Outline of
Quality Standard for Environmental Data Collection, Production, and Use
by Non-EPA (External) Organizations
(CIO 2106-S-0.2.0)

QAPP Requirements

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B3   QAPP Elements and Requirements

B3.1   Overview and General Requirements

B3.2   General Content Requirements
- Must include contributions and requirements for all parties (primary and sub-contracted);
- Statement of objectives including how work is to be performed, and by whom;
- Include methodology and procedures for field sampling, analytical laboratory and data reviewers;
- Use of SOPs and national standards or practices included in QAPP;
- QAPP must include standardized, recognizable management elements that cover the entire scope of the project from planning, implementation, validation/verification, assessment, to final reporting;
- QAPP must address different types of projects that involve environmental data, including:
  - Monitoring and use of direct measurements
  - Laboratory results
  - Use of EPA-approved quality procedures and practices
  - Collection or use of environmental data from other sources (e.g. databases, Internet, literature, etc) that were originally collected without the application of EPA-approved quality procedures and practices
  - Sampling or analytical methods development
  - Generating (or producing) environmental data from the use of mathematical or probabilistic models and computer software
- QAPP must specify the level or degree of QA and QC activities required for the particular environmental data or model operation. The QA/QC technical requirements of a project should be commensurate with:
  - The data quality objectives of the environmental data collection (e.g. enforcement action, research and development studies, etc.)
  - Type of work being performed (e.g. monitoring, site characterization, model simulation, bench level proof of concept)
  - State intended use of the results (e.g. regulatory enforcement, Total Maximum Daily Load [TMDL] development, permit approval, research publications and journal articles)

- Basic QAPP elements of the project life cycle are; Plan; Do; Check; and Act:
  - Project Management (Plan)
    - Project history
    - Project objectives
    - Technical and quality objectives
    - Roles and responsibilities of participants
    - Define the project goal and state that the participants understand the goal and approach to be used
  - Data Acquisition (Do)
    - Describe all aspects of measurement and data acquisition systems design and implementation
    - Scope of intended measurements
    - Data collection activities or acquisition methods
    - Various elements required for the project, including monitoring, acquisition from other sources, and modeling
  - Assessments (Check)
    - Assessment activities to determine the effectiveness of the project implementation and associated QA/QC activities
    - Ensure that the QAPP is properly implemented and that project actions are implemented as expected
  - Review, Evaluation of Usability, and Reporting Requirements (Act)
    - Post data collection QA activities
      - Data quality objectives assessment
      - List any limitations or restrictions on the use of the data that will have to be identified and documented
- Reference applicable information to satisfy particular QAPP elements to reduce the size of the QAPP, preparation and review time, such as:
  - Approved Work Plan(s), SOPs, model calibration reports, etc.
  - Attach all reference documents to the QAPP itself
  - QAPP must identify and describe related QA planning documentation (e.g. QMP) from subcontractors or suppliers of services critical to the technical and quality objectives of the project or task.

B3.3   Project Management
- Project description
- Include all elements that address the basic project management and objectives (refer to *Guidance on Quality Assurance Project Plans*, CIO Guidance 2106-G-05 QAPP for specifics):
  - Title, version number, and approval/sign-off sheets
  - Distribution list
  - Project organization and schedule

- o Project/problem background
- o Project/problem description
- o Project quality objectives (Data Quality Objectives) and measurement performance criteria
- o Special training requirements/certification
- o Documentation and records requirements

B3.4   Data Acquisition
- • Collection, production, and use of environmental data may include:
  - o Monitoring/direct measurements – traditional sampling and analysis activities, taxonomic observations, or testing (e.g. ecological monitoring, biological studies, etc)
  - o Collection of data from other sources – data retrieved from databases, literature, or other electronic sources (e.g. Internet) or provided by other organizations
  - o Sampling and analytical/testing methods – development of sampling or analytical methods or other testing methods (e.g. biological, ecological, GIS, etc)
  - o Development, modification, and use of mathematical and probabilistic models and other software applications (information technology products)

NOTE: 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
- • Collection of new data or information using traditional sampling and analysis activities:
  - o Sampling collection design, experimental design, and sampling tasks
  - o Sampling procedures and requirements
  - o Sample handling and custody requirements
  - o Sample collection documentation
  - o Analytical methods requirements
  - o Analytical tasks description
  - o Quality control requirements
  - o Instrument/equipment testing, inspection, and maintenance requirements
  - o Instrument calibration and frequency
  - o Inspection/acceptance requirements for supplies and consumables
  - o Data management

NOTE: Refer to *Guidance on Quality Assurance Project Plans*, CIO Guidance 2106-G-05 QAPP 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

- QAPP must address the use of environmental data of undocumented quality, other than from direct measurements:
  - o Indentify and describe the data sources
  - o Types of data required (needed) by the project
  - o Define acceptance criteria for use
  - o Limitations on the use of the data resulting from uncertainty in its quality
  - o Describe integration procedure of above data with data of known quality
- Address key elements of the review process of environmental data for potential use:
  - o Need to satisfy the major requirements of the Information Act (2002) (e.g. objectivity, utility, and integrity)
  - o Description of the data collection methodology employed
  - o Principal indicators of environmental quality (e.g. precision, bias, representativeness, comparability, completeness, and sensitivity)
  - o General usability factor (e.g. relevance, temporal compatibility, spatial inclusivity, credibility, aggregation level, compatibility, reproducibility, and degree of augmentation)
- QAPP must address aspects of measurement systems design and implementation in the project. Where applicable, the elements to be addressed include:
  - o Proposed data source sponsor
  - o Publication information
  - o Project background
  - o Description of how proposed data applies to the project
  - o Data format and accessibility
  - o Establishment of acceptance criteria
  - o Documentation of sample quality assurance procedures

  NOTE: Refer to *Guidance on Quality Assurance Project Plans*, CIO Guidance 2106-G-05 QAPP for specifics on satisfying requirements in these areas.

B3.4.3 Sampling and Analytical/Testing Methods Development

- Activities involving 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:
  - o Identify all relevant customers, and their needs and expectations, for the results of the work to be performed
  - o 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
- 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.

NOTE: Refer to *Guidance on Quality Assurance Project Plans*, CIO Guidance 2106-G-05 QAPP for specifics on satisfying requirements in these areas.

B3.4.4 Development and Use of Mathematical and Electronic Model and Other Software Applications
- QAPP must describe the development and use of mathematical and electronic models (i.e. information technology products) as well as the development of other software applications
- Use of Information Technology methods and sources must address:
  - QAPPs (Section 7.6.3)
  - General Requirements (Section 7.7.1):
    - Computer and mathematical models and other electronic methods
    - EPA-owned information systems
    - Other information systems
    - Internet
  - Computer Models, Mathematical Models, and Other Electronic Methods (Section 7.72)
  - Design of Modeling Projects (Section 7.8.4)
  - Project Documentation (Section 7.8.5)

B3.4.4.1 Quality Assurance Project Plan Requirement for Model Development/Modification
- QAPP must consider and address the development and documentation of the specifications for model development, as follows:
  - Problem Specification and Identification of Model Purpose and Scope
    - QAPP must define:
      - Objectives (i.e. what questions the model needs to answer)
      - Important functions that the software application must perform
      - Scope of the model (e.g. spatial, temporal and process detail)
      - Any boundary or initial condition specifications
      - Determination of quantitative/qualitative model performance criteria
  - Model Development or Selection Process
    - QAPP must identify and define:

- Theory used to form basis for the model, mathematical algorithms, and approaches used in model computations
- Existing software used in selection and development of a new model
- Computer hardware and operating system requirements for software application
- Assumptions, limitations, and effect on model applicability
- Procedures for controlling, documenting, and archiving all significant changes to software and hardware.
  - Data Requirements
    - QAPP must clearly define:
      - Data needs/inputs/sources
      - Data quality and quantity objectives for model input and data used for model development.
  - Evaluation of the Model
    - QAPP must define:
      - Science underlying each component the model will evaluate
      - Model testing strategies including design and code verification, individual module tests, integration tests, systems testing, acceptance testing, and beta testing (as applicable)
      - Procedure utilized for each test and process confirming test results (refer to *Guidance on the Development, Evaluation, and Application of Environmental Models*. EPA/100/K-09/003)
      - Use of uncertainty and sensitivity analysis
      - Provide requirements for project documentation (e.g. design document, source code, and user guide)

B3.4.4.2   QAPP Requirements for Model Application
- The QAPP shall include consideration and documentation of the detailed specifications for model application, indentified 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.

- o Model Application
  - The QAPP needs to define:
    - The scenarios to be simulated; and
    - How the modeling analysis and its results will be documented.
- o 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.
- o Evaluation of the Model
  - The QAPP must define:
    - The quality objectives to be used in the model evaluation;
    - The requirements for qualitative and/or quantitiative 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
- QAPP other software applications shall address and include descriptions of the:
  - o Purpose of the model or software application, including how it can be used;
  - o Technical and quality objectives;
  - o Discussion of the scientific theories that form the basis for model;
  - o Description of the inputs needed;
  - o Description of the development process, including any testing and evaluation of the model; and
  - o Description of how the model will be documented (including instruction for its use).

B3.5   Assessments
- The QAPP shall describe how the requirements specified in Clause 7.10 of the Standard will be addressed, including:
  - o Assessment, Oversight, and Response
    - General Requirements (7.10.1);
    - Objectivity, Independence, and Competence of Assessment Personnel (7.10.2);
    - Assessment Planning and Implementation (7.10.3);
    - Assessment Reporting (7.10.4);
    - Corrective Action and Verification (7.10.5);

- o QAPP elements that address the processes for assessing the effectiveness of the implementation of the project and associated QA/QC Activities:
  - Assessments and response/corrective actions;
  - Data management tasks; and
  - Reports to management.

- o Types of assessments include:
  - Technical system 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.

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

B3.6.1 Implement and Document Review, Verification and Validation, and Evaluation of Usability
- QAPP elements that address the processes for review, assessment, and verification of usability include:
  - o Review information;
  - o Verification and validation targets and methods;
  - o Peer review information;
  - o Potential limitations on interpretation;
  - o Reconciliation with user requirements; and
  - o Reports to management.

B3.6.2 Implement and Document Model Review
- Review of a model or its application shall be conducted by individuals who are independent of the work ;
- Utilize internal and external peer review, when applicable, to ensure that the model is technically adequate, competently performed, properly documented, and satisfies established quality requirements by reviewing:
  - o Assumptions, calculation, extrapolations, alternate interpretations, methodology, acceptance criteria and/or conclusions from a model or its application.
  - o The process of reviewing a model or its application shall be documented in the QAPP.