



Minnesota Pollution Control Agency Quality Assurance Project Plan Guidance

Overview

The following guidance is for use in building Quality Assurance Project Plans (QAPPs) for the Minnesota Pollution Control Agency (MPCA) Remediation Programs. This guidance is **not** to be used for QAPP submittals under Federal DSMOA contracts. The guideline will save time for those who follow it, but will add time if deviated from as this will be used as the minimum requirements for QAPP submittals to the MPCA. Questions or comments about this guidance may be addressed to Bill Scruton, MPCA QA Coordinator (at 651-757-2710 or bill.scruton@state.mn.us) or Sandy McDonald, MPCA QA Coordinator (at 651-757-2560 or sandy.mcdonald@state.mn.us).

Prior to starting

Before writing the QAPP, the author must identify if a QAPP is required for the work being done. The U. S. Environmental Protection Agency (EPA) requires QAPPs any time data is being collected for use in making a decision. This normally would require a QAPP for all projects, but the MPCA does use Sampling and Analysis Plans in certain circumstances (e.g. Voluntary Investigation and Cleanup projects, small Resource Conservation Recovery Act sites, Leaking Underground Storage Tanks (LUST) site reports, etc.). If you are unsure of what type of plan is required, contact the project manager at the MPCA. The author **must** identify a laboratory (or multiple labs if required), have the laboratory QA Manual and appropriate SOPs for inclusion or reference for the QAPP. The consultant firm/author must identify the timeline for the work to be performed. If one of the major parties is changed (e.g. a new laboratory or consultant is hired) then an amendment to the QAPP must be written. The EPA and MPCA consider a QAPP to be the final word when a disagreement arises on the site dealing with anything covered by the document. Therefore, it is imperative that the document be complete and agreed to by all parties. Additionally, all parties must have a copy of the QAPP available for reference prior to and when the work is being performed (especially the laboratory and sampling crew).

Document preparation consideration

- a. A QAPP is defined by the MPCA as an agreement between the regulator, the responsible party, the consultant, the laboratory, and other interested parties concerning what work will be performed, how it will be performed, why the work is being performed, the analytical methods used, and the quality assurance/quality control that must be met for the project.
- b. The QAPP must be paginated with sections and subsections clearly marked on every page.
- c. Pages **cannot** have written notes present that are not dated and initialed in pen.
- d. Items to be removed from the document must have a single line drawn through them with the date and initials of the individual making the change clearly visible.

- e. Referencing other documents (or providing links to those documents) is allowed as long as the documents are available to be reviewed with the QAPP. The references must be **very** specific as to the section, subsection and page the information is found. References to a general policy, a SOP, or another manual without specific reference information included are not acceptable.
- f. QAPPs that reference material that is not included in the submission will not be approved.
- g. References to National Standards (such as EPA SW-846, EPA QA/G-4, ISO 17025, etc.) as SOP for a firm or laboratory are not acceptable. Specific information is required.
- h. A laboratory or firm must submit SPECIFIC information for the laboratory. Generic “corporate” information that is **not** specific to actual site work or practice will be rejected.
- i. The QAPP must be written so individuals doing work covered by the QAPP can clearly understand what is being done, why, by whom, and what the anticipated outcome of the work will be.
- j. If a section does not apply, do not skip it. List the heading and note “there is nothing to be added to this section”.

Group A: Project management elements

A1-Title page and approval sheet: Include the title of the project, the name of the firm or organization implementing the project, the revision number, the effective date of the Plan, and the names, titles, signatures, and approval dates of the signatories (the responsible organization’s project manager, the consultant firm(s) project manager, the consultant QA officer, the laboratory’s (or laboratories’) project manager and QA Officer, and the MPCA project manager’s signature. The QAPP must have all signatures to be considered complete.

A2-Table of Contents: Include the table of contents including a list of acronyms used within the document, a list of figures, tables, references, and appendices. A document control format should be instituted for the QAPP.

A3-Distribution list: Document the list of individuals who are to receive a copy of the approved QAPP and any subsequent revisions.

A4-Project and task organization: The author will clearly list who is involved and performs the work covered by the QAPP. The description of duties to be performed and names of the consultant firm Project Manager (PM) and QA officer, the responsible party representative, laboratory PM and QA Officer, hydrologist/sampling supervisor, all subcontractors, data review firms (as appropriate), and MPCA PM will be contained in this section. Identify the person responsible for maintaining the approved QAPP. Include an organization chart that shows the relationship and lines of communication of all of these individuals.

A4-Tips:

- a. Ensure you include information on who will do data review.
- b. Define who is ultimately responsible for ensuring QA on the site.
- c. Define who audits the field sampling and the laboratory.
- d. Identify who will maintain the QAPP.
- e. Define who prepares the annual/semiannual/final reports for the project

A5-Problem definition and background: This section will **clearly** define the specific problem to be solved, why the work is being done, what outcomes are to be achieved, and what has been done in the past and by whom. A reference to another report for this information is **not** acceptable. Historical information does not need to be extensive, but should hit the “high” points on what has happened and what will happen in the future on-site. Ensure that prior analytical results are discussed (e.g. state the chemicals of concern as well as analyses performed that found no contamination). Include a map of the site showing the boundaries or study area and where work will be done.

A5-Tips:

- a. Describe via a chronology what has been done on-site and by whom.
- b. Ensure all analyses performed in the past are at least mentioned and if any contamination was found.
- c. Do not reference another report for the basic background information (although detail may be referenced).
- d. Assumptions, when made, must be identified in this section (and all others of the QAPP).

A6-Project/task description: In detail, describe the work to be performed on site. Include a map showing the work planned. Describe the measurements to be made (in a table form). Specify the regulatory program the work is being done under. State the action levels the data is being compared to (for example Health Risk Limits, Applicable or Relevant and Appropriate Requirement, Health Based Values, Soil Reference Values, To Be Considered, etc.). Ensure the reporting limits from the methods selected are lower than the action levels required on-site.

A6-Tips:

- a. Ensure the laboratory can meet the minimal reporting limits on the matrix you are sampling prior to proposing a method.
- b. Do not reference guidance from programs outside of the work being performed for guidance (such as LUST Factsheets or 40 CFR 136 when performing Superfund work).
- c. Ensure the method used for analysis meets the DQOs as laid out in Section A7 (e.g. enough Quality Control (QC) in the method, sensitivity, compound list, possibility of flagging the data, need for TICS, etc.).

A7-Quality objectives and criteria for measurement data: State the data quality objectives for the site. Use EPA QA/G-4 and, in a table or text form, describe each step of the DQOs (you may use the MPCA guidance memo on DQOs as a guide found on the Question and Answers website at www.pca.state.mn.us/programs/qa_p.html). EPA recommends the use of a table laying out each step of the DQOs. The discussion of DQOs must have the concurrence of all parties involved on site. Do not attempt to develop DQOs after the work has been completed, or without input from all, or the entire process will not be effective. Define the data quality indicators for sensitivity, precision, accuracy, representativeness, comparability, and completeness. These performance criteria must be met in order for the data to be used on the project.

A7-Tips:

- a. Quality control limits used by the laboratory and also the limits used for data validation should be referenced within this section in an attached table.
- b. These control limits must be as good as or better than the data quality indicators.
- c. Give the equations for percent recovery and relative percent difference, and define how this information is used on site.
- d. Completeness is a measure of the laboratory and also of the overall limits. MPCA recommends a minimum of 90 percent completeness for both. This must be measured and reported in the annual / semiannual / final report(s). Note that rejected data or sampling points that do not yield a usable sample count against the percent completeness. Completeness is critical to measuring how well the project was managed and completed.

A8-Special training requirements and certifications: Ensure and document that all samplers will have current 40 hour OSHA training. Ensure and document that the laboratory personnel have been trained in analytical techniques and are receiving concurrent training on a yearly basis (at a minimum) on laboratory safety, right to know, emergency procedures, etc. Describe the documentation of training and identify the individual that is responsible for maintaining the training records.

A9-Documentation and records: Define how records are secured by the laboratory, the consultant, and the responsible party (as applicable). Specify where the records will be stored and document the retention schedule for the records. Ensure data is accessible and readable in all forms. Electronic/Magnetic forms of data storage must be recoverable (this has been a problem). Note that all records are to be maintained, not just the reports themselves (e.g. sampling records, laboratory raw data, extraction/digestion logs, instrument data, etc.).

Group B: Data generation and criteria

B1-Sampling process design: Define the type of sampling to be done. Define the rationale behind the sampling plan, and why specific points were chosen. Be very specific as to location, sampling frequency, matrices to be sampled, type of sampling scheme used (random, grid, etc.), and the criteria for grab vs. composite samples.

B2-Sampling method requirements: Identify the actual sampling methods (often in SOP form included in the appendices). Discuss and reference tables as appropriate for equipment needed for sampling. Include tables outlining the holding times, preservation, and volume of sample needed. Identify exactly who will be sampling and how corrective actions in the field will be handled if a sampling issue arises (e.g. a well goes dry or a sampling point can't be reached because of flooding). Ensure documentation, the chain of command for corrective actions, and notification of the MPCA is included within this section. Discuss decontamination on site for equipment and personnel (as needed).

B3-Sample handling and custody: Describe the process of custody of samples in the field, during transportation / shipping, and receipt by the laboratory. Describe how samples are packaged, how the chain of custody (required for all sampling) is zip locked within the cooler (if being shipped), taping of the cooler, and receipt at the laboratory.

B3-Tips:

- a. Reference the laboratory QA manual by section describing the procedures for custody within the laboratory (or an appropriate SOP).
- b. Ensure the description of custody maintained by the sampler is included. Example language could be; "the sample is within view of the sampler or secured within a locked area at all times until shipped or signed over to the laboratory".
- c. Ensure description of the chain of custody Chemicals of Concern (COC) form is given and an example COC is present.
- d. If legal proceedings are expected on site, include sample tag pictures and information on how they will be used.
- e. If the samples are being hand delivered, clearly state this. If the samples are being shipped, describe the shipping method and state the laboratory will keep a copy of the shipping bill for proof of custody within transit.
- f. Discuss how samples are numbered in the field. MPCA recommends that duplicates be blind to the laboratory.
- g. Discuss briefly field notebooks and what records are kept within them.

B4-Analytical methods requirements: Identify analytical methods by the EPA (or other recognized source) method number as well as the Standard Operating Procedure (SOP) number for the laboratory in a table. Identify who is responsible for corrective actions at the laboratory. Discuss the documentation and levels of review by management of corrective actions. Specify the turn-around time for the samples needed for the project. Specify any nonstandard methods being used and how these methods are validated or reviewed by the laboratory for use on the project.

B4-Tips:

- a. The SOPs can be attached to the QAPP or, if the SOPs are on file and current at the MPCA, reference these methods in a table by SOP number.
- b. Include a copy of the laboratory corrective actions report.

Ensure coordination with the laboratory for short, turn-around time analyses.

B5-Quality control requirements: Discuss frequency of spikes, duplicates, spike duplicates, blanks (field, trip, and method). Reference a table to be attached which states the limits used by the consultant in reviewing the data, as well as by the laboratory for acceptance of raw data prior to reporting (or would cause a flag/corrective action). If statistical data manipulation for QC purposes is being performed, explain the procedure in this section.

B5-Tips:

- a. There is field QC as well as laboratory QC. Specify the rate of QC samples for each set of data.
- b. In the field environment, replicate samples should be collected at a rate of 1 per 10 environmental samples and equipment/field blanks should be collected at a rate of one per day of sampling.
- c. In the laboratory, the MPCA expects a 1:10 spike rate for inorganic analyses, a 1:20 rate of matrix spike/matrix spike duplicates (MS/MSD) for organic analyses, and, for volatile analyses, a trip blank analyzed per cooler. One method blank and one laboratory control sample should be analyzed per QC batch of up to 20 samples.

- d. The outside limits used by MPCA for data review of spikes, surrogates and control samples are; 75-125 percent recovery of volatiles (except gases), 75-125 percent recovery for all metals, 30-150 percent recovery for all semivolatile compounds, and 50-150 percent for other inorganics. These are **outside** limits and should not be used as laboratory control limits in place of Shewart charts or recommended method control limits, but consultants should flag data that fails to meet these limits at a minimum.
- e. MPCA defines blank limits as having no concentration of a chemical of concern above the laboratory reporting limit, unless this compound is considered a common laboratory contaminant (e.g. methylene chloride, phthalates, etc.).
- f. Laboratory internal quality control requirements should be specified within this section. This includes laboratory programs to improve quality which would be found in the QA Manual. Examples of internal QC include: internal audits, blind check samples, data audits by their QA staff, certifications held within other states, ISO, NELAC, etc.

B6-Instrument/equipment testing, inspection, and maintenance: Describe how field and laboratory equipment is maintained, how maintenance is documented, and how the maintenance is verified / tracked. Be detailed on what information is included in maintenance logbooks. Ensure spare parts are kept on hand (or extra field equipment) to replace items that break down. Laboratories should have agreements in place with other laboratories, or branches offices of their laboratory, for massive failures of equipment.

B6-Tips:

- a. The MPCA recommends a chart of field equipment be constructed that shows all preventative maintenance done as well as corrective actions performed when problems arise.
- b. The laboratory should have a chart in the QA manual (or SOP) describing maintenance procedures for all major analytical equipment that can be referenced.

B7-Instrument calibration and frequency: The QAPP will detail the calibration of major field and laboratory equipment in general terms. This means the QAPP **will give information** on the policy of calibration for the firm and laboratory. If the laboratory does not have this information in the QA manual (for reference purposes), then it **will** appear in the QAPP. This includes calibration records, standards and traceability, frequency of calibration, and minimum number of standards used for calibration.

B7-Tips:

- a. The MPCA has established policy for instrument calibration in Guidance Document "Laboratory Quality Control and Data Policy" (p-eao2-09a - <http://www.pca.state.mn.us/index.php/view-document.html?gid=16288>).
- b. Calibration records must be tied to data for possible future reference. The laboratory and field sampling crews **must** be able to demonstrate that the original calibration will be easily tied to the data.
- c. The MPCA recommends a table be produced that lists the major instrumentation and the policy describing calibration by the laboratory.
- d. Include corrective actions for calibration failures.
- e. State within this section those calibration standards are verified for purity and concentration against other known standards prior to being used for calibration (or that more than one standard source is used in calibration/calibration verification).

B8–Requirements for supplies and consumables: State that supplies and consumables are inspected for usability and quality upon receipt by the consulting firm and laboratory. The consulting firm should note that all equipment is verified to be free of contamination prior to the commencement of sampling.

B9–Data acquisition requirements for non-direct measurements: The consulting firm shall describe how secondary data, reference data, or historical information is verified for usability. Discuss how the project is using this type of data for decision making. Any data used to make decisions that is not being directly measured by this project must be mentioned within this section along with justification for the data use.

B10–Data management: This section must describe how data is managed from sampling until storage of the data for historical purposes. Define how data is reviewed (not at the specific laboratory level, but overall) for quality. Define the equipment used by the laboratory and consultant for data handling, any manipulations that are performed, and how they are documented (e.g. modeling, calculations performed using the data, etc.), and how all of this information is recorded. Any forms used for data tracking should be included within this section.

B10-Tips:

- a. A chart tracking data from start to finish is highly recommended by the MPCA.
- b. Clearly state how data will be stored and accessed.
- c. Define who will keep the “final” report file (the state, the consulting firm, or a client?).
- d. Discuss data security.

Group C: Assessment and oversight

C1–Assessment and Response Actions: This section is used to describe all audits and assessments done upon the field sampling and laboratory. At a minimum, the consultant firm will self audit its field operations if there is more than three days of field sampling being done. If less than three days of work are being performed, include text on when the firm has been audited and how this is performed. The laboratory should provide information on their internal auditing program, when the audits are done on each section, a schedule followed for auditing, and an example of the auditing forms used. Additionally, the laboratory will include a list of states that audit the laboratory (and accreditations held). Describe how and to whom the results of the audit will be reported.

C1-Tips:

- a. State when work can be stopped by the assessor in the field or laboratory. Describe the documentation this (these) individuals will use, and how the assessment will be used for future improvement of the processes.
- b. Describe the process of corrective actions associated with a failed assessment/audit.
- c. Discuss how corrective actions are verified as effective.
- d. Be very clear on when and how audits will be done. Generalized “corporate” language is not acceptable as this function is critical to production of data of quality by both consulting firms and laboratories.
- e. Keep in mind assessments are done on records as well.
- f. Identify if external firms are auditing the data or any part of the project.

C2- Reports to management: Describe the frequency of reports to the MPCA by the consulting firm. Describe the frequency of field reports to the consulting firms' management (e.g. daily field updates, monthly status reports, etc.). Describe the expectations for analytical reports (and what will be contained within the data packet). Specify that QA will be reported as a separate section within the reports to the MPCA with information describing usability of the data, bias, results of assessments (data and field), and changes to the QAPP, major personnel changes, corrective actions performed, and any issue that may affect the decisions made on-site.

Group D: Data validation and usability

D1-Data review, validation, and verification methods: State the verification/validation processes used to ensure quality assurance from sample planning throughout sampling, sample shipping, analytical procedures, data review by the laboratory, data review or validation by the consultant to the final report.

D1-Tips:

- a. State how data are reviewed by the laboratory. This will include a peer review process.
- b. State how the consulting firm reviews the data (the laboratory data checklist used by the MPCA is appropriate for this and may be included in the appendices).
- c. State if full validation is being performed. Validation is defined by the MPCA as use of the National Functional Guidelines (or like document) which includes review of raw data, calibration, QA parameter (spikes, blanks, etc.), and all documentation surrounding the samples. Normally, federal superfund sites that have potential for litigation may require from 10-100 percent of data to be fully validated. Further note that validation cannot be performed by the same firm responsible for sampling or data processing. This should be done by a separate firm (or, if approved, a separate branch of the consultant firm).
- d. The consulting firm must reference a table that contains the requirements (as referenced earlier) for acceptance of data (e.g. minimal recoveries, etc.).
- e. The laboratory must state minimal limits applied for internal QC (e.g. spikes, duplicates, etc.).
- f. Provide examples of any forms used for data review or validation.
- g. Define flagging of data by the laboratory and the consultant.

D2-Reconciliation of the data with user requirements: Specify how the data will be reconciled with the data quality objectives as specified in Section A7. Specify how the data will be analyzed and used for planning future work. Define if limitations are set upon the data, and how this will be reported. The review should include discussion of precision, accuracy, representativeness, sensitivity, comparability, and completeness.

References:

1. "Instructions on the Preparation of a Superfund Division Quality Assurance Project Plan", Region V USEPA, Revision 0, June 2000.
2. "EPA Requirements for Quality Assurance Project Plans", EPA QA/R-5, EPA/240/B-01/003, USEPA, March 2001, Re-issued May 31, 2006.
3. "Guidance for Quality Assurance Project Plans", EPA QA/G-5, EPA/240/R-02/009, USEPA, December 2002.
4. "Guidance on Systematic Planning Using the Data Quality Objectives Process", EPA QA/G-4, EPA/240/B-06/001, USEPA, February 2006.
5. "Data Quality Objectives Memo", MPCA, July 1998.
6. "Laboratory Quality Control and Data Policy", Guidance Document p-eao2-09a, MPCA, July 2011.