provides a venue for identifying, coordinating, and, when appropriate, establishing consensus for high priority, cross-Agency science and technology policy issues focusing on issues that require high-level action and are relevant to the Regions and Program Offices.

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The STPC is supported by the:

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Forum on Environmental Measurements.

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Laboratory Enterprise Forum, Peer Review Advisory Group, and

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Risk Assessment Forum

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Office of General Counsel (OGC) and Offices of Regional Counsel: Provide legal advice on issues related to environmental information operations.

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OMS-EI Office of Enterprise Information Programs (OEIP) and Enterprise Quality Management Division (EQMD) Directors: Serve as Office and Division Directors respectively and are responsible for oversight of the Agency's Quality Program. Execute actions on behalf of the DAA/CIO.

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EPA Quality Assurance Managers (QAMs): Have delegated authority for the management of their Quality Program as described in their organization's QMP.

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Agency Personnel: Perform work associated with environmental information operations as identified in their organization's QMP.

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Recipients of Extramural Agreements: Perform all environmental information operations in accordance with this Policy's requirements as defined in their extramural agreements.

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8. **RELATED INFORMATION**

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These citations are valid at the time of issuance of this Policy. Since these documents are subject to periodic review, users of this Policy should refer to the current version.

307 308 309

CIO 2105-P-01.1 EPA Environmental Information Quality Procedure

310 311 CIO 2105-P-02.0 EPA QA Field Activities Procedure4 CIO 2105-P-03.0 CIO Notification Procedure for Environmental Data Quality

312 313

ASQ/ANSI E4, Quality management systems for environmental information and technology programs—Requirements with guidance for use (2014)

314 315 Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and

316 317

Integrity of Information Disseminated by the Environmental Protection Agency U.S. EPA Scientific Integrity Policy

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U.S. EPA Peer Review Handbook **Enterprise Architecture Policy**

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4 The current version of this document is available at https://www.epa.gov/sites/production/files/2015-03/documents/2105-p-02.pdf

⁵ The current version of this document is available at https://www.epa.gov/sites/production/files/2020-08/documents/cio notificaton for environmental data quality issues procedure.pdf



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- Data Standards Policy
- Enterprise Information Management Policy

9. DEFINITIONS

While this Policy uses multiple sources as the foundation for the terms defined, ASQ/ANSI E4 (2014), CIO 2105, and CIO 2106 serve as primary references. The intent of this Policy is to ensure consistency with these primary references and to make modifications where necessary to be applicable to the Agency.

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, surveillance, or readiness review (including competency assessment, pre-award assessment of proposal, or technical assessment), peer consultation, product review (e.g., data inspection, software testing, pre-dissemination review, or review of contractor deliverables).

Audit—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.

Consensus Standards—Standards that are developed and adopted by achieving agreement with all affected parties. These standards are developed in accordance with procedures used by the International Organization for Standardization or organizations accredited by the ANSI.

Data—A quantitative or qualitative representation of values, facts, observations, or ideas in a formalized manner capable of being transmitted, processed, stored, analyzed, interpreted, and/or communicated by some process, whether on paper or in electronic form.

- Qualitative data—is descriptive.
- Quantitative data—is numerical.
- Primary data—are data observed, collected, stored, or generated directly for a specific purpose as defined by a QAPP.
- **Existing data**—are data that have been collected, derived, stored, or reported in the past or by other parties (for a different purpose and/or using different methods and quality criteria). Sometimes referred to as data from other sources.
- Metadata—is information about data required to facilitate its use, understanding, and management. Metadata should answer questions about data such as why they were collected, how they were collected, what was done to the data, what they were used for, and what were their limitations. Metadata makes tracking and working with specific data easier.

Data Quality Objectives (DQOs)—Qualitative and quantitative statements derived from the DQO Process that clarify study objectives, define the appropriate type of data, and



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specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data Standard—Documented consensus-based agreement on the format and definition of common data.

Environmental Information—Includes data and information that describe environmental processes or conditions which support EPA's mission of protecting human health and the environment. Examples include but are not limited to:

- direct measurements of environmental parameters or processes:
- analytical testing results of environmental conditions (e.g., geophysical or hydrological conditions);
- data on physical parameters or processes collected using environmental technologies;
- · calculations or analyses of environmental data;
- data provided by environmental data models; and
- environmental data compiled or obtained from databases, software applications, decision support tools, websites, existing literature, and other sources.

Environmental Information Operations—A collective term for work performed to collect, produce, evaluate, or use environmental information and the design, construction, and operation of environmental technology.

Environmental Measurement—A subgroup of Environmental Information that includes or produces values derived from tools, instruments, observational results, laboratory operations on environmental samples, or other sampling and testing equipment. It is any data collection activity or investigation involving the assessment of chemical, physical, or biological factors in the environment which affect human health or the quality of life.

Environmental Processes—Manufactured or natural processes that produce discharges or that impact human health and the environment.

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 monitoring, measurement and control devices and systems, treatment processes and storage facilities and site remediation processes and their components, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants or prevent them from entering the environment. Examples include but are not limited to:

- wet scrubbers (air),
- soil washing (soil),
- granulated activated carbon unit (water), and
- filtration (air. water).



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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.

Environmental Technology does not account for QA associated with the development and design of an IT system.

Extramural Agreement—A legal agreement between EPA and an organization outside EPA. Such agreements include but are not limited to contracts, work assignments, delivery orders, task orders, cooperative agreements, research grants, state and local grants, and EPA-funded interagency agreements. Refer to CIO 2105-P-01.1, *Environmental Information Quality Procedure*, for additional details related to QA documentation associated with extramural agreements.

Information Quality Guidelines—An Agency document that establishes EPA's policy and procedural guidance for ensuring and maximizing the quality of Agency disseminated information. The Guidelines outline EPA's pre-dissemination review of information products and describe administrative mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe do not comply with EPA guidelines.

Information System—An organized collection, storage, and presentation system of data for decision making, progress reporting, and for planning and evaluation of programs. It can be manual or computerized, or a combination of both.

Intergovernmental— Between the EPA and international, other federal, state, tribal, territorial, area-wide, regional or local governments and agencies.

Management System—A management system may describe the polices, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization.

Organization— An EPA organization is an office, region, national center, or laboratory. An external organization is a state, tribe, 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 Procedure.

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.

Product—The intended result or final output of an activity or process that is disseminated or distributed among EPA organizations or outside of EPA.

Quality—The totality of processes, procedures, 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.



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Quality Assurance (QA)—Management of an integrated system of 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 organization.

Quality Assurance Manager (QAM)—The individual designated as the principal manager within the organization having oversight authority and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the Quality Program for the organization.

Quality Assurance Project or Program Plan (QAPP)—A planning document related to a project or program that describes in comprehensive detail the necessary QA/QC requirement and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the DQOs and stated performance criteria.

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.

Quality Management—The aspects of the organization's overall management system that drive the implementation of an organization's Quality Program. Quality Management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to an organization's Quality Program.

Quality Management Plan (QMP)—A formal document that describes a Quality Program 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 Program—The totality of management controls, processes, and documentation in EPA's planning, implementation, and assessment of applying quality in the creation of Agency environmental information and technology products and services.

10. WAIVERS

N/A

11. MATERIAL SUPERSEDED

- Policy and Program Requirements for the Mandatory Agency-Wide Quality Management System (CIO 2105.0, May 5, 2000)
- EPA Quality Manual for Environmental Programs (CIO 2105-P-01-0, May 5, 2000)
- Quality Policy (CIO 2106.0, October 20, 2008)
- CIO Clarification Memorandum, Subject: EPA Quality Policy (CIO 2016.0, December 10, 2010)



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524 525 526 527 528 529 530 531 532 533 534 535 536	AA ANSI ASQ CFR CIO DAA DQA DQOS EI EPA EQMD FMFIA FY	Assistant Administrator American National Standards Institute American Society for Quality Code of Federal Regulations Chief Information Officer Deputy Assistant Administrator Director of Quality Assurance Data Quality Objectives Environmental Information Environmental Protection Agency Enterprise Quality Management Division Federal Managers Financial Integrity Act Fiscal Year
537 538	IM IQA	Information Management Information Quality Act
539 540 541 542	IQG IT LSASDD MSDD	Information Quality Guidelines Information Technology Laboratory Services and Applied Services Division Director Mission Support Division Director
543 544 545 546	NTTA OEIP OGC OMB	National Technology Transfer and Advancement Act Office of Enterprise Information Programs Office of General Counsel Office of Management and Budget
547 548 549 550	OMS QA QAM QAPP	Office of Mission Support Quality Assurance Quality Assurance Manager Quality Assurance Project or Program Plan
551 552 553 554 555 556 557	QC QMP RA RQAM SAC SIO STPC	Quality Control Quality Management Plan Regional Administrator Regional Quality Assurance Manager Strategic Advisory Committee Senior Information Official Science and Technology Policy Council