Quality Assurance Plans Made Easy Workbook

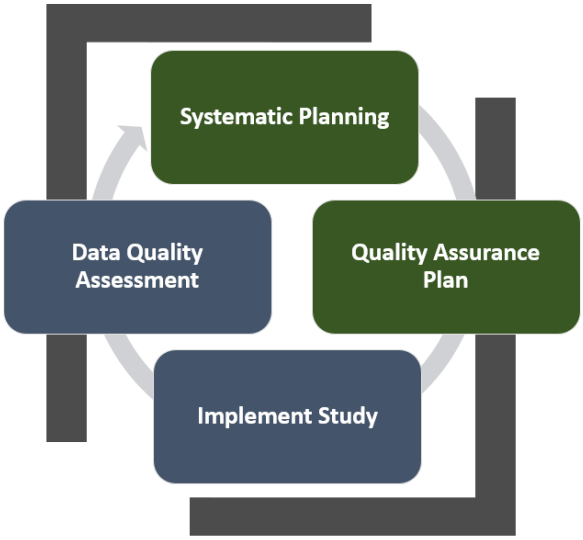
Reminder #1: The goals of developing and following a Quality Assurance Plan are to assist in the development and implementation of successful projects and communicate information about that project to others!

Reminder #2: Quality Assurance Plans should be simple, straightforward, and scalable. The plan should address the information necessary and specific to the project and its size should reflect the complexity of the project!

Reminder #3: No project is too small to benefit from the principles of project management. Setting realistic expectations and objectives, and careful planning ensures that your project can deliver the data you need!

Project Management Lifecycle– Monitoring and Data Use

1. Systematic Planning
2. Quality Assurance Plan
3. Implement the Study
4. Data Quality Assessment



Systematic Planning: Developing Data Quality Objectives

Developing Data Quality Objectives (DQOs) for a new project is essential to ensuring effective data collection and usability. EPA developed a systematic process to develop project DQOs. Through this process, project planners will be able determine how much and what quality of data is needed to support the goals of the study. It follows a series of questions that build upon each other to obtain a sufficient level of detail and comprehensiveness to design an effective monitoring project and develop a full-scale Quality Assurance Plan.

The DQO process can be further broken down into six core questions:

1. What is the project going to study?
2. How are the data going to be used?
3. What data and information are needed?
4. What are the limits of the study?
5. How will decisions be made?
6. How much error is acceptable?

This workbook will guide you through the six core questions and provide additional elements to think about while designing your project. The last two pages of this workbook is a table that crosswalks the answers to these questions to the twenty-four elements of a Quality Assurance Plan.

Step 1. What is the Project Going to Study?

The first step of the DQO process is to identify the issue the project would like to evaluate and develop a conceptual model of the issue (EPA QA/G-4).

What this means is that you should think about the problem you are trying to address and seek to understand the problem as both a single issue and how it fits into a larger context.

- State the purpose of the study or problem the study will evaluate (Problem Statement)
- Provide a brief background or context to the problem.
- Identify the Project Team. (Field Crews, Labs, Data Managers, Analysts, QA Officers, etc.)

Step 2. How are the data going to be used?

The second step of the process is to evaluate how the data from the study will be used; the goals of the study. Identify specific study questions and define alternative outcomes where possible. The project goals should explain how the data will be used to answer questions or provide more information.

- Identify the decision or information to be made from the study.
- Identify any alternative actions that may result.
- Identify the priority or priorities that the project will address.
- Describe how the project may support other activities or decisions.

Step 3. What kind(s) of Data and Information are needed?

The third step is to determine what kinds of measurements and observation will be needed to support project goals. Use the information from step one and two to answer the questions below.

For example, if a project is intended to identify if mercury is a problem in a watershed, then you should identify the water quality threshold that is appropriate for the study area and the population that is to be protected.

Tip: When selecting Reporting Limits for a study, the project should aim to select reporting limits that fall well below the needed water quality thresholds to ensure that the measurements collected are useful to the study.

- What measurements and/or observations are already available to use?
- What measurements and/or observations will need to be made?
- What assessment thresholds will be used?
- What reporting limits (RLs) are needed?
- What other information inputs could be included? (climate, pesticide use, geology, land use, etc.?)

Step 4. What are the boundaries and limits of the study?

The fourth step is to define the boundaries and limits of the study. The project should balance the information described in the previous steps to identify the spatial(location) and temporal(time) scale, and restraints of the project. Project planners will also need to consider physical and financial limits to the study, including site access, available data sets, partnerships, natural and unnatural variations in weather and land use and other fiscal and process constraints that may affect the project.

- Identify the geographical area.
- Identify the time frame.
- Identify the sampling frequency.
- Identify the practical constraints for the project (including budget, access, etc.)

Step 5. How will decisions be made?

The fifth step is to identify an existing decision-making process or design one. To design one, create “if---then” statements that link results with conclusions or future actions.

- Identify or develop a decision rule using if/then statements that includes:
    - the population parameter of interest
    - the action or threshold levels, including frequency and magnitude of occurrence
    - the scale of the decision
    - the alternative actions
    - any calculations if used

Step 6. How much error is acceptable?

In step six, you will be specifying the performance and/or acceptance criteria for use in the hypothesis test and/or decision making. For projects that involve hypothesis testing only, project planners should specify the probability limits for decision errors. For estimations and other analytic approaches project planners should identify performance criteria (for new data being collected) or acceptance criteria (for existing data being considered for use). <Workspace provided on next page>

- Identify the Measurement Quality Objectives (MQOs) for each for each analyte/measurement/observation to be made. MQOs are performance/acceptance criteria that control how much error is acceptable and are often expressed in terms of Data Quality Indicators (DQIs).
    - Sensitivity
    - Accuracy
    - Bias (Native and Non-Native)
    - Precision
    - Comparability
    - Completeness

- Determine the limits and consequences of the data not meeting the assigned Data Classification's MQOs.
- Identify Levels of Verification and Validation needed for the project based on these consequences. When should data be rejected?

Verification = Verification is determining whether an activity conforms to the stated requirements for that activity. Requirements include acceptance criteria and contract and data format requirements. This is the on-the-ground review by the project to ensure the data collected followed the plan.

Validation = Validation is determining whether the activities conform to the user needs for the overall project. This is a higher-level review for overall "usability" of the data collected; including quantified error measured, and review of the collection process from beginning to end.

Example MQO Table

Quality Control Sample	**Frequency of Analysis**	**Measurement Quality Objective**	***DQ Indicator***
Laboratory Control Sample	One per analysis batch	75-130% Recovery	Accuracy
Laboratory Replicate	One per analysis batch	< 25% Difference	Precision
Laboratory Blank	One per analysis batch	< Reporting Limit	Bias
Matrix Spike	One per analysis batch	60-140% Recovery	Bias
Field Blank	One per field event	< Reporting Limit	Bias
Field Sample Duplicate	One per field event	< 25% Difference	Precision

Step 7. Optimize the design for obtaining the data.

- Choose or create a sampling design that meets the project Data Quality Objectives, budget, and project limitations.

Build the Quality Assurance Project Plan

Take the answers and information you provided in steps one through seven and use this crosswalk guide to begin filling in your quality assurance plan.

DQO Step	QAPP Element*	Description*
Step 1	A1 Title and Approval Sheet	Title and approval sheet.
	A2 Table of Contents	
	A3 Distribution List	Distribution list for the QA Project Plan revisions and final guidance.
	A4 Project/Task Organization	Identify individuals and organizations participating in the project and discuss their roles, responsibilities and organization.
Steps 1, 2	A5 Problem Definition/Background	1) State the specific problem to be solved or the decision to be made. 2) Identify the decision maker and the principal customer for the results.
Steps 1, 2, 3, 6	A6 Project/Task Description	1) How will the data be used, 2) expected measurements,3) regulations and priorities, 4) assessment tools (technical audits), 5) work schedule and required reports.
Steps 4, 5, 6	A7 Quality Objectives and Criteria	Decision(s), population parameter of interest, action levels/thresholds, summary statistics to be used, acceptable limits on decision errors, and performance criteria. Also, scope of the project (domain or geographical locale).
Steps 3, 6, 7	A8 Special Training/ Certification	Identify special training that personnel will need.
Steps 3, 6, 7	A9 Documents and Records	Itemize the information and records that must be included in a data report package, including report format and requirements for storage, etc..
Steps 5, 7	B1 Sampling Process Design (Experimental Design)	Outline the experimental design, including sampling design and rationale, sampling frequencies, matrices, and measurement parameter of interest
Step 3,6,7	B2 Sampling Methods	Sample collection method and approach
Step 3,6,7	B3 Sample Handling and Custody	Describe the provisions for sample labeling, shipment, chain-of-custody forms, procedures for transferring and maintaining custody of samples

Steps 3,6, 7	B4 Analytical Methods	Identify analytical method(s) and equipment for the study, including method performance requirements.
Step 3, 6	B5 Quality Control	Describe quality control procedures that should be associated with each sampling and measurement technique. List required checks and corrective action procedures.
Step 3, 6	B6 Instrument/Equipment Testing, Inspection, and Maintenance	Discuss how inspection and acceptance testing, including the use of QC samples, must be performed to ensure their intended use as specified by the design.
Step 3, 6	B7 Instrument/Equipment Calibration and Frequency	Identify tools, gauges and instruments, and other sampling or measurement devices that need calibration. Describe how the calibration should be done.
Step 3	B8 Inspection/Acceptance of Supplies and Consumables	Define how and by whom the sampling supplies and other consumables will be accepted for use in the project.
Steps 1, 7	B9 Non-direct Measurements	Define the criteria for the use of data from outside the project, such as data that come from databases or literature.
Steps 3, 6, 7	B10 Data Management	Outline the data management scheme including the path and storage of the data and the data record-keeping system. Identify all data handling equipment and procedures that will be used to process, compile, and analyze the data.
Steps 6, 7	C1 Assessments and Response Actions	Describe the assessment activities needed for this project.
	C2 Reports to Management	Identify the frequency, content, and distribution of reports issued to keep management informed.
Steps 6, 7	D1 Data Review, Verification, and Validation	State the criteria used to accept or reject the data based on quality.
Steps 6, 7	D2 Verification and Validation Methods	Describe the process to be used for verifying and validating data, including the chain-of-custody for data throughout the lifetime of the project.
Data Quality Assessment	D3 Reconciliation with User Requirements	Describe how results will be evaluated to determine if the collected data support the project goals.

*A-4 EPA QA/R-5 EPA Requirements for Quality Assurance Project Plans EPA/240/B-01/003 March 2001

Resources:

EPA Citizen Science Quality Assurance Handbook
https://www.epa.gov/citizen-science/quality-assurance-handbook-and-guidance-documents-citizen-science-projects

EPA Quality Assurance Project Plan Guidance (G-5)
https://www.epa.gov/quality/guidance-quality-assurance-project-plans-epa-qag-5

EPA Quality Assurance Project Plan Development Tool
https://www.epa.gov/quality/quality-assurance-project-plan-development-tool

CA Water Boards Quality Assurance Project Plan HeldDesk
https://www.waterboards.ca.gov/water_issues/programs/quality_assurance/qapp.html

CA Water Boards Surface Water Ambient Monitoring Program (SWAMP IQ) Homepage
https://www.waterboards.ca.gov/water_issues/programs/swamp/swamp_iq/

Additional Questions? Send your questions to: OIMA-Helpdesk@waterboards.ca.gov