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Pursuant to Delegation 1-19, dated 07/07/2005*

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## U.S. Environmental Protection Agency

# QUALITY STANDARD FOR ENVIRONMENTAL DATA COLLECTION, PRODUCTION, AND USE BY NON-EPA (EXTERNAL) ORGANIZATIONS

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### 1. PURPOSE

This *Quality Standard for Environmental Data Collection, Production, and Use by External Organizations* (2106-S-02.0), including its Annexes:

- defines and establishes the needed and appropriate quality requirements and management controls for non-EPA organizations that provide products and services derived from environmental data collection, production, and use;
- defines how EPA quality requirements in CIO Standard 2106-S-01.0, *Quality Standard for Environmental Data Collection, Production, and Use by EPA Organizations*, shall be applied to non-EPA organizations under authorized agreements governed by Federal regulations;
- conforms to *EPA Quality Policy* CIO Policy 2106 (Current Edition), and *Procedure for Quality Policy* CIO Procedure 2106-P-01 (Current Edition), for environmental data-related products and services that are disseminated outside the Agency;
- reaffirms the applicability of and conformance to ANSI/ASQ E4 (Current Edition) for the planning, implementation, documentation, and assessment of extramural programs that collect, produce, and use environmental data;
- replaces EPA QA/R-2, *EPA Requirements for Quality Management Plans*, March 2001 (Reissued May 2006) and EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans*, March 2001 (Reissued May 2006) in their entirety with exceptions as specified under Clause 2.3;
- conforms to ISO/IEC Directives, Part 2, *Rules for the Structure and Drafting of International Standards* (Fifth Edition, 2004) in order to establish compatibility with other international consensus standards when needed;
- provides the basis for non-EPA organizations to define effective processes, practices, and management controls for planning, implementing, and assessing quality activities defined in their approved Quality Management Plans (QMPs) when environmental data collection, production, and use are integral parts of the organization's scope and mission on behalf of EPA;
- requires the use of Quality Assurance Project Plans (QAPPs) or equivalent documents to establish quality specifications in individual project activities that collect, produce, and use environmental data; and
- identifies expected quality responsibilities for managers and staff in external organizations for activities involving environmental data collection, production, and use for EPA.

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This Standard, along with other applicable EPA standards, and with other relevant regulations, statutes, and external agreement terms and conditions, provides the foundation for the implementation of the EPA Quality Policy among non-EPA organizations performing work on behalf of EPA through external agreements. Such external agreements include contracts, grants, assistance agreements, and enforcement agreements. This Standard includes several annexes which contain detailed specifications and guidance to support the requirements presented in the Standard. Normative annexes are additional requirements beyond those requirements in the body of the Standard and shall be regarded as part of the requirements of the Standard. Informative annexes (or parts thereof) may become requirements if so decided by the external organization using the Standard and this decision is documented in the external organization's QMP.

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## 2. SCOPE AND APPLICABILITY

### 2.1 SCOPE

The scope of this Quality Standard is consistent with EPA Quality policies and procedures, and encompasses EPA expectations for all program activities conducted by external organizations that involve the collection, production, and use of environmental data for EPA. It applies to environmental data produced or used in the development and delivery of products and services to EPA through approved external agreements. Environmental data may be:

- collected from environment media directly in the form of physical samples or from existing electronic databases;
- produced from analytical methods or instrumentation, and mathematical or electronic computational models or programs;
- collected from the literature or other existing data sources (e.g., web sites on the Internet ); and
- used in a variety of analyses and evaluations to document environmental conditions and to support Agency decisions pertaining to such conditions.

This Quality Standard establishes the quality requirements for non-EPA organizations for work performed through external agreements that involve the collection, production, and use of environmental data for use by EPA. Such agreements include acquisition (i.e., contracts), assistance (i.e., grants), interagency, and cooperative agreements. Other legal instruments with EPA may include memoranda of agreement, enforcement settlement agreements, consent decrees, consent orders, or other compliance/enforcement mechanisms implemented to comply with Federal environmental regulations.

Activities involving environmental data encompassed by this Standard include, but are not limited to:

- direct and indirect field and/or laboratory measurements;
  - evaluating the operation and performance of environmental technology (e.g., remediation);
  - inspections;
  - survey development or application;
  - enforcement and compliance monitoring or assessments;
  - application of environmental management systems;
  - environmental safety and health monitoring;
  - scientific research;
  - regulatory development;
  - statistical or economic analyses using environmental data;
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- use of information technology (e.g., the development and use of models such as pollutant transport and ground water migration, databases) supporting Agency programs;
- use of information sources outside of direct EPA management controls or authority (e.g., academic institutions); and
- use of data obtained from other sources (e.g., literature, Internet).

## 2.2 APPLICABILITY

***This Standard applies to all non-EPA organizations having external agreements with EPA and shall be explicitly applied to all external agreements involving the collection, production, and use of environmental data for EPA.***

The terms and conditions of applicable external agreements shall include this Standard by reference as the requirements for quality management processes, applications, and personnel responsibilities. Affected organizations may include, but not be limited to:

- States, Tribes, local governments;
- regulated parties;
- entities party to EPA settlement or consent agreements resulting from enforcement actions;
- volunteer organizations;
- contractors;
- cooperative agreement holders;
- grantees;
- other federal government departments and agencies;
- non-governmental organizations;
- international governments/organizations; and
- educational institutions.

## 2.3 QUALITY MANAGEMENT REQUIREMENTS APPLICABLE TO NON-EPA ORGANIZATIONS

Prior to this Standard, the quality management requirements for non-EPA organizations were given in two extramural reference documents. These were:

- EPA QA/R-2, *EPA Requirements for Quality Management Plans* (March 2001 Edition, re-authorized in May 2006); and
- EPA QA/R-5, *EPA Requirements for Quality Assurance Project Plans* (March 2001 Edition, re-authorized in May 2006).

***These documents are hereby deleted as requirements for use in new or revised external agreements effective with this Standard, and are replaced by this Standard.***

### 2.3.1 Existing External Agreements

The use of QA/R-2 and QA/R-5 by non-EPA organizations in existing external agreements may be allowed by EPA organizations under one or more of the following circumstances:

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- the documents have been explicitly incorporated or referenced into an extramural agreement or enforcement/consent agreement and, as a result, are legal requirements;
- current Federal and/or EPA regulations explicitly cite the documents;
- other EPA policies and orders explicitly cite the documents; or
- use of the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP) is explicitly required.

***Under these conditions, the requirements of QA/R-2 and QA/R-5 shall replace those of CIO Standard 2106-S-02 for the term of the particular external agreement, but shall be limited to the defined period of performance of the agreement. EPA will confirm the appropriate continued use of these deleted documents in existing external agreements in accordance with Clause 2.3.1, CIO Standard 2106-S-01.***

### **2.3.2 New and Revised External Agreements.**

***All new work performed through external agreements shall comply with this Standard, effective with the approval of this Standard and its implementation since QA/R-2 and QA/R-5 are now inoperative for such work.***

***When the use of QA/R-2 and QA/R-5 is allowed for an external agreement, it is the responsibility of EPA to monitor the implementation of the agreement to ensure that criteria for their continued use are met. Such monitoring will be accomplished in accordance with this Standard (See Clause 7.5).***

***If an existing external agreement (i.e., contract Statement of Work, assistance terms and conditions, etc.) is modified by the Agency during its period of performance and the external agreement includes the use of EPA QA/R-2 and EPA QA/R-5, the Agency shall determine if it is beneficial to the Government to invoke the quality requirements as included under CIO Standard 2106-S-02. If it is determined to be beneficial to the Government, the use of EPA QA/R-2 and EPA QA/R-5 shall cease and the requirements of CIO Standard 2106-S-02 shall apply and shall be invoked in the modification to the agreement.***

Existing external or other agreements may be revised by EPA before their end dates to require the elements of this Standard in lieu of QA/R-2 and QA/R-5. Other Federal/EPA regulations will be revised when practicable to replace QA/R-2 and QA/R-5 with the requirements of this Standard.

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### **3. AUDIENCE**

The principal audience for this external Quality Standard is all non-EPA organizations and their employees (managers and staff) responsible for planning, collecting, assessing, and/or using environmental data as part of work in support of EPA's mission and to personnel who are assigned specific quality management duties and responsibilities within the non-EPA organization.

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### **4. BACKGROUND**

Since 1979, EPA has required all extramural organizations performing work for EPA that collect, produce, and use environmental data to comply with quality requirements defined by EPA Orders.

Originally issued in 1984 and reauthorized in 2000, EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-Wide Quality System*, required application of the Quality Program to environmental data collected and/or used by or for EPA and the design, construction and

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operation by EPA organizations of environmental technology systems such as pollution control and abatement systems; treatment, storage and disposal systems; and remediation systems. EPA Order 5360.1 A2, which was later re-designated CIO Policy 2105.0, also expanded the scope of environmental data itself to include, in addition to information collected directly from measurements, data compiled from other sources (i.e., databases, scientific literature), environmental models, and the performance of environmental technology. EPA Order 5360 A1, *EPA Quality Manual for Environmental Programs*, was developed to provide instructions for implementing the requirements of this Policy. This order was subsequently re-designated CIO Procedure 2105-P-01.0. The relevant content of CIO Procedure 2105-P-01.0 for extramural agreement holders was consolidated into two documents pertaining to required quality documentation: EPA QA/R-2 (for QMPs) and EPA/QA R-5 (for QAPPs).

CIO Policy 2105.0 and CIO Procedure 2105-P-01.0 are replaced by current editions of CIO Policy 2106, CIO Procedure 2106-P-01, CIO Standard 2106-S-01.0, and this Standard.

The previous policy and procedure documents required EPA and non-EPA organizations to develop, document, and implement a quality management system (QMS) that conformed with all applicable EPA policies and procedures, with relevant clauses in the current edition of American National Standard ANSI/ASQ E4, *Quality Systems for Environmental Data and Technology Programs – Requirements with Guidance for Use*, and with applicable Federal regulations on quality in extramural agreements. ANSI/ASQ E4 is a national consensus standard authorized by the American National Standards Institute (ANSI) and was developed by the American Society for Quality (ASQ). ***The requirement for QMS conformance with ANSI/ASQ E4 is continued in this Standard.***

This Standard extends the EPA quality requirements to non-EPA organizations performing work on behalf of EPA through external agreements as prescribed by Federal extramural agreement regulations, results of enforcement actions, and voluntary partner activities. Accordingly, non-EPA organizations shall have a QMS in place for the work to be performed that provides the necessary management controls and instructions to plan, implement, document, and assess the effectiveness of quality assurance (QA) and quality control (QC) activities applied to environmental programs to be conducted for EPA. Specifically, the non-EPA organizations are required, within the scope of the applicable external agreement, to:

- establish quality management policies and guidelines for the development of organization- and project-specific quality plans;
- establish QMS containing appropriate management controls, criteria, and guidelines for planning, implementing, documenting, and assessing activities to obtain sufficient data of adequate quality for their intended use;
- identify the components and activities of the organization to which the QMS shall apply;
- identify and describe products and services to which the QMS shall apply;
- identify a focal point within the organization on QA and QC concepts and practices;
- perform management and technical assessments to ascertain effectiveness of quality management controls and implementation of quality practices in programs; and
- ensure that all relevant staff members shall have sufficient competency and shall maintain proficiency related to quality program implementation for the work prescribed in the agreement.

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## 5. AUTHORITY

Authorities applicable to this Standard include:

- CIO Policy 2106, *Quality Policy* (Current Edition); CIO Procedure 2106-P-01, *Procedure for*
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- Quality Policy (Current Edition); and
- CIO Standard 2106-S-01, *Quality Standard for the Collection, Production, and Use of Environmental Data by EPA Organizations* (Current Edition).

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## 6. RELATED REGULATIONS, POLICIES, AND PROCEDURES

In addition to the documents listed in Clause 5 above, the following documents are indispensable for the application of this Standard. They contain provisions which, through reference in this text, constitute provisions of this Standard. Since regulations, policy documents, and standards are subject to periodic revision, users of this Standard should apply the current editions of the documents listed below as well as all citations provided throughout this Standard:

- 40 CFR 30, "Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations";
- 40 CFR 31, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments";
- 40 CFR 35, "State and Local Assistance";
- 48 CFR 46, Federal Acquisition Regulations (FAR), "Quality Assurance";
- U.S. EPA, Office of Grants and Debarment's *Implementation of Quality Assurance Requirements for Organizations Receiving EPA Financial Assistance* (Current Edition);
- EPA Manual 1610, *Interagency Agreement Policies, Procedures and Guidance Manual* (Current Edition);
- CIO Policy 2155.1, *Records Management* (Current Edition); and
- ANSI/ASQ E4 (Current Edition), *Quality Systems for Environmental Data and Technology Programs – Requirements with Guidance for Use*, American National Standard, American National Standards Institute, and American Society for Quality.

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## 7. REQUIREMENTS

### 7.1 CONFORMANCE WITH POLICIES, PROCEDURES, AND STANDARDS

This Standard conforms to the following policies, and procedures, and with applicable clauses in current editions of consensus standards, all of which are integral to its effective implementation and use.

#### 7.1.1 EPA Policies, Procedures, and Standards

- EPA Quality Policy CIO Policy 2106 (Current Edition).
- Procedure for Quality Policy CIO Procedure 2106-P-01 (Current Edition).
- *Quality Standard for the Collection, Production, and Use of Environmental Data by EPA Organizations*, CIO Standard 2106-S-01 (Current Edition).

#### 7.1.2 International/American Consensus Standards

- ANSI/ASQ E4, *Quality Systems for Environmental Data and Technology Programs – Requirements with Guidance for Use* (Current Edition).

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## 7.2 ORGANIZATIONAL AND PROGRAM FIELD OF APPLICATION

### 7.2.1 Applicability to Environmental Programs

This Standard applies to, but is not limited to, the collection, production, and use of environmental data:

- to characterize environmental or ecological systems and the health of human populations;
- to directly measure environmental conditions or releases, including sample collection, analysis, evaluation, and reporting of environmental data;
- collected originally for other purposes or from other sources, including, but not limited to, the literature, industry surveys, and compilations from databases and information systems;
- to develop, evaluate, modify, and apply mathematical or probabilistic models of environmental processes and conditions; and
- to ensure the occupational health and safety of personnel in EPA facilities (e.g., indoor air quality measurements) and in the field (e.g., chemical or radiation dosimetry) when performed under extramural agreements.

### 7.2.2 Organizational Applicability

***This Standard applies to all non-EPA organizations performing authorized activities that collect, produce, or use environmental data on behalf of EPA.***

Non-EPA organizations are subject to the technical requirements described in this Standard (e.g., QMP and/or QAPP documentation) when the requirements have been incorporated by reference into an extramural agreement or other legal agreement in accordance with Federal statutes and regulations. These requirements may also be invoked as part of negotiated agreements such as memoranda of understanding and consent agreements. Non-EPA organizations or entities that may be subject to this Standard include:

- any organization or individual under direct contract to EPA to furnish services or items or perform work (e.g., a contractor) under the authority of 48 CFR 46 (including applicable work assignments, delivery orders, and task orders);
- 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 30;
- State, local, and Tribal governments receiving financial assistance under the authority of 40 CFR 31 and 35;
- organizations implementing settlement or consent agreements resulting from enforcement actions;
- partner organizations participating in voluntary monitoring and measurement programs; and
- other international, Federal, State, or local government agencies and organizations with which EPA has negotiated agreements.

Prime recipients are responsible for monitoring subrecipients to ensure that the quality of products and services provided by the subrecipients are specified, documented, and meet the technical requirements and acceptance criteria defined in the external agreement. Prime recipients shall describe in their QMP how they will ensure that their applicable subrecipients shall meet and report on these requirements. The requirements apply to those subrecipients whose products and services may affect the quality of results from environmental programs.

Environmental data may be collected and submitted to the Agency for its use through voluntary partner

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programs with non-governmental organizations, industry groups, and other interested parties. To the extent possible and practicable, the collection of environmental data through voluntary programs should be planned, implemented, and documented based on this Standard. This will help to ensure that the quality, utility, integrity, objectivity, and transparency of the environmental data are known, documented, and evaluated against technical requirements.

### 7.3 ORGANIZATION, RESPONSIBILITY, AND AUTHORITY FOR QMS

#### 7.3.1 General Requirements for the Organization

Each organization shall establish and maintain an effective QMS for the environmental programs it conducts or directs under the applicable external agreement. The QMS shall include the quality management controls and management elements needed for planning, implementing, and assessing the effectiveness of quality processes and practices applied to the collection, production, and use of environmental data. These elements shall be used in conjunction with the other applicable clauses of this Standard to formulate a complete QMS. Many of the management elements contained in this Standard are consistent with requirements found in other consensus standards (e.g., ISO 9001 [Current Edition]). The QMS shall generally:

- identify internal and external factors that are relevant to the organization's purpose and that affect its ability to achieve the expected outcomes of the QMS;
- identify and document the QMS and its content in an approved QMP;
- describe how the organization plans to achieve the expected outcomes of work to be performed, including prevention of undesired results;
- describe and affirm management commitment to the QMS;
- provide a statement of the organization's Quality Policy;
- describe and chart organizational roles, responsibilities, and authorities;
- describe how work conducted through sub-agreements with other organizations will be evaluated;
- describe the activities expected to be performed within the scope of the QMS, including documentation of the work and quality practices to be applied in a QAPP or equivalent document, and describe the process for its approval and implementation;
- describe and document the process for addressing issues and concerns;
- describe how the competence of persons doing work shall be determined and maintained;
- describe how internal and external communications related to the QMS scope will be ensured ;
- describe the control of required quality documentation;
- describe and document how performance will be measured and reported, including internal assessments and management reviews; and
- discuss how problems and nonconformities will be corrected and documented.

The QMS shall be planned, established, documented, implemented, and assessed as an integral part of a management system for the organization's environmental programs.

The QMS shall be documented in the organization's QMP and shall be established and operational before the initiation of the work defined in the external agreement. In some circumstances, a combined QMP and QAPP may be utilized to document these requirements. This described in Clause 7.5 below.

The QMP shall be reviewed and approved for implementation by the external organization and then shall be reviewed and approved by EPA in accordance with EPA policy and applicable procedures (See CIO 2106-S-01, Clause 7.6.2).

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### 7.3.2 Leadership

The top management of the organization (See Clause 8.1) is responsible for implementation of the QMS throughout the organization, and for defining and implementing sufficient and adequate management controls to sustain an effective QMS for the organization's environmental data collection, production and use activities, and for its implementation during the external agreement. For the purposes of this Standard, top management includes the manager having executive responsibility for the organization.

Management at all levels shall establish and implement quality policies and procedures necessary to ensure that environmental programs covered by this Standard produce the type and quality of results that are needed and expected. Management shall ensure that personnel are competent to perform the work needed, have sufficient resources, apply the appropriate quality practices, and produce the expected products or services. Management shall ensure that sufficient resources are provided to ensure that adequate personnel competence, proficiency, and performance are achieved and maintained as necessary to satisfy the requirements of the external agreement. Management shall ensure that the ongoing competency of personnel necessary to fulfill the organization's mission and objectives is assessed regularly.

Management shall define appropriate performance objectives for environmental data collection, production, and use that will satisfy the needs of the external agreement.

Management shall ensure that applicable elements of this Standard are understood by the organization's personnel and that they are implemented in the activities prescribed by the external agreement.

Management is responsible for stopping unsafe work and work that may result in inadequate quality, or shall delegate the authority to do so to others.

Management shall ensure the regular assessment and documentation of the adequacy of the QMS. Management shall define the objectives of the assessment process and determine the measures for ensuring that the QMS has been established, documented, and implemented effectively. Management shall ensure that appropriate response actions are determined as a result of assessments, and shall implement and confirm the effectiveness of such actions in a timely manner. Management shall define a dispute resolution process to address issues pertaining to quality with documentation in the QMP.

Management shall identify and document in the QMP the relevant organizations, functional responsibilities, levels of accountability and authority, lines of communication, and management controls relative to QA and QC for the external agreement. Managers at all levels shall ensure that organizations and individuals responsible for planning, implementing, and assessing the QMS, as well as the work performed under the external agreement, have sufficient authority, organizational freedom, and access to top management for resolution of any disputes.

### 7.3.3 Management Representative for Quality

The organization's top management shall designate or appoint a management representative for quality with defined authority that includes:

- determining that the approved QMS is implemented and maintained in accordance with the requirements of this Standard;
- reporting to top management on the performance effectiveness of the QMS, including needs for improvement; and

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- being independent of operations that directly implement the collection, production, and use of environmental data.

Other management representatives (e.g., QA manager, QA coordinator) should be defined for appropriate levels in the organization as needed and their roles and responsibilities documented in the organization's QMP.

#### **7.3.4 Management Review and Reporting**

At regular intervals or as required by the terms and conditions of the external agreement, management shall evaluate the QMS to confirm its ongoing effectiveness for the work to be performed and its adherence to policies, procedures, and standards included or referenced in the external agreement. The QMS shall be revised to reflect organizational, operational, and policy changes identified during this review or as otherwise determined by management. The changes shall be documented in a revised QMP and shall be reviewed and approved in accordance with this Standard.

### **7.4 PERSONNEL COMPETENCE**

Personnel shall have the competence (i.e., technical skills, demonstrated knowledge, and documented experience) needed to perform assigned duties.

Objective evidence of personnel job proficiency shall be documented and maintained for the duration of the project or activity affected, or longer if required by statute or policy.

### **7.5 MANAGEMENT OF QUALITY REQUIREMENTS FOR SUBAGREEMENTS**

#### **7.5.1 General Requirements**

The organization shall establish and document in its QMP appropriate processes to include quality specifications and acceptance criteria when procuring items and services associated with environmental data operations. Suppliers must be held accountable for supplying items that meet specifications. In addition, the organization shall describe processes in place for monitoring and verifying performance of sub-agreements.

#### **7.5.2 Planning and Verification**

The organization shall describe processes for:

- identifying items and services procured through sub-agreements that directly affect data;
- defining specifications and acceptance criteria for these products and services;
- reviewing procurement documents;
- evaluating the capability of a supplier to meet specifications and acceptance criteria for items and services to be provided;
- inspecting procured items and services and interim deliverables;
- obtaining feedback from the supplier on constraints in meeting specifications;
- issuing "stop-work" orders and requests for corrective action to the supplier; and
- documenting corrective actions and verification of effective corrections.

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## 7.6 DOCUMENTS AND RECORDS MANAGEMENT

### 7.6.1 General Requirements

The organization shall establish and document in its QMP the appropriate procedures to manage documents and records related to quality in accordance with Federal extramural agreement regulations and applicable Agency policies (See Clause 6). Such procedures shall be controlled and kept current. The procedures shall address the necessary steps to identify, prepare, review, approve, revise or change, collect, index, file, store, maintain, retrieve, distribute, and dispose of pertinent quality documents and records. Such procedures shall be applicable to all forms of documents and records, including, but not limited to, print and electronic media.

This Standard requires organizations collecting and using environmental data to prepare, use, and maintain specific quality management documents in addition to other documents and records that may be needed in an environmental program using its QMP and associated QAPPs. In some circumstances, a combined QMP and QAPP may be allowed when stated in the terms and conditions of the external agreement (See Clause 7.6.4 below).

References to guidance on document control may be found in Clause 11.

### 7.6.2 QMPs

The QMP (or equivalent document) for the organization shall describe when, how, and by whom controls shall be applied to the specific technical or project efforts required in the external agreement, and shall outline how these efforts are planned, implemented, and assessed. The QMP shall address all applicable parts of this Standard and shall identify why any parts are not applicable. The QMP shall identify and describe activities which directly or indirectly affect quality and shall include as a minimum:

- identification of policies and standards with which the QMS conforms;
- identification of all organizations and business lines and programs to which the QMP applies;
- description of the organization, management and staff responsibilities and authorities, and quality management personnel responsibilities and authorities;
- description of the QMS;
- description of processes to assess the effectiveness of the QMS;
- description of processes to ensure personnel competency;
- description of processes for including appropriate quality requirements in sub-agreements;
- description of documents and records management processes and practices;
- description of processes involving the development and use of Information Technology (IT) methods and sources;
- description of general processes for planning, implementing, and assessing environmental data collection, production, and use activities; and
- description of processes for reviewing, assessing, and verifying data usability.

The QMP shall reflect the current practices of the organization for its QMS. The organization's QMP shall be reviewed and approved by the organization and by EPA for implementation.

The specific requirements for the content of QMPs are contained in Annex A of this Standard and must be addressed by the organization. Advice on how to satisfy the QMP requirements may be found in *Guidance on Developing Quality Management Plans*, CIO Guidance 2106-G-02 QMS, (EPA 2012).

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### 7.6.3 QAPPs

The QAPP, or equivalent document, shall document the project goals and objectives, and shall define the QA procedures, QC specifications, and other technical activities that must be implemented to ensure that the results of the project or task to be performed will meet project objectives. The organization shall prepare a QAPP, or equivalent quality document, for all applicable projects and tasks involving environmental data collection, production, and use as listed previously in Clause 2.1.

***All QAPPs and equivalent documents shall be reviewed and approved by the organization's QA Manager and its management (as applicable) before submission to EPA. The EPA QA Manager must then review and approve the QAPPs.***

Moreover, all QAPPs must be approved prior to any data collection, production, or use except under circumstances explicitly defined in the terms and conditions of the external agreement. Under these exceptions, the non-EPA organization shall have standard operating procedures (SOPs) and other quality-related documents available to support such activities, and the actual activities shall be documented in order to provide a complete record.

The organization shall ensure that QAPPs are kept current for the term of the agreement and that, when modifications are needed, the changes are made in a timely manner and communicated to all appropriate personnel. When QAPPs apply to multi-year projects, the project officer shall at least annually confirm their continued relevance and applicability. If a revision is needed, the revised QAPPs shall be reviewed by the organization's QA Manager (or authorized representative as defined in the QMP). The review and approval shall be conducted in the same manner as the original documents, including review and approval by EPA.

Other forms of project-level quality planning documents which are equivalent to an EPA QAPP shall be described with their review and approval processes in the organization's QMP. Other acceptable QAPP formats (e.g. UFP-QAPP) which satisfy the requirements of this Standard and its Annex B should also be described in the organization's QMP.

The QAPP should encompass the project-specific activities and proposed timeframe to accomplish the work defined in the terms and conditions of the agreement. The QAPP's effective period of approval shall be defined by EPA.

The specific requirements for QAPPs are contained in Annex B of this Standard and must be addressed by the organization in all individual QAPPs.

Advice on how to satisfy the QAPP requirements in this Standard may be found in *Guidance on Developing Quality Assurance Project Plans*, CIO Guidance 2106-G-05 QAPP. (EPA 2012b).

### 7.6.4 Combined QMP/QAPP

In some circumstances, EPA may recommend the preparation of a combined QMP and QAPP as a more appropriate means to document organizational level and project-level environmental data activities in external agreements, particularly when a full QMP is not needed. These activities may include research projects, inspection programs, and monitoring networks involving multiple participants, among others, and may include external, non-EPA implemented projects. The specific elements to be addressed are included in the terms and conditions of the external agreement and are typically taken from the lists given in Clause 7.6.2 and 7.6.3 above; however, the EPA organization shall determine the final list of elements

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to be addressed in the combined QMP/QAPP. As such, all of these elements must be addressed by the non-EPA organization. The combined QMP/QAPP is subject to EPA review and approval.

### 7.6.5 Documents

Documents requiring control shall be identified and the processes used for document control shall be described. Documents, including revisions, shall be reviewed by qualified personnel for conformity with technical, quality, and peer review, and shall be approved for release by authorized personnel.

Documents used in the external agreement to perform work (e.g., technical manuals and operating procedures) shall be identified and maintained current for use. Measures shall be taken to ensure that users understand the documents to be used. Obsolete or superseded documents shall be identified and measures shall be taken to prevent their inadvertent use, including removal from the immediate workplace and from the possession of or access by users when practical. Obsolete or superseded documents shall be retained in accordance with applicable statutes, policies, and procedures that specify retention schedule and disposal requirements.

### 7.6.6 Records

Sufficient records shall be specified, prepared, reviewed, authenticated, and maintained to reflect the achieved level of quality for completed work and/or to fulfill all records requirements. (See CIO Policy 2155, *Records Management*.)

The processes for maintenance of records shall be documented and shall include provisions for retention, protection, preservation, traceability, and retrieval. Where evidentiary records are involved, the maintenance of records shall also include establishing and implementing appropriate tracking, chain of custody, and confidentiality procedures including the handling of information identified as sensitive or confidential for the affected records.

Retention times for records shall be determined based on applicable external agreement requirements, records schedules, or, if none stated, as specified by management. Records shall be protected from damage, loss, and deterioration.

## 7.7 USE OF INFORMATION TECHNOLOGY METHODS AND SOURCES

### 7.7.1 General Requirements

Environmental data encompassed by this Standard may include results from information technology (IT) methods and sources, such as services that collect and provide access to data and information. Such sources of these environmental data may include:

- computer and mathematical models and other electronic methods;
- EPA-owned information systems;
- other information systems; and
- the Internet.

Organizations shall develop and document in their QMP the general processes, procedures, and personnel responsibilities for evaluating the suitability of environmental data obtained from information technology sources and control of general software and hardware relevant to its products and services.

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Project-specific processes, procedures, and evaluation criteria shall be developed and documented in a QAPP or other equivalent quality documentation as defined in the organization's QMP. Environmental data from IT methods and sources shall be assessed by the generator and the user in order to confirm its suitability for use. Any limitations or restrictions on the use of such data shall be documented and reported with the data.

### **7.7.2 Computer Models, Mathematical Models, and Other Electronic Methods**

The development, evaluation, and application of mathematical or computerized models of environmental processes and conditions, including computer software, require QAPPs.

Environmental data produced from computer models and other electronic methods (or software) shall be reviewed, evaluated, verified, and validated in order to confirm their suitability for use (See Clause 7.11 and Annex B). The specific process and procedure shall be documented in applicable quality documentation and shall be reviewed and approved for use. Any limitations or restrictions on the use of such data shall be documented and reported with the data.

### **7.7.3 Information Systems and Internet**

Environmental data collected from information systems outside the domain and control of EPA (including the Internet) shall require special attention (e.g., due diligence) to ensure that the data can be used for their intended purpose. Project specific evaluation criteria shall be developed and documented in the applicable QAPP. Any limitations or restrictions on the use of such data shall be documented and reported with the data. Data standards (or data fields with definitions) and metadata (information about the data including acceptance criteria met, quality control results, and quality objectives met) shall be used where applicable and documented to ensure that supplied data retain their meaning for appropriate interpretation by the end-user.

Organizations shall develop documented protocols, provide sufficient training, and implement oversight to enable verification of data entry, storage, and retrieval processes and to preserve the integrity of the supplied data.

### **7.7.4 Control of Computer Software and Hardware**

The organization shall ensure that computer software and hardware relevant to the mission and objectives of the organization are controlled appropriately and satisfy the organization's objectives. The organization shall describe in its QMP the processes and the roles, responsibilities, and authorities of management and staff for the control of computer software and hardware (See Annex A).

## **7.8 PLANNING**

### **7.8.1 General Requirements**

Any activities involving the collection, production, or use of environmental data shall be planned and documented using a systematic planning process that is established, implemented, controlled, and documented as necessary to:

- identify all relevant customers, and their needs and expectations, for the results of the work to be performed;

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- identify the technical and quality goals that meet the needs and expectations of the customer;
- translate the technical and quality goals into specifications that will produce the desired result;
- consider any cost and schedule constraints within which project activities are required to be performed; and
- identify measurable acceptance criteria or performance measures by which the results will be evaluated and the suitability of the environmental data for their intended use is determined.

The general planning processes (including applicable design steps) shall be described in the organization's QMP. All planning documentation shall be reviewed and approved for implementation by authorized personnel before the affected planned work commences. Such documentation includes, but is not limited to, work plans, schedules, SOPs, and QAPPs. In some cases, it may be appropriate to subject general planning documents to independent review (e.g., internal or external peer review) in order to confirm their suitability. The reviews of other planning documents do not replace the required reviews of quality documents (e.g., QMPs, QAPPs).

### 7.8.2 Planning and Scoping

The type, quantity, and quality of environmental data needed for their intended use shall be identified and documented using a systematic planning process.

Project-specific planning shall involve the key users and clients as well as the technical staff responsible for obtaining, analyzing, and evaluating the data. Results of planning activities shall be subject to review for conformity to technical, performance, and quality expectations.

Systematic project planning shall be coordinated among participating organizations and EPA. Details on project planning elements that should be considered are given in Annex C.

### 7.8.3 Design of Environmental Data Projects

The design of data collection or production operations shall be controlled to the extent required, verified, and documented. The design process shall identify relevant activities pertaining to environmental data operations, establish performance specifications, and identify appropriate controls. Details on design elements that should be considered during the design process are given in Annex C. The environmental data collection design process shall ensure that data are traceable to the procedures (including revisions) used to produce the data and to the personnel generating or collecting the data. The importance of obtaining a truly representative sample through careful environmental data collection design cannot be overemphasized; details of the elements that should be considered are given in Annex C.

Key variables that determine or directly affect the quality of environmental data produced shall be identified and controlled as appropriate according to the specifications determined during design.

Data transfer, reduction, verification, and validation requirements shall be determined and documented. Data interpretation and analysis needs, such as the use of specific statistical methods, shall be determined and specified in the design.

Any reports to EPA (as specified in the terms and conditions of the agreement) regarding the status of work, interim results of work, and results of assessment activities shall be identified and documented.

Restrictions on the use of any results (interim or final) shall be identified and stated with the data in a manner that clearly defines the nature of the restriction and the specific data to which it applies. If the

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data are stored in electronic media, the restrictions shall be encoded with the data as well as reported in any accompanying documentation, to the extent practicable.

#### **7.8.4 Design of Modeling Projects**

The design of the development, evaluation, modification, and application of models (e.g., probabilistic, mathematical) shall be controlled, verified, and documented to the extent required in the QAPP or equivalent document. The design process shall identify relevant activities pertaining to modeling operations, establish performance specifications, and identify appropriate controls.

#### **7.8.5 Project Documentation**

The results of the design process for data collection or for model design shall be documented in a QAPP (see Annex B) or other equivalent planning document according to the requirements of the organization's QMS or required in the terms and conditions of the external agreement. The QAPP may need to refer to SOPs or other procedures as applicable.

The QAPP and/or other planning documents shall be reviewed and approved by designated persons in the organization who, together, are technically capable of evaluating all aspects of the project. The organization's QMP shall identify who shall review and approve the project-specific QAPP and other applicable planning documents, and describe the process by which this review is conducted. The QAPP shall also be reviewed and approved by EPA before actual environmental data collection or model work commences.

Changes to data collection procedures, including field changes, or model designs shall be subject to the same review and approval protocols as the original documents. When QAPPs apply to multi-year projects, the organization shall at least annually confirm to EPA their continued relevance and applicability. If a revision is needed, the revised QAPPs shall be reviewed by the organization's QA Manager (or authorized representative as defined in the QMP) and by EPA. The review and approval shall be conducted in the same manner as the original documents.

### **7.9 IMPLEMENTATION OF WORK**

#### **7.9.1 General Requirements**

All work by the organization involving environmental data collection, production, or use shall be performed according to approved planning and technical documents (e.g., QAPPs, SOPs) and in the prescribed sequence described in them. Implementation of work shall be accomplished with a level of management oversight and verification commensurate with the importance of the particular project and the intended use of the project results.

Environmental data collection, production, and use shall be implemented by competent personnel in accordance with the approved planning documents. Data collected during implementation shall be traceable to the planning documents used, procedures and equipment used, and to the personnel collecting the data.

The development, modification, and use of models shall be implemented by competent personnel in

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accordance with the approved planning documents. Results produced from the model shall be traceable to the planning documents used, the specific model, and to the personnel using the model.

Only qualified and accepted services and items shall be used in the environmental data operations. Acceptance shall be identified on the items themselves and/or in documents traceable to the items.

Implementation of work shall be monitored by the organization and may include the routine measurement of performance against established technical and quality specifications to ensure continued satisfactory performance. The independence of personnel monitoring the work performance shall be commensurate with the nature and importance of the activity. In addition, similar monitoring and oversight may be performed by EPA personnel through surveillance and assessments.

### **7.9.2 Documentation of Implementing Procedures**

Procedures (e.g., SOPs, reference methods, statistical or mathematical methods) for implementing environmental data collection, production, and use and for the use of models shall be developed, documented, and implemented for appropriate routine, standardized, special, or critical operations. Procedures shall be written in a format that can be readily understood by the user and shall have sufficient detail and clarity to ensure that consistent results are achieved effectively. As a minimum, the process for the documentation of procedures shall include:

- identification of operations needing procedures;
- preparation of procedures, including form, content, and applicability;
- testing and evaluation of procedures (as necessary) to confirm their acceptable performance; and
- review and approval of documented procedures.

Procedures that specify technical requirements shall be reviewed for adequacy and approved before use by qualified personnel who are independent of the person developing the procedure.

The process and roles and responsibilities of personnel for implementation of procedures shall be described in the organization's QMP or the approved QAPP for the project.

### **7.9.3 Deviations and Waivers from Approved Processes**

Deviations from approved processes and procedures shall be documented and reported to management. The impact and significance of the deviation on planned operations shall be determined, and appropriate adjustments shall be made as needed. The process for addressing deviations and waivers shall be described in the organization's QMP.

Changes to planning documents and to operating procedures, guides, and manuals shall be made following appropriate levels of technical and management review. Documentation of changes shall be distributed to EPA and to appropriate project personnel to replace previous versions of the documents in accordance with the external agreement. Waivers from approved processes shall be approved by EPA before any changes are implemented.

### **7.9.4 Measurement and Testing Equipment**

Inspections and acceptance testing of measurement and testing equipment (M&TE) (e.g., sampling devices, measurement equipment, analytical instrumentation, computer equipment, and other measurement systems) and their components shall be conducted in accordance with the requirements of

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the approved QAPP. Such testing will confirm the capability of the M&TE to satisfy their intended use as specified by the design. When acceptance criteria are not met, the cause of the deficiencies shall be determined, problems resolved, and reevaluation performed prior to equipment use.

Tools, gauges, instruments, and other sampling, measuring, and testing equipment used for activities affecting quality shall be controlled as required and, at intervals given in the QAPP or as specified by applicable statute or regulation, calibrated to maintain accuracy within specified limits. Equipment found to be unsuitable for its prescribed use shall be identified in a conspicuous manner. The validity of any measurements and tests performed with unsuitable equipment shall be evaluated and such measurements and tests shall be repeated as required. The basis for the calibration and the frequency of calibration and verification shall be documented. Documentation of calibration shall be maintained and shall be traceable to the equipment and to the operating personnel.

Periodic preventive and corrective maintenance of M&TE shall be performed to ensure availability and satisfactory performance of the systems. All equipment subject to maintenance or repair shall be recalibrated according to the specification of the methods used before the equipment is used.

The general processes and roles and responsibilities of personnel relative to measurement and testing equipment shall be described in the organization's QMP. Specific processes and roles and responsibilities of personnel pertaining to individual projects should be described in the applicable QAPPs.

#### **7.9.5 Integrity of Samples and Data**

Handling, processing, storage, cleaning, packaging, shipping, and preservation of field and laboratory samples shall be performed in accordance with required specifications, protocols, or procedures to prevent damage, loss, deterioration, or the formation of artifacts and interferences. Sample chain of custody shall be tracked and documented, and shall be reported to EPA in accordance with the external agreement terms and conditions.

Data or information management, including transmittal, storage, validation, assessment, processing, and retrieval, shall be performed in accordance with the approved instructions, methods, and procedures unless a previously agreed upon alternative is being used.

The general processes and roles and responsibilities of personnel relative to sample and data handling and custody shall be described in the organization's QMP. Specific processes and roles and responsibilities of personnel pertaining to individual projects should be described in the applicable QAPP.

#### **7.9.6 Performance Monitoring**

The organization shall conduct monitoring of work pertaining to the collection, production, and use of environmental data to ensure that approved work instructions, procedures, and other planning documents are followed and that expected project quality objectives are being met. Performance monitoring may be accomplished using a variety of assessment and inspection tools including surveillance and performance audits, and these tools shall be documented in the QAPP. Corrective actions resulting from performance monitoring shall be resolved, confirmed, and documented.

EPA may conduct performance monitoring through surveillance or assessments during the term of the agreement.

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The general processes and roles and responsibilities of personnel relative to performance monitoring shall be described in the organization's QMP. Specific processes and roles and responsibilities of personnel pertaining to individual projects should be described in the applicable QAPPs.

## **7.10 ASSESSMENT, OVERSIGHT, AND RESPONSE**

### **7.10.1 General Requirements**

Management shall determine during planning the level of routine oversight appropriate for the particular project and shall assign oversight responsibilities to higher level project personnel. Personnel having authority to issue stop-work orders shall be identified and documented in the applicable QAPP.

Management shall determine during the planning stage the type of assessment activity appropriate for a particular project and the assessment tool to be used. Types of assessments may include:

- management systems assessments;
- technical systems audits;
- performance audits of measurement and analytical systems;
- surveillance of operations;
- interim assessments of data quality; and
- data quality audits.

Assessments of environmental programs, including projects implemented through external agreements, shall be planned, scheduled, and conducted by the organization regularly (not to exceed five years or the term of an external agreement). Their results shall be evaluated to determine the suitability and effectiveness of the implemented QMS and of the quality performance of the environmental programs to which it applies.

The scope and objectives of every assessment shall be documented in an assessment plan. Assessments shall be performed according to approved written procedures, based on careful planning of the scope of the assessment, and the information needed. Assessment results shall be documented, reported to, and reviewed by management.

The general processes and roles and responsibilities of personnel relative to planning and implementing assessments, implementation of response actions, and verification of responses shall be described in the organization's QMP. Specific processes and roles and responsibilities of personnel pertaining to assessment of individual projects shall be described in the applicable QAPP.

### **7.10.2 Objectivity, Independence, and Competence of Assessment Personnel**

Personnel conducting assessments shall be competent to perform the assigned assessment based on project-specific requirements and the type of assessment being conducted.

The responsibilities and authorities of the organization's personnel conducting assessments shall be defined clearly and documented in the QMP. Personnel shall have sufficient organizational independence and authority, access to programs and managers, and organizational freedom to:

- identify and document problems that affect quality;
- identify and cite noteworthy practices that may be shared with others to improve the quality of

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their operations and products;

- propose recommendations (if requested) for resolving problems that affect quality;
- independently confirm the implementation and effectiveness of solutions; and
- provide documented assurance (if requested) to line management such that, when problems are identified, further work performed is monitored carefully until the problems are suitably resolved.

When conducting assessments, personnel shall use the care, due diligence, skill and judgment expected of any auditor or assessor in similar circumstances.

### **7.10.3 Assessment Planning and Implementation**

The assessment process shall be planned and documented to provide the organization with the desired level of confidence in the reliability of the assessment findings and any assessment conclusions. Findings shall be supported by objective evidence.

Assessment planning should determine if the assessment will be a self-assessment or an independent assessment. Self-assessments are conducted by the organization on its own programs. Independent assessments are conducted by persons or groups from outside the organization being assessed, for example, EPA or national accredited audit bodies.

The assessors should endeavor to obtain assessment evidence of sufficient quality and quantity that other competent assessors or reviewers working independently of each other will reach similar findings from evaluating the same assessment evidence against the same assessment criteria.

### **7.10.4 Assessment Reporting**

Assessment findings shall be communicated to the assessment client (e.g., the organization, EPA) in a written report. Unless specifically excluded by the client, the assessed organization shall always receive a copy of the assessment report. Assessment reports shall be prepared promptly and delivered within a timeframe agreed by all parties.

Nonconforming methods or instruments shall be reported to the organization responsible for them and on a timely basis to ensure the implementation of effective corrective actions.

### **7.10.5 Corrective Action and Verification**

When warranted by findings of deficiency or nonconformity with requirements (e.g., deviation from approved protocols, poor performance of the measurement systems), appropriate corrective actions shall be taken promptly. The adequacy and effectiveness of the corrective actions shall be confirmed, verified, communicated to participants, and documented.

Results obtained from nonconforming methods or instruments shall be evaluated to determine the impact of the nonconformity on the quality of the data. The adequacy and effectiveness of corrective actions taken shall be confirmed, verified, and documented.

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## 7.11 DATA REVIEW, VALIDATION AND VERIFICATION, AND DATA USABILITY REPORTING

### 7.11.1 General Requirements

Results obtained from products or services involving environmental data shall be reviewed, verified, validated, and qualified according to their intended use. The general processes and roles and responsibilities of personnel relative to the assessment and verification of data usability shall be described in the organization's QMP. Specific processes and roles and responsibilities of personnel pertaining to assessment of individual projects shall be described in the applicable QAPPs.

The data shall be evaluated according to approved and documented procedures and shall be qualified appropriately before use. Any limitations or restrictions on the use of the data shall be expressed quantitatively to the extent practicable and shall be documented in any reporting of the data.

Environmental data shall satisfy applicable data reporting requirements for data definition and source reporting and for review and certification (when necessary).

Any project reports that contain data, or report the results of environmental data operations (e.g., data summaries), shall be reviewed independently (i.e., by others than those who produced the data or the reports) to confirm that the data or results are presented correctly. These project reports must have a readily identifiable section that describes the applied QA and QC and discusses the usability of the data.

The reports shall be reviewed internally by the responsible project manager and QA Manager (or authorized representative defined in the QMP) to confirm that the report's conclusions are supported by sound science and that the data quality objectives have been met. This review shall be completed and any issues resolved prior to submission to EPA or any applicable external peer review, release, publication, or dissemination.

### 7.11.2 Peer Review

Organizations may use peer review as an assessment tool. Peer review is a documented critical review of a specific scientific or technical work product. When applied, peer review shall be planned, implemented, and documented in accordance with the organization's peer review policies and procedures. (EPA may apply its peer review process at interim or final stages of the project.)

Peer review in the early stages of model development helps to evaluate the conceptual basis of models and potentially save time by redirecting misguided initiatives, identifying alternative approaches, or providing strong technical support for EPA positions. Peer review in the later stages of model development is useful as an independent external review of model code (i.e., model verification).

### 7.11.3 Review of Data of Undocumented Quality for Potential Use

Environmental data collected from sources that did not use a QMS equivalent to this Standard or whose quality is unknown or undocumented shall be reviewed and evaluated to confirm their suitability for use. In addition, data collected for purposes other than that of the current project shall also be reviewed and evaluated for their suitability for use. These data, which sometimes have been called "data for secondary use" or simply (but inaccurately) "secondary data," shall be assessed according to approved and documented procedures and shall be qualified appropriately before use.

Key elements of the review of environmental data for potential use include:

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- the need to satisfy requirements for objectivity, utility, and integrity;
- the principal traditional indicators of environmental quality (e.g., precision, bias, representativeness, comparability, completeness, and sensitivity); and
- the general usability factors (e.g., relevance, temporal compatibility, spatial inclusivity, credibility, aggregation level, compatibility, reproducibility, and degree of augmentation).

These elements shall be compared to the requirements established by the acceptance criteria defined in the approved QAPP. (See Annex B and EPA 2012b) The documentation of how well these elements met the acceptance plan then becomes part of the metadata that would accompany the data under consideration if accepted for use. If the data are not acceptable, the information regarding that decision shall be documented.

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## 8. ROLES AND RESPONSIBILITIES

### 8.1 GENERAL MANAGEMENT ROLES AND RESPONSIBILITIES

The top management of the organization is responsible for implementing a QMS that covers all environmental programs for which the management is accountable. Top management includes the principal executive responsible and accountable for mission accomplishment and overall operations of the organization.

The QMP must be approved by the top manager of the organization and be approved and signed by the QA manager of the organization. The top manager may require the concurrence on the QMP by appropriate subordinate line managers to encourage the acceptance and implementation of the QMS. When the QMP and the QAPP describe work for EPA, they shall be approved by EPA before the start of work.

The following clauses list specific roles and responsibilities for managers and quality management personnel.

### 8.2 QUALITY MANAGEMENT PERSONNEL

Quality management personnel (e.g., Quality Assurance Manager, Quality Assurance Representative, Quality Assurance Coordinator) 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 organization may assign and deploy other quality management personnel to support the day-to-day quality functions listed below. In some situations, such quality staff may be delegated specific quality management responsibilities as described in this Standard, including approval of quality documentation such as QMPs, QAPPs, SOPs, etc. A description of the coordination and deployment of all quality management personnel, including their roles and responsibilities, shall be documented in the organization's QMP.

The functions of the quality management personnel may be totally related to quality management system activities or be in conjunction with other functions and responsibilities within the organization. If these personnel have other concurrent functions to perform, there must be no conflict of interest. Specific duties and responsibilities of all quality management personnel shall be documented in the organization's QMP. Quality management personnel shall:

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- review and approve QMPs, QAPPs, and other quality documents prior to their submission to EPA;
- provide oversight of QA and QC implementation in the environmental programs conducted by or for the organization; and
- perform assessments of implemented environmental programs when needed to confirm the effective application of QC and QA practices, report results to management, and confirm the effectiveness of corrective actions.

### 8.3 TECHNICAL MANAGERS AND STAFF

Technical managers at all levels shall:

- ensure that all organizational components and programs comply fully with the requirements of this Standard;
- ensure that all work specified in the applicable external agreement for which the manager is responsible complies fully with the requirements of this Standard; and
- perform all other applicable quality management roles and responsibilities assigned to them in their organization's QMP.

Staff members shall:

- ensure that all work specified in the applicable external agreement for which the staff member is responsible complies fully with the requirements of this Standard;
- ensure that the results of environmental programs are of sufficient quantity and adequate quality for their intended use; and
- perform all other quality management roles and responsibilities assigned to them in their organization's QMPs.

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## 9. DEFINITIONS

Several definitions given in CIO Policy 2106, CIO Procedure C2106-P-01, and CIO 2106-S-01 are repeated below for added clarity and utility to this Standard.

**Approved:** The documented determination that the proposed quality document is suitable for the intended purpose and meets the requirements specified in the applicable Quality Standard.

**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.

**Competence:** The ability to apply knowledge, skills, and experience to an activity to achieve intended results.

**Conformity:** The fulfillment of a requirement.

**Corrective Action:** An action to eliminate the cause of a nonconformity or undesirable situation and to prevent recurrence.

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**Data:** A collection of facts and estimates from which conclusions may be drawn.

**Data Standard:** A documented consensus-based agreement on the format and definition of data.

**Data Usability:** The process of determining and ensuring that the quality of the data produced meets the intended use of the data.

**Environmental Data:** Any data or information pertaining to the environment that describe measured outputs from processes; environmental conditions in a specific location; ecological effects and consequences; health effects and consequences; biological, chemical, and radiological conditions; 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 databases, information systems, literature, or the Internet.

**Environmental Data Collection:** The process of acquiring or gathering environmental data through various means including (but not limited to) sampling and analysis activities, retrieval from information systems literature, and receipt from EPA partners and the regulated community.

**Environmental Data Operations:** The work performed to collect, produce, use, or report environmental data.

**Environmental Data Production:** The process of generating environmental data through various means including (but not limited to) the use of measurement instrumentation, information technology, computer models, and data analysis tools (e.g., statistics, risk assessment methods).

**Environmental Programs:** The 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.

**Extramural Agreement:** A legal agreement between EPA and a non-EPA organization for the acquisition of items or services by EPA or financial assistance to a non-EPA organization. Such agreements include acquisition agreements (e.g., contracts, work assignments, delivery orders, task orders), assistance agreements (e.g., cooperative agreements, research grants, State and local grants), and EPA-funded Interagency Agreements (IAs) with other governmental entities.

**Equivalent Document:** A set of documents that contains all the information and management controls (signatures) as the required documents used in the Standard.

**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.

**Guidance:** A non-mandatory compilation of advice, examples, best practices, or past experience. Guidance may supplement procedures.

**Information:** For purposes of this Standard, information means any communication or representation of knowledge such as facts or data, in any medium or form, including, but not limited to, textual, numerical, graphic, cartographic, narrative, or audiovisual forms.

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**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 either manual or computerized, or a combination of both.

**Information Technology:** The study, design, development, implementation, support, or management of computer-based information systems, particularly software applications and computer hardware.

**Integrity (Information):** Assurance that the information is protected from unauthorized access or change and is not compromised through corruption or falsification.

**Life Cycle:** The life span of a product or service from its initial planning and development, to its use and maintenance, and to its final closure or disposal.

**Management Controls:** A system of management functions to enable managers to determine that the operations of a program or organization satisfy predetermined goals and objectives, that performance is in line with standards and specifications, and to implement any remedial actions needed to ensure that human and other resources are being used in the most effective and efficient way possible in achieving the organization's mission.

**Management System:** A system to establish policy and objectives and to achieve those objectives (ISO 9001). A management system may describe the policies, objectives, principles, authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing products and services. Management systems include ISO 9001 on quality management, ISO 14001 on environmental management, and OHSAS 18000 on occupational health and safety.

**Material Transfer Agreement (MTA):** A contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use it for its own research purposes.

**Metadata:** The information about data required to facilitate its use, understanding and management. For example, metadata should answer questions about data such as why they were collected, how they were collected and by whom, what was done to the data, what they were used for, what were their limitations, and what were the acceptance criteria.

**Normative Annex:** A part of a Standard that gives provisions (requirements) additional to those requirements in the body of the Standard. A normative annex is considered to a part of the Standard when setting audit criteria.

**Normative Element:** An element that describes the scope of a Standard and which sets out provisions (requirements) of the Standard.

**Organization:** A company, corporation, firm, enterprise, or institution, or part thereof, incorporated or not, public or private, that has its own functions and administration.

**Objectivity (Information):** The assurance that information is presented in an accurate, clear, complete, and unbiased manner, and, as a matter of substance, is accurate, reliable, and unbiased.

**Policy:** A high-level statement about an Agency requirement designed to influence and determine decisions, actions, and other matters.

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**Prime Recipient:** An organization that directly receives funding, support, or authorization to implement a project or program.

**Procedure:** The required steps, course of action, or processes needed to accomplish or satisfy a policy.

**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 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):** A management or oversight function that deals with setting policy and running an administrative system of management controls that cover planning, implementation, review, and maintenance to ensure products and services are meeting their intended use.

**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 QMS for the organization. NOTE: Other personnel having QA or QC duties may be referred to as QA Officer and QA Coordinator.

**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 objectives and criteria.

**Quality Control (QC):** The overall system of technical activities that measure 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:** That aspect of the overall quality management system of the organization that determines and implements the quality policy. Quality management typically includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the application of quality practices to the organization's programs.

**Quality Management Plan (QMP):** A formal document or manual that describes the QMS 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 Management System (QMS):** 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 QMS provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.

**Required Element:** An element whose presence is obligatory in a Standard.

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**Requirement:** An expression of the content of a Standard conveying a criterion to be fulfilled if compliance is to be claimed and from which no deviation is permitted.

**Service:** A discrete function that performs one or more operations and returns a set of results to an external requester.

**Standard:** An accepted, consensus-based specification which defines systems, processes, methodologies, or practices. It provides a basis for assuring consistent and acceptable minimum levels of quality, performance, safety, and reliability. Standards usually are included in or accompany procedures.

**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.

**Sub-award:** A legal instrument that provides support for the performance of any portion of the project or program award in an external agreement that the recipient awards to an eligible subrecipient. A subaward may be provided through any legal external agreement.

**Sub-recipient (Sub):** Generally an external organization that receives a subaward from a prime recipient and that is accountable to the prime for products and/or services under that agreement.

**Transparency (Information):** The assurance that information is supported by sufficient metadata when disseminated.

**Usability Assessment:** The evaluation of data based upon the results of data validation and verification for the decision(s) being made. Reviewers assess whether the process execution and resulting data meet quality objectives based on the criteria given in the QAPP.

**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.

**Utility (Information):** The assurance that information is useful for its intended purpose.

**Validation (Information):** The confirmation by examination and provision of objective evidence that the particular requirement for which the information is intended is fulfilled; the process of determining whether the specifications were appropriate and that the verified results will meet the data user's needs.

**Verification (Information):** The confirmation by examination and provision of objective evidence that validated information fulfills specified requirements; the process of checking whether the information met the project's specifications.

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## 10. WAIVERS

None.

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## 11. REFERENCES

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**EPA 2009.** *Guidance on the Development, Evaluation, and Application of Environmental Models.* Council for Regulatory Environmental Modeling, EPA/100/K-09/003, U.S. Environmental Protection Agency.

**EPA 2012a.** *Guidance on Developing Quality Management Plans,* CIO Guidance 2106-G-02 QMS, Quality Staff, U.S. Environmental Protection Agency.

**EPA 2012b.** *Guidance on Developing Quality Assurance Project Plans,* CIO Guidance 2106-G-05 QAPP, Quality Staff, U.S. Environmental Protection Agency.

**ISO 2004.** *Rules for the Structure and Drafting of International Standards* (Fifth Edition, 2004), ISO/IEC Directives, Part 2, International Organization for Standardization, Geneva.

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## 12. MATERIAL SUPERSEDED

This Standard replaces EPA/QA R-2 and EPA/QA R-5 in their entirety.

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## 13. ADDITIONAL INFORMATION

Other information and documentation on the EPA Quality Program may be found at <http://www.epa.gov/quality>. The following Annexes contain detailed specifications and information that clarify the requirements and use of this Standard. These are:

- Annex A – Requirements for Quality Management Plans for Non-EPA Organizations (Normative)
- Annex B – Requirements for Quality Assurance Project Plans in External Agreements (Normative)
- Annex C – Guidelines on Planning for Projects Involving External Agreements (Informative)

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**ANNEX A (NORMATIVE)**  
**REQUIREMENTS FOR QUALITY MANAGEMENT PLANS FOR NON-EPA ORGANIZATIONS**

**A1. Introduction**

Clause 7.3.1 in CIO Standard 2106-S-02 requires external organizations that collect, produce, or use environmental data to describe and document their quality management system (QMS) in a Quality Management Plan (QMP) or equivalent document acceptable to EPA.

The QMP is unique to an organization and shall describe the management and technical processes and practices necessary to plan, implement, document, and assess the effectiveness of the organization's QMS applied to the work prescribed by the external agreement. Since non-EPA organizations may participate in more than one external agreement with EPA, the organization's QMP may contain common management information that may be applied to several agreements and not require an individual QMP for each agreement. The specific quality assurance (QA) and quality control (QC) practices will be found in the Quality Assurance Project Plan (QAPP) for each external agreement (See Annex B).

The QMP defines an organization's quality-related elements that represent the core of the QMS including:

- management controls, policies, and objectives;
- processes for and areas of applying quality practices; and
- roles, responsibilities, and authorities of managers and staff.

The QMP, therefore, is a management document that should be appropriately tailored to the needs of the organization. The QMP must be sufficiently inclusive, explicit, and readable to enable managers, supervisors, and staff to understand the priority that senior management places on QA, the established QA policies and procedures, and their respective QA roles. The QMP must be constructed and written so that an assessment can be made of the QMS's effectiveness following implementation. This enables managers to determine whether the QMS is being implemented in a way that ensures successful results can be obtained. The QMP shall focus on the processes used to plan, implement, document, and assess the programs to which it is applied. The level of detail should be based on a common sense, graded approach that establishes QA and QC requirements commensurate with the importance of the work, the available resources, and the unique needs of the organization.

QMPs shall be modified as the requirements change. This Annex describes the quality management practices which are normally considered to be critical to an effective QMS. A non-EPA organization implementing an external agreement shall evaluate these core elements to determine their applicability to its QMS for environmental data collection, production, and use. If additional quality management elements are useful or necessary to adequately describe the QMS, these elements shall be developed and discussed in the QMP.

Guidelines for satisfying these requirements may be found in *Guidance on Quality Management Plans*, EPA QA/G-2A, (EPA 2012).

**A2. Preparation, Submission, Review, and Approval**

**A2.1 Preparation Responsibility**

The top management of the non-EPA organization is responsible for the preparation of a QMP that covers all work specified by the applicable external agreement and for which the organization's management is accountable. Top management includes the senior executive responsible and accountable for mission accomplishment and overall operations. Top management shall ensure that the QMS documented in the QMP conforms to the requirements of this Standard.

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## **A2.2 Non-EPA Organization QMP Submission and Approval**

A QMP must be approved and signed by the top manager in the organization prior to being submitted to EPA for review and approval. The QMP must also be approved and signed by the QA manager (or equivalent position) in the organization.

The top manager may require the concurrence on the QMP by appropriate subordinate line managers to encourage the acceptance and implementation of the QMS.

## **A2.3 EPA Review and Approval of the QMP**

Following internal organization approval, the non-EPA QMP must be submitted to the EPA organization responsible for the external agreement for review and approval. Each QMP will be reviewed to determine compliance with general EPA Quality requirements including conformance with this Standard. QMPs that adequately address all program elements described in Clause 7 of this Standard should be approved and be valid for a period not to exceed the term of the external agreement.

## **A2.4 QMP Revisions**

A non-EPA QMS must be reviewed at least annually by the organization to confirm its continued accuracy and relevance in describing the QMS. This review must include an evaluation of the effectiveness of the QMP. When necessary, the organization shall revise its QMP to incorporate changes to the QMS. Revisions to a QMP may become necessary due to:

- a change in the scope (i.e., statement of work) in the external agreement,
- significant changes in the non-EPA organization's mission or structure, or
- any major change to the organization's QMS.

A revised QMP may be submitted to EPA at any time and is subject to the same review and approval processes as the original QMP. All personnel performing work for the organization shall be notified of changes to the QMS and the QMP.

## **A3. Quality Management Plan Requirements**

### **A3.1 General Requirements**

***The QMP shall address all of the requirements of this Standard pertaining to environmental data collection, production, and use as given in Clause 7 of this Standard.***

The QMP shall document all quality-related terms and conditions specified in the external agreement and describe their implementation.

The QMP shall contain descriptions of the processes by which the organization plans, implements, documents, and determines the effectiveness of its quality management practices, including QA and QC activities, to help management to obtain results of its technical work that are of the type and quality needed for their intended use. Information about the organization's structure and mission should be included in the QMP to provide context for the external agreements. A brief description of the organization's background and history may be included in the QMP for completeness.

The QMP should reflect the organization's commitment to quality management principles and practices, and may be tailored by the organization to meet their needs.

To reduce duplication between QMPs and QAPPs, the QMP shall include discussion of those activities, policies, and procedures that are common to projects governed by other external agreements (e.g.,

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multiple contracts, work assignments, assistance agreements). Such discussions provide an “umbrella” under which individual project activities may be performed.

The remainder of Annex A, Clause 3, provides the elements that must be addressed in the organization’s QMP. If the organization believes that an element does not apply to its QMS and should be omitted, the QMP must contain an explanation of why it does not apply.

The QMP shall always include:

- title page;
- table of contents;
- evidence of the review, approvals page, and revision history of the QMP; and
- applicable references.

### **A3.2 Conformance with Policies, Procedures, and Standards**

The QMP shall identify all EPA Policies, Procedures, and Standards ( and any internal organization policies and procedures to which the QMS conforms.

### **A3.3 Organizational and Program Field of Application**

The QMP shall identify and describe:

- all parts of the organization to which the QMP applies, and
- all business lines, programs, or actions involving the collection, production, and use of environmental data to which the QMS applies.

### **A3.4 Organization, Responsibility, and Authority**

The QMP shall include the following:

- a statement of the organization’s policy on QA, including the importance of quality in its environmental data products and services to the organization and its mission, and why; the general objectives/goals of the QMS; and the policy for resource allocation for the QMS, including personnel, intramural and extramural funding, and QA-related travel funding for EPA-related work;
- an organization chart that identifies all of the components of the organization and, in particular, the organizational position and lines of reporting for the QA Manager (and any QA staff) that confirm and document the independence of the QA Manager from groups collecting, generating, using, and evaluating environmental data;
- a discussion of the organizational structure of the QMS and the responsibilities and authorities of the QA Manager and any other QA staff;
- a discussion of the specific quality management controls required by the QMS and the work to which the controls apply; where oversight of delegated, contracted, or other external programs is needed to ensure that objectives for data quality and usability are attained; and where internal coordination of QA and QC activities among organizational units needs to occur;
- a discussion of the QA and QC roles and responsibilities of line management, technical staff, and any other staff, and how accountability is defined;
- a discussion of the organization’s process for resolving disputes regarding QMS requirements, QA and QC procedures, assessments, or corrective actions;

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- a discussion of how management shall ensure that applicable elements of the QMS are understood and implemented in all programs involving environmental data; and
  - an approval page for the signatures of the top manager, senior line management (as appropriate), and the QA manager of the organization. This approval page may be part of a title page or a separate sheet following the title page.

### **A3.5 QMS Description**

The QMP shall provide a description of the QMS and its implementation in the organization. The QMP shall describe the principal components in the QMS and how they are used to implement the QMS. These components include, but are not limited to,

- QMS documents (e.g., Division or subordinate organization QMPs),
- management assessments (self and independent),
- staff competence,
- systematic planning processes,
- project-specific quality documentation (e.g., QAPPs or equivalent documentation),
- standard operating procedures (SOPs),
- technical audits/assessments (self and independent), and
- data assessments.

This discussion shall also identify how and when the components of the QMS are to be applied to individual projects and tasks in the external agreements.

The QMP shall document how the organization complies with EPA requirements for competence in external agreements.

### **A3.6 Personnel Competence**

The QMP shall include a statement of the organization's policy for ensuring the competence of managers and staff to implement the QMS effectively and to provide training to ensure continued effectiveness by personnel. The QMP discussion shall include the processes and the staff responsible for:

- identifying statutory, regulatory, or professional certifications that may be required to perform certain operations; and
- identifying, designing, performing, and documenting technical, quality, and project management training.

The QMP shall also describe how staff proficiency in critical technical disciplines is maintained and documented.

### **A3.7 External Agreements**

The QMP shall describe the organization's process for ensuring that appropriate quality requirements are included and implemented in all external agreements subject to this Standard. The QMP shall also discuss the organization's process for sub-agreements with other entities (e.g., subcontractors) for support to the statement of work in applicable external agreements.

### **A3.8 Documents and Records Management**

The QMP shall describe (or provide a reference to) the processes by which the requirements contained in Clause 7.6 of this Standard are met, including the responsibilities and authorities of management and staff. In general, the QMP shall address the documents and records processes:

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- for identifying quality-related documents and records requiring control;
  - for handling documents and records to ensure their accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities for management and staff;
  - by which all technical guidance documents are prepared, reviewed, approved, issued, used, and revised;
  - by which all planning documents (e.g., QAPPs, Sampling and Analysis Plans) are prepared, reviewed, approved, issued, used, and revised;
  - that ensure compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs and that provides adequate preservation of key records necessary to support the mission of the organization;
  - for formal and informal reviews of products (e.g., reports, peer reviewed journal articles); and
  - for reviews to confirm that performance and acceptance criteria were established and documented.

The QMP shall describe how documents and records, including revisions, are reviewed for conformance with QMS requirements and with the terms and conditions of external agreements, and are approved by authorized personnel before general use.

The QMP shall describe or provide a reference to the management process that ensures that records accurately reflect completed work and/or fulfill statutory and contractual requirements, including any specific record keeping requirements defined in applicable EPA policies and procedures. The maintenance of records includes defining requirements and responsibilities for record transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrieval.

The QMP shall identify how the disposition of records, in accordance with regulatory requirements, schedules, or directives from senior management, is accomplished.

### **A3.9 Use of Information Technology Methods and Sources**

The QMP shall describe how the organization satisfies the requirements of Clause 7.7 of this Standard and shall include the responsibilities of management and staff.

### **A3.10 Planning**

The QMP shall describe how the organization satisfies the planning requirements given in Clause 7.8 of this Standard, including the responsibilities and authorities of management and staff. The descriptions shall address:

- planning and scoping;
- design of environmental data collection or acquisition;
- design of model development, evaluation, and application; and
- documentation of environmental data collection or acquisition and model design.

The QMP shall describe the process for communications between the organization and any suppliers to ensure that there is a clear understanding by all participants of the needs and expectations of the organization and the products or results to be provided by the supplier.

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The QMP shall describe how the results of planning are documented in a QAPP or equivalent document and are approved by authorized personnel for implementation.

The QMP shall also describe or discuss the process for how information or data obtained from sources outside EPA that did not use an EPA-approved QAPP (or equivalent planning document) for data collection shall be evaluated and qualified for use. The QMP shall describe the review process for qualifying such data, including the use of data for purposes other than for which the data were originally collected .

### **A3.11 Implementation of Work**

The QMP shall describe how the organization satisfies the implementation of work requirements given in Clause 7.9 of this Standard, including the responsibilities and authorities of management and staff.

This description shall address and include processes for:

- identification of operations needing procedures;
- documentation of implementation procedures (e.g., reference methods, SOPs);
- testing and evaluation of procedures to confirm their acceptable performance;
- ensuring that work is performed according to approved plans;
- deviations and waivers from approved procedures;
- use of measurement and testing equipment and models;
- use of data obtained from other sources;
- ensuring the integrity of samples and data; and
- monitoring of performance.

The QMP shall also describe how appropriate management controls for the release, change, and use of planned procedures are implemented. Such management controls provide for the necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

The QMP shall contain the organization's process for identifying the need for SOPs, the process for developing SOPs, and the policy for using SOPs. The QMP shall also describe the process by which SOPs are reviewed for initial and subsequent use.

The QMP shall also describe the organization's process for deviations and waivers from approved procedures and the necessary reviews and approvals.

### **A3.12 Assessment, Oversight, and Response**

The QMP shall describe how the organization satisfies the requirements for assessment, oversight, and response as given in Clause 7.10 of this Standard, including the responsibilities and authorities of management and staff.

This description shall address and include processes for:

- routine oversight;
- identifying appropriate assessment methods for use;
- ensuring the competence of personnel conducting oversight and assessments;
- ensuring the objectivity, independence, and competence of assessment personnel;
- assessment planning and implementation;
- assessment reporting; and
- corrective action and verification.

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The QMP shall describe how assessment methods are chosen and the expected frequency of their application to environmental programs. In particular, the QMP shall document how senior management assesses the adequacy of the QMS.

The QMP shall describe how the competence of personnel conducting assessments is determined. Personnel conducting assessments shall be competent, based on project-specific requirements, to perform the assigned assessment. Management is responsible for choosing the assessors, defining acceptance criteria, approving audit procedures and checklists, and identifying goals prior to initiation of an assessment. Assessors shall be technically knowledgeable with no real or perceived conflict of interest. If the assessors are chosen from within the organization, they must have no direct involvement or responsibility for the work being assessed. The exception to this requirement is for self-assessments, which must be identified as such.

The QMP should also discuss the authority for and conditions under which “stop work” orders may be needed. It should also discuss when and how such decisions shall be made, and with whom any coordination will be needed.

The QMP shall describe how management will respond to the results (or findings) and recommendations from assessments. The QMP will indicate how follow-up action shall be taken and documented to confirm the implementation and effectiveness of the response action. In addition, processes for identifying, trending, and correcting common non-conformances found in different parts of the organization will be described to ensure QMS improvement. The QMP shall also describe how disputes, if encountered, as a result of assessments are resolved and by whom.

#### **A3.13 Data Review, Validation and Verification, and Data Usability Reporting**

The QMP shall describe how the organization satisfies the requirements for the review, validation, and verification of data and for data usability reporting as given in Clause 7.11 of this Standard, including the responsibilities and authorities of management and staff.

This description shall address the processes for:

- review of results involving data to confirm that technical and quality objectives were met;
- review of data of undocumented quality for potential use;
- review of data collected previously for other purposes but being considered for new use;
- documenting the use of environmental data for Agency products and services; and
- planning, implementing, and resolving peer review.

#### **A4. General References**

**EPA 2012.** *Guidance on Quality Management Plans*, CIO Guidance 2106-G-02 QMP, Office of Environmental Information, U.S. Environmental Protection Agency.

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**ANNEX B (NORMATIVE)**  
**REQUIREMENTS FOR QUALITY ASSURANCE PROJECT PLANS IN EXTERNAL AGREEMENTS**

**B1. Introduction**

This *Quality Standard for the Collection, Production, and Use of Environmental Data by Non-EPA (External) Organizations* (See Clauses 7.3.1 and 7.5.1) requires that all work performed by non-EPA organizations on behalf of EPA involving the collection, production, or use of any environmental data shall be implemented in accordance with an Agency-approved Quality Assurance Project Plan or approved equivalent planning document (hereafter referred to as a QAPP). The QAPP defines and documents how specific activities involving environmental data shall be planned, implemented, and assessed during a particular project. Therefore, it is the “road map” of how to achieve satisfactory results in such external agreements.

This Annex presents the minimum specifications for quality assurance (QA) and for quality control (QC) practices that must be addressed in a QAPP prepared by non-EPA organizations for external agreements, and describes the process for its preparation, review, and approval. Supplemental guidelines on how to meet these QAPP requirements can be found in *Guidance on Quality Assurance Project Plans*, CIO 2106-G-05 QAPP (EPA 2012).

The QAPP is a critical planning document for any environmental data operation since it documents how environmental data operations are planned, implemented, documented, and assessed during the life cycle of a program, project, or task. The ultimate success of an environmental program or project depends on the adequacy and sufficiency of the quality of the environmental data collected, produced, and used in estimation or decision-making. This depends significantly on the adequacy of the QAPP and its effective implementation. Quality planning (Clause 7.8) is an absolutely essential component of project management and the QAPP provides the mechanism for documenting the results of the planning process. Additional guidance on planning for projects may be found in Annex C of this Standard.

**B2. QAPP Responsibilities and Application**

**B2.1 QAPP Preparation Responsibilities and Approvals**

The EPA organization’s Quality Management Plan (QMP) (See Clause 7.6.2 and Annex A of Standard 2106-S-01) establishes how, when, and by whom development, review, approval, and effective oversight of QAPPs occur. In some cases, it may be necessary to add special requirements to the QAPP. The EPA organization sponsoring the work shall define any specific requirements beyond those listed in this Annex.

***No work involving environmental data collection, production, or use shall be started until the QAPP has been approved by the EPA QA Manager (or authorized representative).***

In some extraordinary circumstances, EPA may find it necessary to waive this requirement when immediate action is implemented to protect human health, the environment, or operations conducted under police powers. However, under these circumstances, the organization shall have standard operating procedures (SOPs) and other quality-related documents available to support such activities. The actual activities also shall be documented and these documents will serve collectively in lieu of the QAPP.

As noted in Clause 7.6.4 of this Standard, EPA may elect to require a combined QMP and QAPP (e.g., small environmental research projects). A combined QMP/QAPP incorporates some elements of the QMP and some elements of the QAPP. The specific elements to be addressed are typically taken from the lists given in Clause 7.6.2 and 7.6.3 of this Standard; however, the EPA organization shall determine the final

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list of elements to be addressed in the combined QMP/QAPP. As such, all of these elements must be addressed by EPA organizations and non-EPA organizations holding external agreements. The combined QMP/QAPP is subject to the same review and approval process (both by the external organization and by EPA) as any other QMP and QAPP.

## **B2.2 QAPP Implementation and Revision**

The organization performing the work shall implement the approved QAPP and ensure that all personnel involved in the work have copies of the approved QAPP and all other necessary documents and procedures.

Due to the complex and diverse nature of many programs involving environmental data collection, production, and use, changes to original QAPPs are often needed. The organization's project manager, with the assistance of the QA Manager as appropriate, must determine the impact of such changes on the technical and quality objectives of the project. There should be agreement as to what changes would have minimal impact on the work and can be authorized in the field by the project manager (e.g., change in sample location) and what changes would require a revision to an approved QAPP (e.g., change in chemical analysis method). When a substantive change is warranted, the organization shall modify the QAPP to document the change and submit the revision for approval by the same authorities that performed the original review. The change shall be implemented only after the revision has been approved and received (at least verbally with written follow-up) by project personnel and EPA.

It is essential that the QAPP be kept current and that all personnel involved in the work have easy access to a current version of the QAPP. For programs or projects of long duration, such as multi-year monitoring programs, the QAPPs should be reviewed at least annually by the organization. If revisions are necessary to reflect current needs, the QAPP shall be revised and resubmitted for review and approval by the same authorities that performed the original review.

## **B2.3 Applicability of QAPPs**

The QAPP requirements in this Annex apply to all activities that acquire, generate, compile, or analyze environmental data that are performed on behalf of EPA through external agreements. Such agreements may include:

- acquisition of services and items through contracts, task orders, and other acquisition agreements;
- assistance agreements such as grants and cooperative agreements;
- interagency agreements with other Federal, State, local, or international governments or entities;
- enforcement agreements (e.g., administrative orders, consent agreements); and
- voluntary partner programs (e.g., voluntary monitoring).

Where specific Federal regulations require QA and QC activities, QAPPs shall be prepared, reviewed, and approved in accordance with the specifications contained in this document for the data collection activity unless superseded by the regulation. QA and QC requirements are negotiated into the applicable interagency and international agreements, including sub-agreements, since EPA cannot unilaterally impose its QA and QC requirements in these agreements.

## **B3. QAPP Elements and Requirements**

### **B3.1 Overview and General Requirements**

Clause B3 describes the minimum elements and information that are generally required for a QAPP for most operations involving environmental data collection, production, and use by external organizations. Due to the diversity of Agency programs, some elements described in this Annex may not be applicable

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to all programs. The final decision on the applicability or use of any or all of these elements for QAPPs shall be made by EPA and may be specified in the statement of work for the external agreement.

The content and level of detail in each QAPP may vary according to the nature of the work being performed and the intended use of the data. This is called “the graded approach” and allows for a flexible design of the QAPP content. The intent of the “graded approach” is to achieve sufficient and adequate detail in the QAPP to satisfy the scope and objectives of the project and the intended use of the data. The final decision on QAPP content and level of detail belongs to EPA.

### **B3.2 General Content Requirements**

The QAPP must integrate the contributions and requirements of all parties in the work, including sub-agreement holders, into a clear, concise statement of what needs to be accomplished, how it shall be done, and by whom. It must provide understandable instructions to those who must approve or implement the QAPP, including the field sampling team, the analytical laboratory, and the data reviewers. The use of SOPs and, when possible, national standards or practices are encouraged in all aspects of the QAPP. When these are used, they must be cited in the QAPP.

The QAPP must include standardized, recognizable management elements that cover the entire scope of the project from planning, implementation, validation/verification, assessment, to final reporting. The QAPP must also recognize that there are different types of projects that may involve environmental data including, but not limited to:

- monitoring and use of direct measurements and laboratory results by EPA or its extramural partners to collect environmental data using EPA-approved quality procedures and practices;
- collection or use of environmental data from other sources (e.g., obtained from databases, Internet, literature) that were collected originally without the application of EPA-approved quality procedures and practices;
- sampling or analytical methods development; and
- generating or producing environmental data from the use of mathematical or probabilistic models and computer software.

In order to be effective, the QAPP must specify the level or degree of QA and QC activities needed for the particular environmental data or model operations. The QA and QC technical requirements of a project should be commensurate with:

- the purpose of the environmental data collection (e.g., enforcement action, research and development studies) or model use;
- the type of work to be done (e.g., monitoring, site characterization, model simulation, bench level proof of concept); and
- how the results shall be used (e.g., regulatory enforcement, Total Maximum Daily Load [TMDL] development, permit approval, research publications and journal articles).

The QAPP elements that follow are presented in that order and have been arranged for convenience into four general groups reflecting the logical flow (Plan, Do, Check, Act) of the project life cycle. The four groups of elements and their intent are summarized as follows:

- Project Management (Plan) - These elements cover the basic area of project management, including the project history, project objectives, technical and quality objectives (e.g., Data Quality Objectives), and roles and responsibilities of the participants. These elements document that the project has a defined goal and that the participants understand the goal and the approach to be used.
- Data Acquisition (Do) - These elements cover all aspects of measurement and data acquisition systems design and implementation. It includes the intended measurements, data collection, or

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acquisition methods appropriate for achieving project objectives. Elements are presented for the different types of projects discussed above ( i.e., monitoring, acquisition from other sources, and modeling).

- **Assessments (Check)** - These elements address the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities. The purpose of assessment is to ensure that the QAPP is implemented as prescribed and that project actions are implemented as expected.
- **Review, Evaluation of Usability, and Reporting Requirements (Act)** - These elements cover the QA activities that occur after the data collection (or use) phase of the project is completed. Implementation of these elements will help to determine that the data conform to the specified criteria, thus achieving the project objectives and ensuring that data usability is documented in a final project report. Included are any limitations or restrictions on the use of the data that will have to be identified and documented.

***All applicable elements must be addressed in the QAPP. For some projects, only part of the QAPP elements discussed may apply to work being performed. If so, the elements that do not apply to the work should be noted in the QAPP.***

Documentation, such as an approved Work Plan, SOPs, model calibration reports, etc., may be referenced in response to a particular required QAPP element to reduce the size of the QAPP and the time required for preparation and review. All referenced documents must be attached to the QAPP itself or be placed on file with EPA and available to users when needed. Such references must be kept current by the submitter. The QAPP shall also identify and describe related QA planning documentation (e.g., QMPs) from subcontractors or suppliers of services critical to the technical and quality objectives of the project or task.

The format of the QAPP is not critical except that all required elements must be addressed. The organization should present the content of the QAPP in a logical, easily understood manner. The following items may be helpful in making the QAPP more user-friendly and useful:

- table of contents;
- document control format;
- applicable references (e.g., methods, SOPs, handbooks); and
- embedded internet links.

### **B3.3 Project Management**

The QAPP must describe the project adequately. Elements that address the basic project management and objectives of the work include:

- title, version number, and approval/sign-off sheets;
- distribution list;
- project organization and schedule;
- project/problem background;
- project/problem description;
- project quality objectives (Data Quality Objectives) and measurement performance criteria;
- special training requirements/certification; and
- documentation and records requirements.

Refer to EPA 2012 for specifics on satisfying requirements in these areas.

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### **B3.4 Data Acquisition**

The collection, production, and use of environmental data may include:

- monitoring/direct measurements—traditional sampling and analysis activities, taxonomic observations, or testing (e.g., ecological monitoring, biological studies);
- collection of data from other sources - data retrieved from data bases, literature, or other electronic sources (e.g., Internet) or provided by other organizations;
- sampling and analytical/testing methods - the development of sampling or analytical methods or other testing methods (e.g., biological, ecological, GIS); and
- development, modification, and use of mathematical and probabilistic models and other software applications (information technology products).

The QAPP shall include sufficient descriptions of planned activities in order to meet the requirements given in Clauses 7.3 and 7.8. In addition, Annex C (Planning) may be particularly helpful in defining project planning needs.

#### **B3.4.1 Monitoring/Direct Measurements**

The following QAPP elements cover aspects of measurement and testing equipment (M&TE) systems design and implementation in the project. These elements reflect traditional sampling and analysis activities for the collection of new data or information. The elements shall include:

- sampling collection design, experimental design, and sampling tasks;
- sampling procedures and requirements;
- sample handling and custody requirements;
- sample collection documentation;
- analytical methods requirements;
- analytical tasks description;
- quality control requirements;
- instrument/equipment testing, inspection, and maintenance requirements;
- instrument calibration and frequency;
- inspection/acceptance requirements for supplies and consumables; and
- data management.

Refer to EPA 2012 for specifics on satisfying requirements in these areas. For assistance in sampling process design, the organization should refer to *Guidance for Choosing a Sampling Design for Environmental Data Collection*, EPA QA/G-5S, (EPA 2002a).

#### **B3.4.2 Collection of Data from Other Sources**

For those circumstances in which environmental data of undocumented quality are being acquired from sources other than direct measurements by EPA or its partners, the QAPP shall describe how the requirements of Clause 7.11.3 and this Annex will be met. Similarly, when data from EPA or its partners are intended for a use other than for which it was collected originally, the QAPP shall document the acceptance criteria for the use of these data.

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The QAPP shall identify and describe the data sources and types of data needed for the project that are to be obtained from other sources, and shall define acceptance criteria for the use of such data in the project. This discussion should consider any limitations on the use of the data resulting from uncertainty in its quality and from the possible impact of adding more error to the results. The acceptance criteria shall be sufficiently detailed to allow for both quantitative and qualitative criteria to be developed. Quantitative criteria will allow for the statistical consideration of data, while qualitative data or information will allow for contextual consideration of data and information. If data from other sources is to be integrated into new data or information, the acceptance criteria shall address how the integration will be achieved and verified for appropriateness. If the quality of the data cannot be determined, the QAPP shall document this limitation and the outputs or products of the project include disclaimers reflecting this limitation.

Key elements of the process of reviewing environmental data for potential use may include:

- the need to satisfy the major requirements of the Information Quality Act (2002) (e.g., objectivity, utility, and integrity);
- a description of the data collection methodology employed;
- the principal indicators of environmental quality (e.g., precision, bias, representativeness, comparability, completeness, and sensitivity); and
- the general usability factors (e.g., relevance, temporal compatibility, spatial inclusivity, credibility, aggregation level, compatibility, reproducibility, and degree of augmentation).

The QAPP shall discuss requirements for evaluation of soundness of science underlying a model, quality and quantity of available data, degree of correspondence with observed conditions, and the appropriateness of a model for a given application.

The following QAPP elements cover aspects of measurement systems design and implementation in the project. Where applicable, the elements shall be addressed in the QAPP and include:

- proposed data source sponsor;
- publication information;
- project background;
- description of how the proposed data applies to the project;
- data format and accessibility;
- establishment of acceptance criteria; and
- documentation of sample quality assurance procedures.

Refer to EPA 2012 and to Annex C for assistance in constructing qualitative and quantitative acceptance criteria for the investigation of data obtained from undocumented sources.

#### B3.4.3 Sampling and Analytical/Testing Methods Development

Projects for the purpose of developing sampling and analytical testing methods typically will involve the collection, production, and use of environmental data as part of the design, testing, and validation/verification of the method. In some situations, the requirements of Clause B3.4.1 may also apply to methods development and they should be applied as applicable. The QAPP shall describe how the requirements of Clause 7.8 and this Annex will be met.

Refer to EPA 2012 for specifics on satisfying requirements in these areas.

#### B3.4.4 Development and Use of Mathematical and Electronic Models and Other Software Applications (Information Technology Products)

The development and use of mathematical and electronic models (i.e., information technology products) as well as the development of other software applications, shall be described in a QAPP. The QAPP

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shall, at a minimum, meet the requirements of Clauses 7.6.3, 7.7.1, 7.7.2, 7.8.4, and 7.8.5 of this Standard. Refer to EPA 2012 for guidance on addressing QAPP needs for model development, modification, and application.

#### B3.4.4.1 Quality Assurance Project Plan Requirements for Model Development/Modification

The QAPP shall include, but not be limited to consideration, development, and documentation of the specifications for model development identified below. While some of these aspects may not be available at the start of a model development project, the QAPP should be amended as soon as the information becomes available.

##### *Problem Specification and Identification of Model Purpose and Scope*

The QAPP should define:

- the objectives (i.e., what questions the model needs to answer);
- the most important functions that the software application must perform;
- the model scope (e.g., spatial, temporal and process detail);
- any boundary or initial condition specifications; and
- how the quantitative or qualitative model performance criteria will be determined.

##### *Model Development or Selection Process*

The QAPP should identify and define:

- the theory that forms the basis for the model, the mathematical algorithms, and approaches used in executing the model computations;
- the existing software to be used in development of a new model, how it will be used and why it was selected;
- the computer hardware and operating system requirements for the software application;
- any assumptions and limitations and effect on model applicability;
- the procedures for controlling, documenting, and archiving all significant changes to the software and hardware.

##### *Data Requirements*

The QAPP should define clearly:

- the data needs/inputs/sources; and
- the data quality and quantity objectives for model input and data used for model development.

##### *Evaluation of the Model*

It is necessary for the QAPP to define:

- how the science underlying each component of the model will be evaluated;
- the model testing strategies including design and code verification, individual module tests; integration tests, systems testing, acceptance testing, and beta testing, as applicable;
- the procedure for each test shall be provided and the process of confirming the test results included (EPA 2009);
- the use of uncertainty and sensitivity analysis; and
- the requirements for project documentation (e.g., design document, source code, and user guide).

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#### B3.4.4.2 QAPP Requirements for Model Application

The QAPP shall include, but not be limited to, consideration and documentation of the detailed specifications for model application identified below:

##### *Problem Specification, Model Purpose, and Model Selection*

The QAPP should define:

- the research or regulatory objectives and the purpose of model application and analytical work;
- data reporting requirements and format for model inputs and outputs; and
- the basis for the selection of model from other available models.

##### *Model Application*

The QAPP needs to define:

- the scenarios to be simulated; and
- how the modeling analysis and its results will be documented.

##### *Data*

The QAPP should define clearly:

- the quality and quantity of available data and procedures for excluding data;
- the model parameters and method of estimation; and
- the model calibration methods.

##### *Evaluation of the Model*

It is necessary for the QAPP to define:

- the quality objectives to be used in the model evaluation;
- the requirements for qualitative and/or quantitative model corroboration;
- the use of sensitivity and uncertainty analysis;
- any requirements for model post-auditing;
- the requirements for peer review of the model application; and
- how the model evaluation will be documented.

#### B3.4.4.3 Quality Assurance Project Plan Requirements for Other Software Applications

A QAPP for other software applications shall address and include descriptions of the:

- purpose of the model or software application, including how it can be used;
- technical and quality objectives;
- discussion of the scientific theories that form the basis for model;
- description of the inputs needed;
- description of the development process, including any testing and evaluation of the model; and
- description of how the model will be documented (including instructions for its use).

### **B3.5 Assessments**

The QAPP shall describe how the requirements of Clause 7.10, including the roles and responsibilities of project personnel, will be addressed. The QAPP elements that address the processes for assessing the effectiveness of the implementation of the project and associated QA and QC activities include:

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- assessments and response/corrective actions;
  - data management tasks; and
  - reports to management.

Types of assessments include, but are not limited to:

- technical systems audits;
- performance audits of measurement and analytical systems;
- surveillance of operations;
- audits of data quality;
- quantitative comparisons to acceptance criteria;
- qualitative comparisons to acceptance criteria; and
- interim assessments of data quality.

Refer to EPA 2012 for guidance on satisfying requirements in these areas.

### **B3.6 Review, Evaluation of Usability, and Reporting Requirements**

#### **B3.6.1 Implement and Document Review, Verification and Validation, and Evaluation of Usability**

The QAPP shall describe how the requirements of Clause 7.11, including the roles and responsibilities of project personnel, will be addressed in the project. The QAPP elements that address the processes for the review, assessment, and verification of usability include:

- review information;
- verification and validation targets and methods;
- peer review information;
- potential limitations on interpretation;
- reconciliation with user requirements; and
- reports to management.

If the quality of the data cannot be determined, the QAPP shall note that any limitations impacting the work products shall include appropriate disclaimers on the use of the products.

For specific advice in data verification and validation, refer to *Guidance on Environmental Data Verification and Validation*, EPA QA/G-8, (EPA 2002b); for data usability, refer to *Data Quality Assessment: Statistical Methods for Practitioners* EPA QA/G-9S (EPA 2006), and also EPA 2012.

#### **B3.6.2 Implement and Document Model Review**

The critical review of a model or its application shall be conducted by individuals who are independent of the work and who collectively have technical expertise equivalent to those who performed the work. Internal and external peer review may help to ensure that the model is technically adequate, competently performed, properly documented, and satisfies established quality requirements through the review of assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and/or conclusions from a model or its application (modified from EPA 2009). The process for reviewing a model shall be documented in the QAPP.

### **B4. General References**

The current versions of the following general references may be useful to the preparation and use of QAPPs:

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**EPA 2002a.** *Guidance for Choosing a Sampling Design for Environmental Data Collection*, (EPA QA/G-5S). Office of Environmental Information, U.S. Environmental Protection Agency.

**EPA 2002b.** *Environmental Data Verification and Validation*, EPA QA/G-8, Office of Environmental Information, U.S. Environmental Protection Agency.

**EPA 2006.** *Data Quality Assessment: Statistical Methods for Practitioners*, EPA QA/G-9S, .Office of Environmental Information, U.S. Environmental Protection Agency.

**EPA 2009.** *Guidance on the Development, Evaluation, and Application of Environmental Models.* EPA/100/K-09/003, Council for Regulatory Environmental Modeling, U.S. Environmental Protection Agency.

**EPA 2012.** *Guidance on Quality Assurance Project Plans*, CIO Guidance 2106-G-05 QAPP, Office of Environmental Information, U.S. Environmental Protection Agency.

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## **ANNEX C (INFORMATIVE) GUIDELINES ON PLANNING FOR PROJECTS INVOLVING EXTERNAL AGREEMENTS**

Annex B presented the minimum specifications to be addressed in a Quality Assurance Project Plan (QAPP) developed by non-EPA organizations as part of an external agreement. Annex C gives guidelines for systematic planning in addressing projects involving the collection, analysis, and reporting for environmental data, including the development of conceptual models of the data collection activities. Systematic planning involves defining and characterizing the project and desired outcomes, and designing quality assurance (QA) and quality control (QC) requirements and procedures that will ensure the data collected, generated, or used during the project will support expected and needed project outcomes. The elements of systematic planning can be grouped into three process areas:

- project planning (Clause C1);
- design of data collection activities (Clause C2); and
- design and use of conceptual models when appropriate (Clause C3).

The elements in both planning and development are iterative in nature as information from one area may change or alter the results in other areas. For example, a change in the conceptual model that describes the scientific mechanism driving the project can change the design of data collection and even the scope of investigation. The combination and synthesis of all three areas lead to a data collection activity capable of withstanding robust scrutiny.

As an added aid to planning, Clause C4 discusses the relationship between systematic planning and the QAPP, including the Data Quality Objectives (DQO) process and an example application of the DQO process to the Uniform Federal Policy QAPP (EPA 2005).

### **C1. Project Planning**

Project planning should be coordinated among the participants in the external agreement and include, as applicable, the following steps:

- a definition of the project;
- the scope of the investigation;
- the needs or demands of the project;
- the reporting requirements established in the external agreement for the project or investigation

#### **C1.1 Definition of the Project**

The definition step creates an overall framework upon which the project will be developed and should consider:

- the definition of project/task scope and objectives and the desired action or result from the work;
- an identification of program requirements and regulations that will be supported by the project;
- the development of project goals, task/activity lists, time frames and logistical needs;
- the development of a conceptual model that describes the physical, chemical, scientific, engineering or mechanism relating to the objectives of the project;
- the need to plan and conduct pilot or reconnaissance studies that could provide sufficient data to assist in the development of the conceptual model; and
- the identification of the different environmental risk assessment pathways that will be evaluated by the project, if appropriate.

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## **C1.2 Scope of the Investigation**

The scope step defines the boundaries (i.e., temporal, physical, and logistical) of the project and may include:

- an identification of special applicable regulatory requirements and key spatial and temporal constraints such as budget, timing, authorization, permits, and access;
- the recognition of organizations (e.g., sampling groups or analytical laboratories) that need to participate in the project and their role in planning, implementation, and assessment activities;
- an outline of the composition of the project management team (i.e., the management, technical, and administrative support team including any contractors and subcontractors);
- a listing of conditions under which suspension of work will be necessary;
- an identification of necessary personnel, their needed skills, and required types of equipment;
- the results of literature searches and background information collection about the project including industries, products and wastes generated by the industries, and previous analytical results; and
- a preliminary determination of assessment tools needed such as technical reviews, audits, statistical or mathematical analyses, or engineering capability studies.

## **C1.3 Needs or Demands of the Project**

In order to effectively support successful completion of the project, this step gives attention to:

- an identification of data gaps that should be filled by the new project;
- a consideration of accompanying metadata needed for development of the conceptual model;
- a listing of procedures to handle unavoidable deviations from the Agency-approved QAPP;
- an identification of standard operating procedures for developing and implementing corrective actions;
- the identification of possible methods/procedures for characterization and disposal of contaminated sample material that may be accumulated during the project; and
- an outline of the documentation needed to adequately describe the quality of the results.

## **C1.4 Reporting Requirements Established for the Project or Investigation**

Successful projects demand good communication both during the progress of the project and in the reporting of results. The reporting step gives attention to:

- the establishment of communication and authority among the project team participants and identification of the roles and responsibilities of each member of the project team;
- an identification of project reports that will need to be prepared and the frequency of submission to management;
- a working schedule for data reporting;
- a determination of data reporting format; and
- an identification of methods/procedures for storing, retrieving, analyzing, and reporting the data produced (based on the intended use of the data).

## **C2. Design of Environmental Data and Information Collection or Acquisition**

The design process should include, but not necessarily be limited to, consideration and development of detailed plans for the collection or acquisition of data or information, the analysis or synthesis of data and information, and specific data or information reporting requirements.

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## **C2.1 Collection or Acquisition of Data or Information**

Significant attention should be devoted to designing and documenting all aspects of how the environmental data or information are collected. These considerations should include:

- documentation of the degree to which the data or information collected will be representative of the conditions established by the goals of the project;
- documentation of the sampling strategy, rationale, and necessary procedures for collecting the data or information required to achieve the desired action or result;
- documentation of the sampling design and rationale together with the linkage to the conceptual model established for this project;
- the determination of the quantity of data needed to achieve the project goals or support a decision with the desired level of confidence;
- an integration of logistical needs, costs and schedule into the preferred sampling design;
- documentation on the sample locations, sample types and number of subsamples per matrix;
- an assessment of the necessity for on-site field and laboratory assessments to be performed prior to and during project implementation; and
- the selection of field sampling or testing methodology (except where specified by statute or regulation), including specific sampling or field analytical instrumentation requirements and other analytical testing requirements.

Practical advice on how to address these considerations may be found in current guidance from the Quality Staff, including EPA 2002, EPA 2006a, and EPA 2006b, and from standard works on statistics (e.g., Gilbert 1987, Manly 2001, Ginevan & Splitstone 2003).

## **C2.2 Analysis or Synthesis of Data or Information**

After collection, data should be analyzed and information synthesized before definitive conclusions can be drawn. In planning for the analysis or synthesis of data, attention should be given to:

- the selection of analytical methods, test procedures (except where specified by statute or regulation), and their associated quality performance expectations and identification of measureable data quality or QA/QC performance criteria against which results will be compared;
- an identification of measurement data quality criteria or QA/QC requirements necessary to establish the quality of the data collected or produced;
- the selection of analytical facility (or laboratory) together with measures for verification that the laboratory not only is certified to an appropriate and applicable standard, but is competent and has demonstrated capability in performing the analyses needed;
- establishment of measurement quality objectives for specific data quality indicators such as precision, bias, representativeness, completeness, comparability, and sensitivity;
- identification of field and laboratory QA/QC requirements for sample handling, packaging, shipping, custody, and health and safety procedures;
- the integrity of data management procedures in the field and laboratory (e.g., data retrieval, security, QA and QC, storage, and retention);
- the documentation of how information will be summarized and synthesized;
- the construction of acceptance criteria for data or information obtained from external sources;
- an outline of how metadata (or ancillary information) will be used;
- documentation of proposed information privacy and integrity procedures; and
- the integrity of information management procedures in both the field and information collection centers.

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### **C2.3 Specific Data or Information Reporting Requirements**

When an external agreement requires release of data summaries or information reports, care should be given to the documentation needed to ensure the integrity, clarity, transparency, and utility of the data. Attention should be focused on:

- the determination of the levels of data or information validation and verification needed to meet project goals;
- documentation of procedures used for data or information validation and assessment;
- a summary of potential techniques for assessing limitations on data or caveats on information use;
- the data reporting deliverables and electronic data formats to be used; and
- the type of reports expected together with their frequency of submission, e.g.:
  - field sampling/information gathering report,
  - summaries of analytical data results,
  - data validation reports,
  - interim information syntheses, and
  - draft and final project reports.

### **C3. Design of Conceptual Model Development, Evaluation, and Application**

A “model” is something that can be used to make a prediction and, in the first instance, based on the conceptual model that describes the physical, chemical, scientific, engineering, or mechanism relating to the objectives of the project (see Clause C.1, Project Planning). As a conceptual model is only an approximation of a complex environmental phenomenon, attention has to be given to the documentation of conceptual model development so that the context may be understood fully. The documentation of a general conceptual model should include, as applicable:

- the requirements for qualitative and/or quantitative conceptual model corroboration;
- a consideration of the requirements for application of multiple conceptual models;
- the use of conceptual model parameters characterized from direct measurements;
- the integration of cost or schedule constraints into design;;
- the documentation of data reporting requirements and required formatting.
- a listing of the requirements for sensitivity and uncertainty analysis; and
- an outline of the requirements of documentation to ensure transparency of conceptual model development.

### **C4. Relationship of Systematic Planning to the Quality Assurance Project Plan (QAPP)**

The Quality Standard requires the use of systematic planning for any activities involving the collection, production, and uses of environmental data (Clause 7.8.1 of this Standard) and also the documentation of type, quantity, and quality of environmental data for their intended use. Systematic planning is a process based on the widely-accepted scientific method and uses a common sense approach to ensure that the level of documentation and rigor of effort in planning is commensurate with the intended use of the information and the available resources. In addition, the Quality Standard states that the “data interpretation and analysis needs, such as the use of specific statistical methods, shall be determined and specified in the design” (Clause 7.8.3), and further that the results of the design process for data collection and models shall be documented in a QAPP or equivalent document.

The elements of systematic planning include organization, project goal, schedule, data needs, criteria, data collection, QA, and analysis are outlined in Table C-1.

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**Table C-1. Elements of Systematic Planning**

<b>Elements</b>
<b>Organization:</b> Identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, customers, suppliers, and Quality Manager.
<b>Schedule:</b> Identification of project schedule, resources (including budget), milestones, regulatory or contractual requirements, and circumstances that could adversely affect the progress of the project.
<b>Project Goal:</b> Description of the project goal, objectives, study questions, and conceptual model that describes the environmental phenomenon, contamination pathways, and impact on human health.
<b>Quality Assurance (QA):</b> Specification of needed quality assurance and quality control activities to ensure performance criteria (for new data) or acceptance criteria (for existing data) are satisfied.
<b>Data Needs:</b> Identification of the type of data needed, how the data will be used to support the project's objectives, and identification of potential limitations in data interpretation.
<b>Criteria:</b> Determination of the quantity of data needed and specification of performance criteria for measuring quality for new data, or acceptance criteria for the use of existing data.
<b>Data Collection:</b> Description of how and where the data will be obtained (including existing data or data intended for secondary use) and identification of any constraints on data collection.
<b>Analysis:</b> Description of how data will be analyzed, evaluated, and assessed against its intended use with respect to the established performance or acceptance criteria.

#### **C4.1 Types of Systematic Planning**

Various government agencies and scientific disciplines have established and adopted different variations to systematic planning tailored to their specific application areas. For example, the Observational Method is a variation on systematic planning that is used by many engineering professions. However, it is the Data Quality Objectives (DQO) Process that is the most commonly used application of systematic planning in the general environmental community and is EPA's recommended systematic planning process when data are to be used for decision making (e.g., compliance with an environmental standard) or for estimation (e.g., ascertain the mean concentration level of a contaminant).

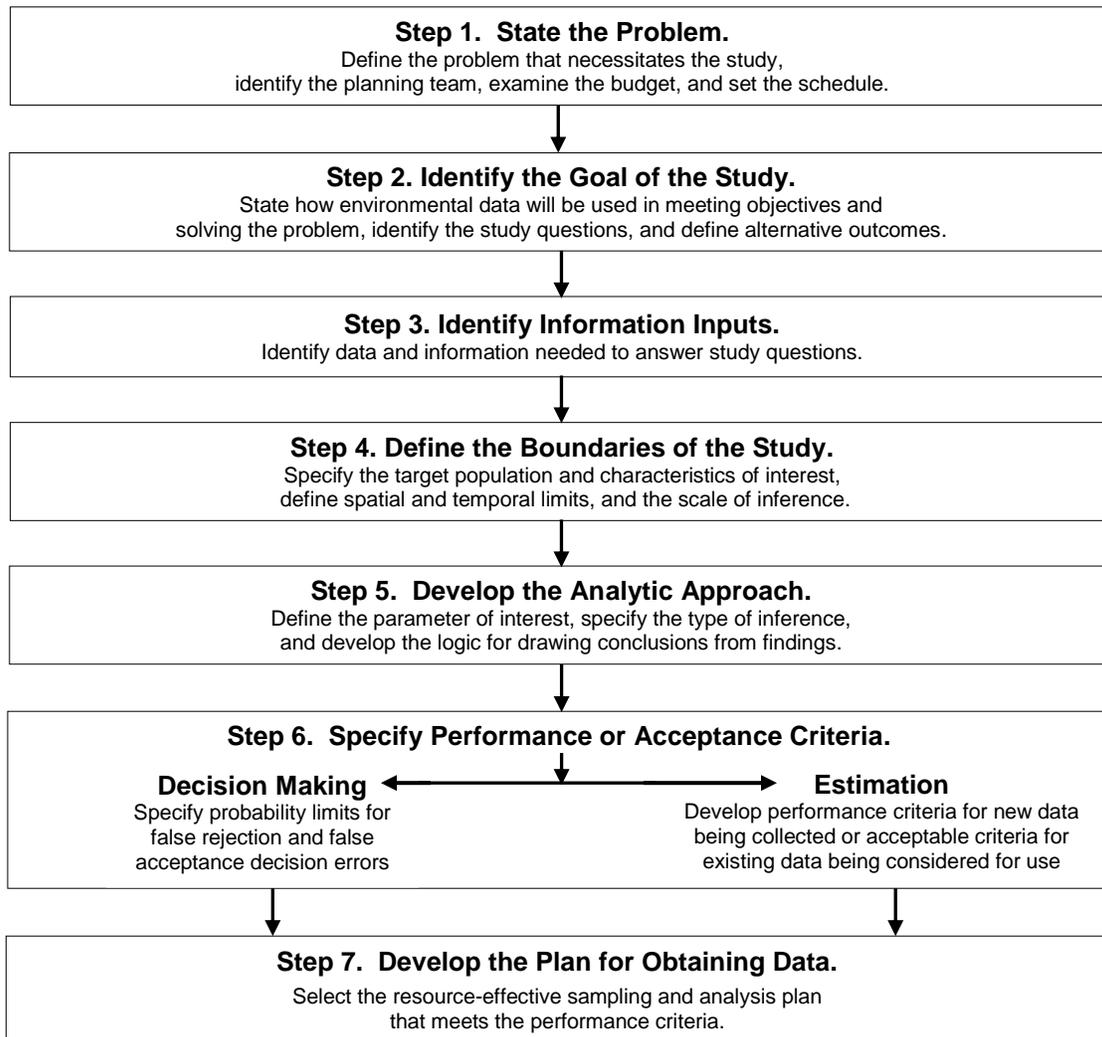
#### **C4.2 The DQO Process**

The DQO Process can be used to establish performance or acceptance criteria, which serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the goals of a study. The DQO Process may be applied to all programs involving the collection and use of environmental data and applies to programs with objectives that cover decision making, estimation, modeling in support of research studies, monitoring programs, regulation development, and compliance support activities. The DQO Process is grounded in the scientific method of hypothesis, experiment, conclusion, and has been broken into seven steps to facilitate ease of employment. The outputs of the DQO Process are used to develop a QAPP, and, after data collection, for use in data quality assessment or statistical analysis of the resulting data or information. The steps of the DQO Process are shown in Table C-2 and discussed in more detail in EPA 2006a.

The QAPP describes in comprehensive detail the necessary QA activities that must be implemented to ensure the results of the work performed satisfy the specified performance or acceptance criteria established for the project. The details of the QAPP may be assembled into convenient groups of elements to facilitate successful implantation. An example is the Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP), EPA 2005, which, although is intended for use at Federal facility hazardous waste sites primarily, draws on multiple Agency documents on QA. The elements of the UFP-QAPP are shown in Table C-3.

The planning outputs from the seven steps of the DQO Process fit into the requirements for implementation of a QAPP. The relationships among systematic planning, the DQO Process, and the elements of a UFP-QAPP are shown below in Table C-4. Several EPA organizations have accepted the UFP-QAPP as an alternative quality document to the EPA QAPP described in Annex B. The use of the UFP-QAPP or any other alternative QAPP document is subject to the approval of the EPA organization responsible for the work.

**Table C-2. The DQO Process**



**Table C-3. The Elements of a Uniform Federal Policy Quality Assurance Project Plan (UFP-QAPP)**

<b>A. Project Management and Objectives</b>	
A1 Title and Approval Page	A6 Project Quality Objectives and Measurement Performance Criteria
A2 Document Format and Table of Contents	A7 Secondary Data Evaluation
A3 Distribution List and Sign-off Sheet	A8 Project Overview and Schedule
A4 Project Organization	
A5 Project Planning/Problem Definition	
<b>B. Measurement/Data Acquisition</b>	
B1 Sampling Tasks	B4 Quality Control (QC) Samples
B2 Analytical Tasks	B5 Data Management Tasks
B3 Sample Collection Documentation	
<b>C. Assessment/Oversight</b>	
C1 Assessments and Response Actions	C3 Final Project Report
C2 QA Management Reports	
<b>D. Data Review</b>	
D1 Overview	D3 Streamline Data Review
D2 Data Review Steps (Verification/Validation)	

**Table C-4. The Relationship between Systematic Planning, the DQO Process, and a UFP-QAPP**

<b>Systematic Planning</b>	<b>DQO Process</b>	<b>Elements of a UFP-QAPP</b>
Organization	Step 1: Define the problem	A1 - A5
Schedule	Step 1: Define the problem	A4, A8, C3
Project Goal	Step 2: Identify goals Step 3: identify information needed for the study	A4, A6
Quality Assurance	Step 3: Identify information needed for the study	B2 - B6
Data Needs	Step 4: Define boundaries Step 5: Develop the analytic approach	A6, B1
Criteria	Step 6: Specify performance or acceptance criteria	A7, B1, C1, D1 - D2
Data Collection	Step 7: Develop the plan for obtaining data	A7 - A8, B1
Analysis	Step 7: Develop the plan for obtaining data	B1, A7, C1 - C2, D3

**C.5 General References**

**EPA 2002.** *Guidance on Choosing a Sampling Design for Environmental Data Collection, EPA QA/G-5S,* Office of Environmental Information, U.S. Environmental Protection Agency.

**EPA 2005.** *Uniform Federal Policy for Quality Assurance Projects Plan Manual,* Intergovernmental Data Quality Task Force, U.S. Environmental Protection Agency and U.S. Department of Defense.

**EPA 2006a.** *Guidance on Systematic Planning using the Data Quality Objectives Process, EPA QA/G-4,* Office of Environmental Information, U.S. Environmental Protection Agency.

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**EPA 2006b.** *Data Quality Assessment: Statistical Methods for Practitioners, EPA QA/G-9S*, Office of Environmental Information, U.S. Environmental Protection Agency.

**Gilbert 1987.** *Statistical Methods for Environmental Pollution Monitoring*, John Wiley, New York.

**Ginevan, Michael E. & Splitstone, Douglas E., 2003.** *Statistical Tools for Environmental Quality Measurement*, Chapman & Hall/CRC, Boca Raton, FL.

**Manly, Bryan F.J., 2001.** *Statistics for Environmental Science and Management*. Chapman & Hall/CRC, Boca Raton, FL.