

Beginner's Guide to Preparing Quality Assurance Project Plans for Environmental Projects

Part 2 Speaker Notes

Slides #1 and #2

no notes

Slide # 3

Environmental projects can range from the simple to the very diverse or complex, from monitoring the pH of a lake to determining the presence of contaminants in fish tissue at a Superfund site.

Remember that “One size” does not fit all. That means that the number of pages in the QAPP will depend on

- ✓ Significance of the environmental problem to be investigated,
- ✓ The number of different tasks you're planning

Slide #4

This section of the QAPP answers the following questions:

- Who will be involved in the project?
- What is the environmental problem?
- What is the background history of the problem?
- What questions must be answered?
- How will the data be used? What decisions will be made with the data?
- What type, quantity and quality of data are needed to support scientifically sound decisions?

Remember! If the element does not apply to your project, just state that in the QAPP and move on to the next element.

Slide #5

The purpose of the Title and Approval Page is to document that the activities planned for the project have been reviewed and approved by EPA. It also documents an internal review by the organization.

Slide #6

Other signatories can be included, for example State Program Managers. This slide may be copied and used as a template for your QAPP.

Slide #7

TOC: The table of contents allows the user to readily locate information and gives the reviewer a quick check on what QAPP elements are addressed.

Page Header information should include the revision number. Use sequential numbers if multiple revisions have been prepared, this will ensure project personnel are following the

correct version of the QAPP. Also, it provides for easy revision of pages without the need to re-number every page of a document.

Slide #8

The purpose of the distribution list is to ensure that all key project personnel and people who have outside interest in the project get a copy of the QAPP. It also identifies who should get revisions of the document. These may include: Project officer, Contractors, Laboratory Director, Field Team Leader, Volunteer Monitors, Modeler, QA Officer, Data reviewers, Subcontractor Laboratory Director and those that need to review and approve the QA Project Plan.

Don't forget to put a QAPP in the project file and to make one available to the local library.

Slide #9

The organizational chart shows the group hierarchy and reporting structure within the organization. If more than one organization is involved, include a separate chart for each organization and show connections between the groups so that you know who reports to whom for this study.

The chart should indicate that the person who is responsible for checking the quality of the data will be separate from those who generate the data. In other words, the QA person should be independent enough from other groups to ensure that they can make objective determinations on quality assurance issues. However, for small projects personnel may fill multiple roles, including the QA responsibility. In this case, identify who will fulfill the QA role and what they will do.

Communication is the key to a successful project. The bigger the project, the more important this is. Communication starts with good planning meetings and continues throughout the project.

You need to think about which activities are potentially problematic and may require coordination. Decide up front who will be responsible for dealing with certain issues. For example, if you're planning wet weather sampling, who will be responsible for making the "go" or "no go" sampling decisions. Or, who will deal with analytical problems raised by the laboratory, e.g., broken sample containers, lost samples.

Slide #10

The purpose of this section is to describe the reason for the data collection activity. The environmental problem should already have been discussed during planning meetings that were held to develop the grant application. Therefore, the environmental problem and background may already be documented in the grant application or in a work plan. If so, include the grant application or work plan with the QAPP.

It is recommended that notes be taken at all meetings to record any agreed upon project actions or changes to previously planned activities.

Slide #11

It is very important to identify who will be using the data and for what purpose. The final report

that you write for the data users should provide data that will meet their needs. For example, if they will use data to determine whether water criteria standards have been exceeded, then you will need to provide those criteria in the final report and compare the collected data to those criteria.

Slide #12

This element of the QAPP provides an overview of the project for the reader. It summarizes the tasks that will be performed. This information will be detailed later in the plan.

This element also defines the limits of the project. Since you can't study every matrix and every type of contaminant on your fixed budget, it's important to define up-front what you will study and what you won't; the boundaries of your project.

In developing the timeline, sometimes it helps to work backwards. In other words, calculate backwards from when the final report is due. Don't forget to figure in laboratory turn-around-times and the amount of time it will take to review the data and write the final report. Also, consider seasonal impacts on sampling (snow, frozen lakes, etc.). It is also critical to consider the amount of time it will take review and approve the QAPP. Remember the QAPP needs to be sent to the EPA QA Unit at least 30 days in advance of sampling.

Note: Grants usually require that a final report be delivered to EPA within 90 days of the completion period of the grant.

Slide #13

During the initial planning, you should determine how "good" your data need to be to characterize the environmental conditions of your study.

Generally, the major quality objective for your project will be to collect representative data; data that truly reflect the conditions of the area you are sampling. It's important to recognize that "variability" is a natural phenomenon that affects your ability to collect representative data. Representativeness is affected by both natural (inherent environmental) and measurement (sampling, analytical, and data reduction) "variability". The quality control activities and data quality indicators (precision, accuracy, comparability, completeness and sensitivity) are designed to determine the degree of that "variability" that you've achieved.

Only after you've decided how good (accurate, precise, sensitive) your data need to be can you choose appropriate sampling and analytical procedures and quantitation limits for your project.

Additional information may be obtained in EPA's national guidance:

Guidance for the Data Quality Objectives Process, EPA QA/ G-4

website: <http://www.epa.gov/quality/qs-docs/g4-final.pdf>

Slide #14

Your goals for precision and accuracy can be presented in table format. It is often helpful to refer to standard methods used in your program to develop general limits for precision and accuracy.

Also, review the quantitation limits (reporting limits) that the laboratory can achieve for the methods you will be using to make sure the lab can achieve the sensitivity you need.

Slide #15

Certain projects require personnel to be specially trained or experienced. For example, electro-shock fishing, trace metal sampling (clean hands/dirty hands technique), analytical field screening techniques. If your project needs special expertise to perform project tasks, then these should be described in this section.

Don't forget to include volunteer monitors and the training they've received.

Slide #16

Note the difference between records and documents:

- a) Records cannot be revised once written, e.g., field notes
- b) Documents can be revised, e.g., QAPPs, SOPs

The purpose of this element is to describe the documents and records that will be generated for the project and how they will be retained. For some projects, where results and conclusions may be challenged (e.g., TMDLs), raw data records and documents should be retained for a specified length of time.

Slide #17

The elements in this group answer the following questions:

- What is the sampling design and the rationale behind it?
- What sample collection methods will be used and what quality control will be used to assure that representative samples are collected?
- What measurement procedures, field techniques and laboratories will be used and what quality control will be used to assure accurate, precise and sensitive data are collected?
- How will sample data be managed?
- Will secondary data (previously collected data) also be used?

Slide #18

This element should describe how you plan to collect representative samples. Statistical sampling designs can be used to help ensure representative samples are collected. However, statistically based sampling designs may be beyond the extent of the project.

For guidance on selecting the appropriate design refer to:

Guidance for Choosing a Sampling Design for Environmental Data Collection, EPA QA/G-5S
Website: <http://www.epa.gov/quality/qs-docs/g5s-final.pdf>

When sampling locations or choice of environmental parameters cannot be predetermined, then describe the logic that will be used in the field to make those decisions.

Create a table that includes:

- sample matrix
- environmental parameter
- sampling collection method
- analytical method reference

- number of field samples
- type and number of field QC samples for each matrix and parameter

Slide #19

Judgmental sampling is a non-statistical approach for selecting sampling locations. Non-statistical approaches are useful in characterizing a relatively homogenous or small population and in finding average values over time. Generally, it is used when budgets limit the number of sampling locations and analyses that can be conducted for a project. Although there is a large degree of bias associated with judgmental sampling and the inference to the total population is questionable, judgmental samples can provide useful information when sample locations are chosen based on prior history, visual assessment, and/or technical judgment.

- **Statistical sampling/grid sampling** is a probability-based approach to selecting sample locations. It's useful in locating areas of contamination at a study site. It provides a uniform coverage of the area and is the best design for locating "hot spots" when you don't know much about a potential problem area. It's used to calculate estimates of uncertainty which directly reflect the representativeness of the project data. Generally, a larger number of samples are collected and data are more representative of the sampling area than when a judgmental sampling approach is used.

Slide #20

Each sampling procedure should describe in detail each step of the procedure, the equipment, materials and supplies, sample preservation techniques, sample holding times, decontamination procedures and disposal of decontamination by-products, sample containers and volumes, quality control acceptance limits and corrective actions that will be used when limits are exceeded.

If written SOPs are used, create a table listing all field sampling SOPs that will be used.

Include:

- Title of SOP
- Date
- Revision number
- Organization that wrote the SOP

Provide another table that includes:

- Parameter
- sample container
- sample volume
- preservation
- holding times for each parameter and matrix.

Describe any modifications to the SOPs that are necessary for your project. Also, if there are any method or equipment options within the SOP, indicate which ones will be used. Indicate how these modifications and option choices will be relayed to the samplers.

Slide #21

Refer to *Guidance for Preparing Standard Operating Procedures (SOPs)*, EPA QA-G/6

Website: <http://www.epa.gov/quality/qs-docs/g6-final.pdf>

In general, SOPs should include the following sections:

- Title and Approval Page/Table of Contents
- Scope and Applicability (purpose of procedure)
- Summary of Procedure
- Definitions
- Health and Safety/Cautions/Interferences
- Personnel Qualifications
- Equipment, materials and supplies (sample containers)
- Sample Collection (Sequential steps and sample volumes)
- Sample Handling, Preservation and Holding Times (shipment, chain-of-custody)
- Sample Analysis (detailed steps including sample preparation)
- Troubleshooting
- Decontamination procedures for both sampling and analysis and disposal of decontamination by-products
- Data Records and Management (field notes, calculations and data sheets)
- QA/QC including QC acceptance limits and corrective actions that will be used when limits are exceeded.
- References

Slide #22

This element describes how you will maintain sample integrity and authenticity (samples won't get corrupted or mixed up). Indicate how samples will be handled, transported, and then held in the laboratory. For example: "Sample bottles will be placed in a plastic bag; samples will be placed in cooler with ice; C-O-C records will be completed and taped to the inside of the cooler lid; container lid to be taped shut with tamper-proof seals; containers to reach shipper by (time) as facility closes at (time)'clock".

Identify who is responsible for each step.

If chain-of-custody is specified for legal purposes, this is where you will discuss the means by which you will be able to trace the possession and handling of a sample from time of collection through analysis.

Slide #23

This element identifies the analytical methods that will be used in the field and in the laboratory. These methods need to be sensitive enough to characterize the environmental conditions. If your project involves making a decision related to a specific regulatory limit or water quality criteria, the analytical methods should be sensitive enough to reach these limits, in other words the quantitation limits (reporting limits) of the method should be low enough to accurately report the substance at a specific concentration.

If the method includes different options for sample preparation or analysis, make sure you identify the option chosen. Also, include any modifications to the procedures that will be used (such as increased sample size)

Standard EPA methods should just be referenced. Remember to include the revision number and/or date. They don't need to be included as attachments. However, organization-specific SOPs should be included as attachments to the QAPP. If SOPs are available on a website, they may be referenced, and the website embedded in the QAPP.

When identifying analytical methods, include any sub-sampling, preparation or extraction methods.

If your data will be compared to previously collected data, you may want to consider using the same analytical methods that were used for the other study.

Slide #24

This element should list all the QC checks you are going to perform to characterize the quality of the data. QC activities do not eliminate or minimize errors, but assist in measuring or estimating their effects.

In many cases, the fieldwork contributes more potential variability than does the laboratory, though it is very hard to measure.

Slide #25

Most analytical method/procedures identify the QC activities and QC samples that should be analyzed with the field samples.

Performance Evaluation Samples (PESs), also call Standard Reference Materials (SRMs), are a good check on laboratory performance. A PES is a sample that mimics actual field samples in all possible aspects, except that its composition is unknown to the laboratory. PESs are provided to test whether a measurement system can produce analytical results within specified acceptance limits. If the laboratory fails to properly detect and/or accurately quantitate the concentrations in the PES, then the associated sample results are suspect.

Slide #26

The answers to these questions should be addressed in the discussion of how you will review and qualify your data. For example, if the calibration check was not acceptable, will you estimate the sample results associated with the calibration. Will you apply a flag to the data, such as a "J" flag?

Remember: QC data are only worthwhile generating if they are used to review and evaluate your data!

Slide #27

The information in this element should describe how you will keep instruments and equipment properly operational during the project.

Examples of equipment that need periodic inspection and maintenance include: autoclaves, pumps, side-scan sonar, boats, etc.

Examples of instrumentation that need calibration include: Field analytical instrumentation: DO probes, pH meters, VOC sniffers, laboratory analytical instrumentation; gas chromatographs, GC/MS

Slide #28

This element identifies all critical supplies. Examples of supplies include: sample bottles, photographic film; test organisms for toxicity testing; chemical standards.

Slide #29

Previously collected data are frequently used in projects. In fact, many modeling projects use secondary data exclusively for developing models. QAPPs still need to be developed for these projects because it's necessary to establish the quality of the data used in developing models. Sources of previously collected data that may be used should be identified and discussed here, such as photographs, topographical maps, meteorological data (air dispersion information), publications, background information from facility or state files, etc.

Slide #30

The information contained in this element describes managing project data, for example, data reduction (converting peak heights to concentrations), transformation (wet weight to dry weight) and reported. It also describes procedures for maintaining data so that they will not be lost or corrupted. Data can be lost during data reduction, data reporting, and data entry onto forms, reports, databases, and even in storage. Indicate how computerized information will be maintained and stored. Any forms or checklists to be used can be attached.

Slide #31

The elements in this group answer the following questions:

- How will you check to make sure that the project is being conducted as described in the QAPP. For example:
 - are field personnel collecting samples at the correct locations?
 - is the laboratory generating accurate data?
- What interim and final reports will be generated?

Assessment findings should be documented in a report with recommendations for corrective actions, if applicable.

Slide #32

For additional information refer to:

Guidance on Technical Audits and Related Assessments, EPA QA/G-7

Website: <http://www.epa.gov/quality/qs-docs/g7-final.pdf>

There are many different types of assessments:. (If you need assistance in designing an assessment to best meet your needs, you may call Ann Jefferies (617.918.8373) or Nora Conlon (617.918.8335) of the QA Unit for guidance.)

Readiness Reviews – these are conducted before the start of specific tasks to determine that personnel, equipment and procedures are in place (i.e., ready to proceed with the project).

Technical Systems Assessments (TSAs) – a thorough on-site review to document the degree to which personnel, equipment, and procedures are being implemented as approved in the Plan, either in the field or laboratory.

Surveillance – to assess conformance of one particular aspect of an ongoing project with

detailed specifications and/or procedures (may be part of a TSA). May be done continuously or periodically.

Performance Evaluation Samples (PESS) – tests the ability of the laboratory to obtain acceptable results. The composition of the PE sample is unknown to the analyst but known to the project manager.

Slide #33

The QAPP should clearly state the type of information that will be included in the final project report. Definitive statements on the usability of the data should always be included.

Slide #34

This element describes how the data will be evaluated to determine whether they can be used to address project objectives. This group of elements answers the following questions:

- How will you check that individual data collection tasks were completed correctly?
- How will you determine that individual sample results are acceptable or unacceptable based on QC data? How will you determine that there are limitations on the use of a data set?
- How will you assess the entire set of project data to determine whether the data are “good” enough to use in making project decisions and conclusions?

Slide #35

Attach any forms and checklists used to perform completeness checks. For example, is there a procedure to check that the samples were correctly preserved? Is there a procedure to check that laboratory data packages are complete (contain all required information)?

Laboratories generally apply flags to reported sample results that do not meet Lab QC limits. For example, if a lab contaminant is present in a method blank, that contaminant would be flagged on the sample report form.

Other items to check include:

- incubation temperatures
- media preparation
- sample holding times

Slide #36

Validation is a review of sample results by an individual who is independent of the generation of the data. That means that the laboratory reporting the data wouldn't perform data validation. Instead (as discussed in the previous slide), the laboratory generally performs an internal verification (QC check) of the data that it generates.

Data validators use mathematical and/or statistical procedures to review measurement data and generate Data Validation Reports to describe the acceptability of the data.

The *EPA New England Functional Guidelines for Evaluating Environmental Analyses* may be used and referenced in this section.

Website: <http://epa.gov/ne/oeme/index.html>

Slide #37

This element describes how you intend to objectively decide whether the data you collected are good enough for the data user to use.

For additional guidance in data usability assessment refer to:

Guidance for Data Quality Assessment, Practical Methods for Data Analysis, EPA QA/G-9

Website: <http://www.epa.gov/quality/qs-docs/g9-final.pdf>

Note that if the project was not based on a statistical sampling design, analysis and inference may be limited to simple descriptions of data quality.

Slide #38

no notes

Slide #39

It is essential that all personnel involved in the project are informed of all changes to the QAPP.

Slide #40

It is very important to keep the QA Project Plan current and to account for any project developments or information that become known after the start of the project. At a minimum, you can expect personnel changes to have occurred.

The same is true of Standard Operating Procedures used on the project.

Slide #41

no notes