

Quality Assurance Plan (QAP)

Department for Environmental Protection
Environmental & Public Protection Cabinet



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Quality System Overview

- A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner.
- It provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance (QA) and quality control (QC) activities.

Quality Management Plan (QMP)

- Documents how an organization will plan, implement, and assess the effectiveness of its quality assurance and quality control operations. Specifically, it describes how an organization structures its quality system, the quality policies and procedures, areas of application, and roles, responsibilities, and authorities.

Quality Assurance Plan (QAP)

- QAP – A Quality Assurance Plan, also known as a Quality Assurance Project Plan (QAPP) documents the planning, implementation, and assessment procedures for a particular project, as well as any specific quality assurance and quality control activities.

QMP and QAP

- QMP – states the overall company policy regarding the level of data quality generated for environmental decisions / compliance
- QAP – describes how the laboratory achieves the level of quality defined in its' parent QMP

QMP vs. QAPP

- Quality Management Plans reflect activities and policies common to all projects; it may be viewed as the "umbrella" document under which individual projects are conducted.
- Quality Assurance Project Plans reflect specific projects.



QAP Requirements

The following items shall be addressed in the laboratory QAP:

1. Laboratory organization and responsibility
2. Process used to identify clients' data quality objectives (DQO);
3. SOPs with dates of last revision;
4. Field sampling procedures;

QAP Requirements Cont.

5. Laboratory sample receipt and handling procedures; including corrective action;
6. Instrument calibration procedures (may reference an SOP);
7. Analytical procedures (may reference an SOP);
8. Data reduction, validation, reporting and verification (may reference an SOP);

QAP Requirements Cont.

9. Type of quality control checks, the frequency of their use and acceptance criteria(may reference an SOP);
10. List schedules of internal and external system and data quality audits and inter-laboratory comparisons (may reference an SOP);

QAP Requirements Cont.

11. Preventive maintenance procedures and schedules;
12. Corrective action contingencies;
13. Record keeping procedures and retention policy;
14. Training.

QAP Template

- Field-only Laboratory QAP Template
- General Laboratory QAP Template
- Available on KY Website after internal review and public comment

QAP Templates

- Based on DRAFT EPA Standard for Quality Assurance Plans;
- Currently on-hold;
- EPA may make modifications based on stakeholder group feedback
- Link to EPA QAP Outline [Outline](#)

Current Quality System Tools

- *EPA Requirements for Quality Assurance Project Plans (QA/R-5);*
- *Guidance for Quality Assurance Project Plans (G-5);*
- *EPA Requirements for Quality Management Plans (QA/R-2);*
- *Guidance for Developing Quality Systems for Environmental Programs (QA/G-1);*
- http://www.epa.gov/quality/qa_docs.html.

DRAFT Quality System Tools

- EPA Quality Standard for Environmental Data Collection, Production, and Use by non-EPA (External) Organizations (CIO Standard 2106-S-02) – DRAFT
 - Replaces QA/R-2 – QMPs
 - Replaces QA/R-5 – QAPPs
- CIO Guidance 2106-G-05 QMP (Draft)
- Handbook for Developing QAPPs (Draft)

Questions?

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Specific Information

The following slides provide specific information to the reader for each of the major topics required in the Wastewater Laboratory Quality Assurance Plan.

Laboratory Organization and Responsibility

- A chart or a table showing the laboratory organization and lines of responsibility, including QA managers;
- List the key personnel who are responsible for ensuring the production of valid measurements and the routine assessment of measurement systems for precision and accuracy(e.g. who is responsible for internal audits and reviews of the implementation of the plan and its requirements);

Laboratory Organization and Responsibility

- Reference the job descriptions of the personnel and describe training to keep personnel updated on regulations and methodology, and document that laboratory personnel have demonstrated proficiency for the methods they perform(e.g. MDL Study, IDC, and ODC annually).

Laboratory Organization and Responsibility

To ensure all key project personnel are aware of their responsibilities and the timeframe for completion.

Process Used to Identify Clients' Data Quality Objectives

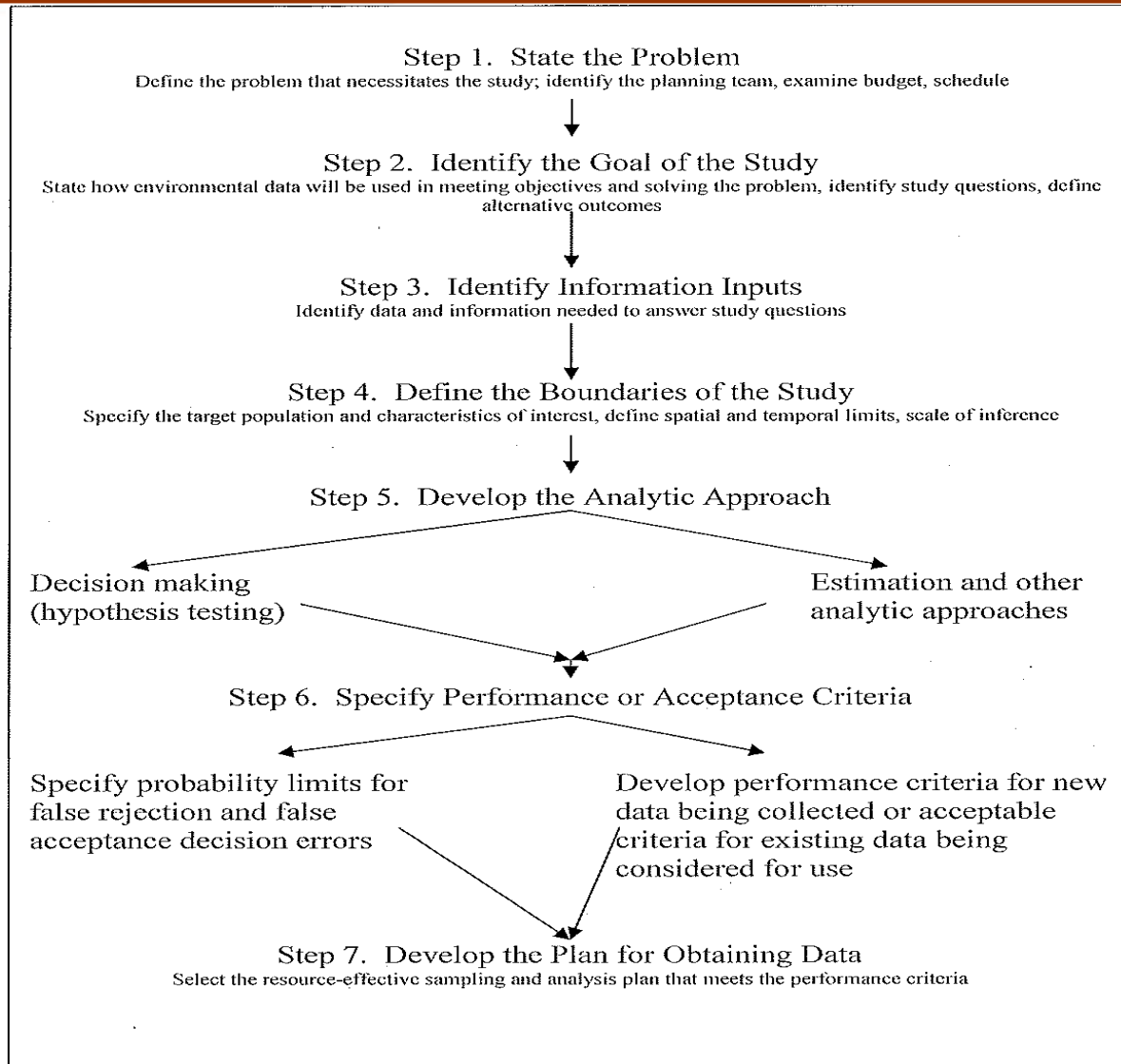
An example:

- Step 1: State the Problem
- Step 2: Identify the Decision
- Step 3: Identify the Inputs to the Decision
- Step 4: Define the Study Boundaries
- Step 5: Develop a Decision Rule
- Step 6: Specify Tolerable Limits on Decision Errors
- Step 7: Optimize the Design

Process Used to Identify Clients' Data Quality Objectives

To provide sufficient information as a foundation for the project goals and to clarify the expected uses of the data.

DQO Process



SOPs with Dates of Last Revision

- The laboratory shall maintain SOPs that accurately reflect all phases of the current laboratory activities;
- A list of SOP's and their effective dates;
- Ensure that current copies of SOPs are in the laboratory and in the QA manager files;
- Ensure that SOPs are reviewed annually and revised as changes to the procedure are made;

SOP's Cont.

- Ensure that SOPs have signature pages and revisions dates;
- Ensure that SOPs are read, understood, and utilized by all applicable laboratory personnel.

SOP's

To be sure that all personnel are doing things the same way and are following the most recent procedural updates.

Field Sampling Procedures

- Describe the process used to identify sample collectors, sampling procedures and locations, required preservative, proper containers, correct sample container cleaning procedures, sample holding times from collection to analysis, and sample shipping and storage conditions;

Field Sampling Procedures Cont.

- Ensure that appropriate forms are legibly filled out in indelible ink or hardcopies of electronic data are available;
- Ensure that sampling protocol is written and available to samplers.

Field Sampling Procedures Cont.

To ensure that appropriate sampling methods are selected to meet project needs and produce data of sufficient quality for project decision making.

Sample Receipt and Handling Procedures

- Bound laboratory notebooks shall be filled out in indelible ink, entries dated and signed (electronic records are acceptable);
- Store unprocessed and processed samples at the proper temperature, isolated from laboratory contaminants, standards and highly contaminated samples. Holding times shall not be exceeded;

Sample Receipt and Handling Procedures Cont.

- Maintain integrity of all samples (e.g. by tracking samples from receipt by laboratory through analysis to disposal – internal sample tracking document);
- Require Chain-of-Custody (COC) procedures for all samples;

Sample Receipt and Handling Procedures Cont.

- Specify criteria for rejection of samples that do not meet shipping, holding time and/or preservation requirements and procedures for notification of sample originators (client/customer or field sampling contractor);
- Describe how samples are checked when they arrive for proper containers and temperature and how samples are checked for proper preservative before analysis.

Sample Receipt and Handling Procedures

To ensure sample authenticity and to avoid sample loss.

Instrument Calibration Procedures (may reference an SOP)

- Specify type of calibration used for each method and frequency of use;
- Describe calibration standard's source, age, storage, labeling;
- Perform data comparability checks;
- Use control charts for calibration check standards to monitor for trends and ensure acceptance criteria are met or utilize acceptance criteria specified in QAP/SOP .

Instrument Calibration Procedures

To avoid poor instrument performance that could impact project data quality.

Analytical Procedures

- Cite complete method reference;
- Describe quality control procedures required by the methods that shall be followed and specify acceptance limits; include what to do if outside of the set limits.

Analytical Procedures

To be methods are being followed as written and can achieve project quality objectives.

Data Reduction, Validation, Reporting and Verification

- Describe data reduction process; method of conversion of raw data to required reporting limits;
- Describe data validation process and frequency of review;
- Describe reporting procedures; include procedures and format(s);
- Describe data verification process and frequency of review;
- Describe procedure for data corrections.

Data Reduction, Validation, Reporting and Verification

To ensure data integrity.

Type of QC Checks and the Frequency of Their Use

For Chemistry and Radiochemistry:

- Instrument performance check standards;
- Frequency and acceptability of MDL calculations;
- Frequency and acceptability of demonstration of low level capability;
- Calibration, internal and surrogate standards;
- Laboratory reagent blank, field reagent blank and trip blank;
- Field and laboratory matrix replicates;

Type of QC Checks and the Frequency of Their Use Cont.

- Quality control and Proficiency Test samples;
- Laboratory fortified blank and laboratory fortified sample matrix replicates;
- Initial demonstration of method capability;
- On-going demonstration of method capability;
- Use of control charts or acceptance criteria;
- Qualitative identification/confirmation of contaminants.

Type of QC Checks and the Frequency of Their Use Cont.

For Microbiology:

- Positive and negative culture controls;
- Confirmation/verification of presumptive total Coliform positive samples;
- Sterility controls;
- Proficiency Test samples and quality control samples.

Type of QC Checks and the Frequency of Their Use Cont.

To provide confidence that the project data are of suitable quality to be used for their intended purpose.

System and Data Quality Audits and Inter-laboratory Comparisons

- Can be internal audits by the QA Officer or external audits by a third party;
- After audits be sure to create a feedback loop to employees to let them know what deficiencies were found and how to correct them or to let them know where they are exceeding expectations.

System and Data Quality Audits and Inter-laboratory Comparisons

To directly test that the SOP's are being followed as written and that the results produced are of a known quality.

Preventive Maintenance Procedures and Schedules

- Describe location of instrument manuals and schedules and documentation of routine equipment maintenance;
- List any maintenance contracts in place;
- Describe laboratory procedure to ensure sample holding times are met (e.g. redundant instrumentation, contracts with other laboratory facilities, etc).

Preventive Maintenance Procedures and Schedules

To avoid poor instrument performance that could impact project data quality.

Corrective Action Contingencies

- Describe response to obtaining unacceptable results from analysis of PT samples and from internal QC checks;
- Position titles of individuals responsible for the various corrective actions;
- Describe how corrective actions taken are documented.

Training

To be sure that the project has qualified personnel to perform all necessary functions.

Training

- Include training procedures for new analysts or technicians;
- Describe the laboratory's policy on cross training for backup analysts.

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