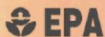


United States
Environmental Protection
Agency

Risk Reduction
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Research and Development

WPA/600/9-89/087 Oct. 1989



*P*reparing
*P*erfect
*P*roject
*P*lans

*A Pocket Guide
for the Preparation of
Quality Assurance Project Plans*



INTRODUCTION

This POCKET GUIDE will help you prepare Quality Assurance (QA) Project Plans thoroughly and easily. It summarizes guidance found in *Preparation Aids for the Development of RREL Quality Assurance Project Plans*, U.S. EPA, Risk Reduction Engineering Laboratory, Cincinnati, Ohio 45268, October 20, 1989. This title is shortened to *Preparation Aids...* in the Pocket Guide.

RREL utilizes a four-tiered project category approach in its QA Program in order to more effectively focus QA. Category I involves the most stringent QA Approach, whereas Category IV represents the least stringent. The RREL Technical Project Manager is responsible for assigning the category that accurately reflects the intended use of the data and the type of work being done. Specific details regarding the category levels can be found in the "Table of Contents."

Because requirements for QA Project Plans depend on the project category, the Pocket Guide has a separate section for each category. Each section contains short summaries of all topics required for your QA Project Plan. At the bottom of each page is a reference to a specific section in *Preparation Aids...* where you can find more detailed information.

Using the Pocket Guide is a simple four-step process:

1. Turn to the appropriate category (I, II, III, or IV) for your project.
2. Read the summaries of each of the topics required for that category.
3. Consult *Preparation Aids...* for additional information, if needed.
4. Then prepare your QA Project Plan, confident that you will include everything needed to ensure that your measurement program meets the data quality objectives for your project.

DISCLAIMER

This material has been funded by the United States Environmental Protection Agency. Although it has been subject to the Agency's review, and has been approved for publication as an EPA document, it does not necessarily reflect EPA policy.

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CATEGORY I PROJECTS are those producing results that are autonomous. These projects are of sufficient scope and substance that their results could be used directly, without additional support, for compliance or other litigation. Such projects are of critical importance to Agency goals and must be able to withstand legal challenge. Accordingly, the quality assurance requirements will be the most rigorous and detailed in order to ensure that such goals are met.

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CATEGORY II PROJECTS are those producing results that complement other inputs. These projects are of sufficient scope and substance that their results could be combined with the results of other projects of similar scope to produce narratives that would be used for rulemaking, regulation making, or policy making. In addition, projects that do not fit this pattern, but have high visibility, would also be included in this category.

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PROJECT DESCRIPTION

Q. *How detailed should the description be?*

A. A technical person unfamiliar with your project must be able to understand what you've written.

Be sure to include:

- General overview
 - Statement of the decision to be made or the question to be answered
 - Purpose of the study in quantitative terms
 - Description of the site, facility, process, or operating parameters to be studied
 - Actual uses of the results
 - Consequences of incorrect decisions or conclusions based on these results

- Experimental design features
 - List of all measurements, differentiating the critical measurements (i.e., process and analytical measurements essential to achieving project objectives) from the non-critical measurements
 - Description of that portion of the environment or physical system to which decisions or conclusions will be applied
 - Summary table covering the following for each sampling location:
 - Total number of samples (including primary, quality control, and reserve)
 - Type of sample (air, water, soil, etc.)
 - All measurements planned for each sample

- Project start-up and ending dates, including preliminary studies and field and laboratory activities

For more information, see
"Preparation Aids...", Category I, Section 1.0

Category I

PROJECT ORGANIZATION AND RESPONSIBILITIES

Q. What's the most important thing to do here?

A. Name all key individuals in charge of every major activity in your project. This applies to your subcontractors, too.

Also include:

- A detailed organizational chart showing management structure and lines of communication
- Telephone numbers to facilitate communication between project officials
- Both technical and QA/QC functions
- An independent QA coordinator
- Geographical locations of contractors and subcontractors
- Procedures for monitoring subcontractors
- Description of type, frequency, and mechanisms of communication between contractor and subcontractors, and among subcontractors
- Description of type, frequency, and mechanisms of communication among the contractor, the contractor's project quality assurance officer, and the EPA project officer
- Descriptions of the relevant certifications held by the responsible samplers, sample custodians, and analysts, and by the prime contractor and subcontractor organizations for the performance of their respective tasks

For more information, see
"Preparation Aids...", Category I, Section 2.0

QUALITY ASSURANCE OBJECTIVES

- Q. What's the most common reason for a QA Project Plan getting a NOT APPROVED rating?**
- A. Inadequate treatment of QA objectives. These QA objectives must be defined in terms of project requirements, not in terms of the capabilities of the test methods used. Project requirements, in turn, must be defined in terms of the Data Quality Objectives (DQOs) developed specifically for the project during the early stages of project planning. When defined in this way, QA objectives should not only be attainable by the chosen methods of sampling, sample preparation, and analysis, but, more important they should be indicative of the minimum quality of data project management requires to draw valid conclusions regarding the objectives of the test program and to support specific decisions or regulatory actions.**

Make sure you cover the following for each critical measurement and each matrix:

- **Summary table of quantitative QA objectives**
 - Method detection limit
 - Precision, both within and between samples
 - Accuracy
 - Completeness (as required to achieve a specific statistical level of confidence)
- **Discussion of qualitative QA objectives**
 - Representativeness
 - Comparability
 - Others, as applicable
- **Discussion of how not meeting the QA objectives will affect decision making and litigious actions**
- **Discussion of how data quality indicators will affect the legal defensibility of the data**

For more information, see
"Preparation Aids...", Category I, Section 3.0

SITE SELECTION AND SAMPLING PROCEDURES

Q. How important is this section?

A. Very important, because collecting representative samples in both time and space is crucial to subsequent decision making and legal defensibility of the data. Obtaining good analytical results on non-representative samples is dangerous because such results could lead to incorrect decisions and/or invalidate the use of the data for support of regulatory actions.

The selection of appropriate sampling sites and sampling strategies is predicated upon the Data Quality Objectives (DQOs) developed specifically for the project during the early stages of project planning. As a result, the appropriate sampling strategy will be one that ensures attainment of the quality of data required by the project management to draw valid conclusions regarding the objectives of the test program and to support specific decisions or regulatory actions.

Your QA Project Plan must describe the following:

- Sampling site selection
 - Scientific and regulatory objectives for sampling, including analyte concentrations of interest
 - Statistical method or scientific rationale for choosing sampling sites and sampling frequencies
 - Extent to which the site selection will affect the validity of the resulting data and the project objectives

- Sampling site description
 - Chart, map, etc., showing sampling sites
 - Site-specific factors affecting sampling
 - Critical process measurements

(Continued)

<p>For more information, see "Preparation Aids...", Category I, Section 4.0</p>

Category I

SITE SELECTION AND SAMPLING PROCEDURES (Cont.)

- Sampling procedures
 - List of analytes and sample volumes to be collected
 - Sampling methods (composite, grab, etc.)
 - EPA-approved or other validated standard methods—cite by reference
 - Non-standard or modified methods—describe fully
 - Preparation and cleaning of sampling equipment, containers, reagents, and supplies
 - Calibration of equipment
 - Preservation, transportation, and storage
 - Holding times of samples, before and after extraction, as applicable
 - Whenever possible, include standard operating procedures (SOPs) to fulfill the above requirements.

For more information, see
"Preparation Aids...", Category I, Section 4.0

Category I

SAMPLE CUSTODY

Q. Is a separate section on Sample Custody really necessary?

A. Yes. A complete description of all custody procedures, forms, documentation, and personnel responsibilities is needed to ensure both the scientific credibility and the legal defensibility of data obtained for all project samples.

You should include a SOP discussing the following topics:

- **Field operations**
 - Names of field sample custodians
 - Records of sample acquisition data, including location, time, sample size, and other pertinent parameters
 - Records of sample preservation methods
 - Documentation of procedures for preparing sampling media and reagents
 - Examples of sample labels, custody seals, and field sample tracking forms
 - Record of field chain-of-custody
 - Documentation of procedures for transporting samples from field to laboratory, including identification of the individuals or organizations responsible for transport

- **Laboratory operations (specify for each laboratory facility, including subcontractor facilities)**
 - Names of laboratory sample custodians
 - Forms for laboratory sample tracking
 - Records of laboratory chain-of-custody
 - Specification of procedures for sample handling, storage, and final disposition
 - Documentation of procedures for disbursement and transfer of samples within the laboratory and between contractor and subcontractor laboratories

For more information, see
"Preparation Aids...", Category I, Section 5.0

Category I

CALIBRATION PROCEDURES AND FREQUENCY

- Q. What important information should this section include?*
- A.* Descriptions of the calibration procedures and frequency of calibration for each analytical system, instrument, device, or technique used to obtain critical measurement data.

Be sure to include the following for each critical measurement and each method:

(Note: Use a summary table whenever possible.)

- Calibration procedures
 - Reference EPA-approved or other validated, standard methods.
 - Describe non-standard or modified methods fully.
 - Append Instrument-specific calibration SOPs as needed to support the use of non-standard or modified methods, or methods that do not include detailed calibration procedures.
 - List standards, including source, traceability, and purity checks.
 - Describe frequency of initial and continuing calibration checks.
 - Define specific acceptance criteria for all calibration measurements.

For more information, see
"Preparation Aids...", Category I, Section 6.0

Category I

ANALYTICAL PROCEDURES

Q. What factors are critical in selecting analytical methods?

A. The methods must be appropriate for all analytes in the specific matrix at the anticipated concentrations. They require extensive validation to show that they meet your QA objectives.

Include the following in your QA Project Plan:

(Note: Use a summary table whenever possible.)

- EPA-approved or other validated standard methods
 - Reference sample preparation and analysis methods for both critical and non-critical measurements for all matrices.
 - Cite by reference if method validation data are appropriate for your critical measurements.
 - Describe your data validation plans for all critical measurements if existing validation data are inappropriate.
 - List independent, validated, confirmatory analytical methods for each critical measurement for which a multi-method confirmatory approach is applicable.
- Non-standard or modified methods
 - Include sample preparation and analysis methods for both critical and non-critical measurements for all matrices.
 - Append pertinent method validation data for critical measurements, if available.
 - Describe plans for conducting preliminary method validation studies as project subtasks if pertinent validation data are not available.
 - Whenever possible, include detailed SOPs to fulfill the above requirements.

~REMEMBER~

Only validated methods should be used for Category I Projects.

<p>For more information, see "Preparation Aids...", Category I, Section 7.0</p>

Category I

DATA REDUCTION, VALIDATION, AND REPORTING

Q. What's the main purpose of this section?

A. You want to collect good data. This section shows how you plan to maintain good data quality throughout data reduction, transfer, storage, retrieval, and reporting.

Here are topics to discuss:

- Data reduction
 - Names of individuals responsible
 - Summary of data reduction procedures
 - Summary of statistical approach for reducing data, including units and definitions of terms
 - Examples of data sheets
 - Description of how results on blanks will be treated in the calculations
 - Presentation of all calculations and significant underlying assumptions

- Data validation
 - Names of individuals responsible
 - Procedures for determining outliers and flagging data
 - Identification of critical control points

- Data reporting
 - Names of individuals responsible
 - Flowchart of the data handling process, covering all data collection, transfer, storage, recovery, and processing steps, and including QC data for both field and laboratory
 - Identification of critical control points

For more information, see
"Preparation Aids...", Category I, Section 8.0

Category I

INTERNAL QUALITY CONTROL CHECKS

Q. What determines which QC checks are needed?

A. The QA objectives for your project and the anticipated uses of your results. QC checks apply to both field and laboratory activities. List the type and number of QC checks, including acceptance criteria.

Here are some QC checks to consider:

(Note: Use a summary table whenever possible.)

- Samples*
 - Collocated, split, replicate
- Spikes*
 - Matrix spikes and matrix spike duplicates
 - Spiked blanks
 - Surrogates and internal standards
- Others
 - Standard reference materials
 - Blanks (field, trip, method, reagent, instrument)
 - Zero and span gases
 - Mass tuning for mass spectral analyses
 - Confirmation with second column for gas chromatographic analyses
 - Control charts
 - Calibration standards
 - Proficiency testing of analysts
 - Independent, multi-method analyses for confirmation of analytical results
 - Independent, multi-laboratory analyses
 - Any additional checks required by the special needs of your project

***Identify all stages in the sampling and analytical process where the QC activity will occur.**

<p>For more information, see "Preparation Aids...", Category I, Section 9.0</p>

Category I

PERFORMANCE AND SYSTEMS AUDITS

Q. What information is most important here?

A. A schedule of all planned performance evaluation audits and technical systems audits.

Be sure to include:

- Schedule of all contractor- and EPA-planned audits
- Personnel responsible for audits
- Explanation if no audits are planned
- Schedule for any interlaboratory performance evaluation studies

For more information, see
"Preparation Aids...", Category I, Section 10.0

Category I

PREVENTIVE MAINTENANCE

- Q. What information needs to be included here?*
- A. A brief description of the types of preventive maintenance needed for adhering to project schedules and for achieving completeness objectives.*

Here's what to include:

(Note: These may be conveniently presented in a table)

- A schedule of important preventive maintenance tasks for critical measurement systems
- A list of critical spare parts
- Reference to current maintenance contracts and standard maintenance procedures for critical measurement systems

For more information, see
"Preparation Aids....," Category I, Section 11.0

Category I

CALCULATION OF DATA QUALITY INDICATORS

Q. *What tells me if my data quality is "good enough"?*

A. Detailed planning of data assessment procedures as summarized here, including statistical treatment planned, equations, units, and assessment frequency. Make sure everything agrees with the QA objectives. You and other data users can then make the needed comparisons.

Here's how to calculate your results:

- Precision

If calculated from duplicate measurements:

$$RPD = \frac{(C_1 - C_2) \times 100\%}{(C_1 + C_2) / 2}$$

RPD = relative percent difference

C_1 = larger of the two observed values

C_2 = smaller of the two observed values

If calculated from three or more replicates, use relative standard deviation (RSD) rather than RPD:

$$RSD = (s / \bar{y}) \times 100\%$$

RSD = relative standard deviation

s = standard deviation

\bar{y} = mean of replicate analyses

(Continued)

For more information, see
"Preparation Aids...", Category I, Section 12.0

Category I

CALCULATION OF DATA QUALITY INDICATORS (Cont.)

Standard deviation, s , is defined as follows:

$$s = \sqrt{\frac{\sum_{i=1}^n (y_i - \bar{y})^2}{n - 1}}$$

s = standard deviation

y_i = measured value of the i th replicate

\bar{y} = mean of replicate measurements

n = number of replicates

● Accuracy

– For measurements where matrix spikes are used:

$$\%R = 100\% \times \left(\frac{S - U}{C_{sa}} \right)$$

$\%R$ = percent recovery

S = measured concentration in spiked aliquot

U = measured concentration in unspiked aliquot

C_{sa} = actual concentration of spike added

– For situations where a standard reference material (SRM) is used instead of or in addition to matrix spikes:

$$\%R = 100\% \times \left(\frac{C_m}{C_{SRM}} \right)$$

(Continued)

For more information, see
"Preparation Aids...", Category I, Section 12.0

Category I

CALCULATION OF DATA QUALITY INDICATORS (Cont.)

%R = percent recovery

C_m = measured concentration of SRM

C_{SRM} = actual concentration of SRM

- **Completeness (statistical)**

Defined as follows for all measurements:

$$\%C = 100\% \times \left(\frac{V}{n} \right)$$

%C = percent completeness

V = number of measurements judged valid

n = total number of measurements necessary to achieve a specified statistical level of confidence in decision making

- **Method detection limit**

Defined as follows for all measurements:

$$MDL = t_{(n-1, 1-\alpha = 0.99)} \times S$$

MDL = method detection limit

S = standard deviation of the replicate analyses

$t_{(n-1, 1-\alpha = 0.99)}$ = Student's t-value appropriate to a 99% confidence level and a standard deviation estimate with $n-1$ degrees of freedom

For more information, see "Preparation Aids...", Category I, Section 12.0
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Category I

CORRECTIVE ACTION

Q. What exactly is a "corrective action" plan?

A. It's a contingency plan spelled out in IF...THEN... statements. ("IF this happens, THEN we will do the following.")

For each measurement critical to the success of your project, discuss the following:

- **Trigger points**

What pre-specified conditions will automatically require corrective action?

- **Personnel**

Who initiates, approves, implements, evaluates, and reports corrective action?

- **Response**

What specific procedures will you use when corrective action is needed?

For more information, see
"Preparation Aids...", Category I, Section 13.0

Category I

QUALITY CONTROL REPORTS TO MANAGEMENT

Q. *What is the main purpose of this section?*

A. It helps you do several things: (1) identify the individuals responsible for reporting; (2) describe the form and contents of all anticipated reports; and (3) present QC data so that management can monitor your data quality effectively.

Here are some things to describe:

- Individuals preparing and receiving reports
- Type of report
 - Written or oral, frequency
 - Interim or final (QA/QC reporting is required in Final Reports)
- Content of various reports
 - Changes in QA Project Plan
 - Summary of QA/QC programs, training, and accomplishments
 - Results of technical systems and performance evaluation audits
 - Significant QA/QC problems, recommended solutions, and results of corrective actions
 - Data quality assessment in terms of precision, accuracy, representativeness, completeness, comparability, and method detection limit
 - Discussion of whether the QA objectives were met, and the resulting impact on technical conclusions and regulatory actions
 - Limitations on use of the measurement data, and discussion of the effects of such limitations on the legal defensibility of the data

For more information, see
"Preparation Aids...", Category I, Section 14.0

Category I

REFERENCES

- Q.** *Are references mandatory, and must they be placed in a separate section?*
- A.** Specific references to primary methods, procedures, validation studies, and supporting information required for the project are mandatory, but they need not be placed in a separate reference section. You can also cite references in the body of the text or as footnotes. If any reference is not readily available, attach a photocopy to your QA Project Plan.

Wherever you put the references, make sure they include the following information:

- Author
- Title
- Source, date, edition
- Volume, page, year
- Document number

For more information, see
"Preparation Aids...", Category I, Section 15.0

Category I

OTHER ITEMS

Q. What else is needed?

A. Before you begin to write a Category I QA Project Plan, Data Quality Objectives (DQOs) must be developed for the project. A definitive discussion of the DQO development process is given in "Preparation Aids...", Category I, Appendix A. After you have written the QA Project Plan, you need a technical editor to ensure that your document is ready to be submitted for review.

Make sure your document has the following items:

- A signed QA Project Plan approval form
- Title page, table of contents, and distribution list, including subcontractors when applicable
- EPA-approved document control format, as shown below, in the upper right-hand corner of each page:

Section No.:	5.0
Revision:	0
Date:	June 22, 1987
Page:	1 of 6

- A good, clear, writing style with correct grammar and spelling
- Inclusion of all appendices, attachments, and figures cited

~REMEMBER~

Your QA Project Plan explains YOUR requirements to the sampling team, analytical laboratory, management, and all other interested parties. Make sure it is well organized and complete to do this critical job effectively.

Category II

PROJECT DESCRIPTION

Q. How detailed should the description be?

A. A technical person unfamiliar with your project must be able to understand what you've written.

Be sure to include:

- General overview
 - Statement of the decision to be made or the question to be answered
 - Purpose of the study in quantitative terms
 - Description of the site, facility, process, or operating parameters to be studied
 - Anticipated uses of the results
 - Consequences of incorrect decisions or conclusions based on these results

- Experimental design features
 - List of all measurements, differentiating the critical measurement (i.e., process and analytical measurements essential to achieving project objectives) from the non-critical measurements
 - Description of that portion of the environment or physical system to which decisions or conclusions will be applied
 - Summary table covering the following for each sampling location:
 - Total number of samples (including primary, quality control, and reserve)
 - Type of sample (air, water, soil, etc.)
 - All measurements planned for each sample

- Project start-up and ending dates, including preliminary studies and field and laboratory activities

For more information, see
"Preparation Aids...", Category II, Section 1.0

Category II

PROJECT ORGANIZATION AND RESPONSIBILITIES

Q. What's the most important thing to do here?

A. Name all key individuals in charge of every major activity in your project. This applies to your subcontractors, too.

Also include:

- A detailed organizational chart showing management structure and lines of communication
- Telephone numbers to facilitate communication between project officials
- Both technical and QA/QC functions
- An independent QA coordinator
- Geographical locations of contractors and subcontractors
- Procedures for monitoring subcontractors
- Description of type, frequency, and mechanisms of communication between contractor and subcontractors, and among subcontractors
- Description of type, frequency, and mechanisms of communication among the contractor, the contractor's project quality assurance officer, and the EPA project officer

For more information, see
"Preparation Aids..." Category II, Section 2.0

Category II

QUALITY ASSURANCE OBJECTIVES

- Q. What's the most common reason for a QA Project Plan getting a NOT APPROVED rating?*
- A. Inadequate treatment of QA objectives. These QA objectives must be defined in terms of project requirements, not in terms of the capabilities of the test methods used.*

Make sure you cover the following for each critical measurement and each matrix:

- Summary table of quantitative QA objectives
 - Method detection limit
 - Precision, both within and between samples
 - Accuracy
 - Completeness (as required to achieve a specific, statistical level of confidence)
- Discussion of qualitative QA objectives
 - Representativeness
 - Comparability
 - Others, as applicable
- Discussion of how not meeting the QA objectives will affect decision making

For more information, see
"Preparation Aids...", Category II, Section 3.0

Category II

SITE SELECTION AND SAMPLING PROCEDURES

Q. How important is this section?

A. Very important, because collecting representative samples in both time and space is crucial to subsequent decision making. Obtaining good analytical results on non-representative samples is dangerous because such results could lead to incorrect decisions.

Your QA Project Plan must describe the following:

- Sampling site selection
 - Scientific and regulatory objectives for sampling, including analyte concentrations of interest
 - Statistical method or scientific rationale for choosing sampling sites and sampling frequencies
 - Extent to which the site selection will affect the validity of the resulting data and the project objectives

- Sampling site description
 - Chart, map, etc., showing sampling sites
 - Site-specific factors affecting sampling
 - Critical process measurements

(Continued)

For more information, see
"Preparation Aids...", Category II, Section 4.0

Category II

SITE SELECTION AND SAMPLING PROCEDURES (Cont.)

- Sampling procedures
 - List of analytes and sample volumes to be collected
 - Sampling methods (composite, grab, etc.)
 - EPA-approved or other validated standard methods—cite by reference
 - Non-standard or modified methods—describe fully
 - Preparation and cleaning of sampling equipment, containers, reagents, and supplies
 - Calibration of equipment
 - Preservation, transportation, and storage
 - Holding times of samples, before and after extraction, as applicable
 - Whenever possible, include standard operating procedures (SOPs) to fulfill the above requirements

- Sample custody concerns
 - Names of sample custodians
 - Records of sample acquisition data
 - Records of sample preservation methods
 - Examples of labels and custody seals
 - Forms for field and lab tracking
 - Records of field and lab chain-of-custody
 - Procedures for transferring samples from field to lab, within lab, and among contractor and subcontractors
 - Whenever possible, include SOPs to fulfill the above requirements

For more information, see
"Preparation Aids....," Category II, Section 4.0

Category II

ANALYTICAL PROCEDURES AND CALIBRATION

Q. *What factors are critical in selecting analytical methods?*

A. The methods must be appropriate for all analytes in the specific matrix at the anticipated concentrations. They require extensive validation to show that they meet your QA objectives.

Include the following in your QA Project Plan:

(Note: Use a summary table whenever possible.)

- EPA-approved or other validated, standard methods
 - Reference sample preparation and analysis methods for both critical and non-critical measurements for all matrices to be studied.
 - Cite by reference if method validation data are appropriate for your critical measurements.
 - Describe your data validation plans for all critical measurements if existing validation data are inappropriate.
- Non-standard or modified methods
 - Include sample preparation and analysis methods for all measurements for all matrices.
 - Describe data validation plans for all critical measurements.
 - Whenever possible, include SOPs to fulfill the above requirements.
- Calibration procedures
 - Reference EPA-approved or standard methods.
 - Describe non-standard or modified methods fully.
 - List standards, including source, traceability, and purity checks.
 - Describe frequency of calibration checks.
 - Define acceptance criteria for all calibration measurements.

For more information, see
"Preparation Aids...", Category II, Section 5.0

Category II

DATA REDUCTION, VALIDATION, AND REPORTING

Q. What's the main purpose of this section?

A. You want to collect good data. This section shows how you plan to maintain good data quality throughout data reduction, transfer, storage, retrieval, and reporting.

Here are topics to discuss:

- Data reduction
 - Names of individuals responsible
 - Summary of data reduction procedures
 - Summary of statistical approach for reducing data, including units and definitions of terms
 - Examples of data sheets
 - Description of how results on blanks will be treated in the calculations

- Data validation
 - Names of individuals responsible
 - Procedures for determining outliers and flagging data
 - Identification of critical control points

- Data reporting
 - Names of individuals responsible
 - Flowchart of the data handling process, covering all data collection, transfer, storage, recovery, and processing steps, and including QC data for both field and laboratory
 - Identification of critical control points

For more information, see
"Preparation Aids...", Category II, Section 6.0

Category II

INTERNAL QUALITY CONTROL CHECKS

Q. What determines which QC checks are needed?

A. The QA objectives for your project and the anticipated uses of your results. QC checks apply to both field and laboratory activities. List the type and number of QC checks, including acceptance criteria.

Here are some QC checks to consider:

(Note: Use a summary table whenever possible.)

- Samples*
 - Collocated, split, replicate
- Spikes*
 - Matrix spikes and matrix spike duplicates
 - Spiked blanks
 - Surrogates and internal standards
- Others
 - Standard reference materials
 - Blanks (field, trip, method, reagent, instrument)
 - Zero and span gases
 - Mass tuning for mass spectral analyses
 - Confirmation with second column for gas chromatographic analyses
 - Control charts
 - Calibration standards
 - Proficiency testing of analysts
 - Any additional checks required by the special needs of your project

***Identify all stages in the sampling and analytical process where the QC activity will occur.**

<p>For more information, see "Preparation Aids...", Category II, Section 7.0</p>
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Category II

PERFORMANCE AND SYSTEMS AUDITS

Q. What information is most important here?

A. A schedule of all planned performance evaluation audits and technical systems audits.

Be sure to include:

- Schedule of all contractor- and EPA-planned audits
- Personnel responsible for audits
- Explanation if no audits are planned
- Schedule for any interlaboratory performance evaluation studies

For more information, see
"Preparation Aids...", Category II, Section 8.0

Category II

CALCULATION OF DATA QUALITY INDICATORS

Q. *What tells me if my data quality is "good enough"?*

A. Detailed planning of data assessment procedures as summarized here, including statistical treatment planned, equations, units, and assessment frequency. Make sure everything agrees with the QA objectives. You and other data users can then make the needed comparisons.

Here's how to calculate your results:

- Precision

If calculated from duplicate measurements:

$$RPD = \frac{(C_1 - C_2) \times 100\%}{(C_1 + C_2) / 2}$$

RPD = relative percent difference

C_1 = larger of the two observed values

C_2 = smaller of the two observed values

If calculated from three or more replicates, use relative standard deviation (RSD) rather than RPD:

$$RSD = (s / \bar{y}) \times 100\%$$

RSD = relative standard deviation

s = standard deviation

\bar{y} = mean of replicate analyses

(Continued)

For more information, see
"Preparation Aids..." Category II, Section 9.0

Category II

CALCULATION OF DATA QUALITY INDICATORS (Cont.)

Standard deviation, s , is defined as follows:

$$s = \sqrt{\sum_{i=1}^n \frac{(y_i - \bar{y})^2}{n - 1}}$$

s = standard deviation

y_i = measured value of the i th replicate

\bar{y} = mean of replicate measurements

n = number of replicates

- Accuracy

- For measurements where matrix spikes are used:

$$\%R = 100\% \times \left(\frac{S - U}{C_{sa}} \right)$$

$\%R$ = percent recovery

S = measured concentration in spiked aliquot

U = measured concentration in unspiked aliquot

C_{sa} = actual concentration of spike added

- For situations where a standard reference material (SRM) is used instead of or in addition to matrix spikes:

$$\%R = 100\% \times \left(\frac{C_m}{C_{srm}} \right)$$

(Continued)

For more information, see
"Preparation Aids..." Category II, Section 9.0

Category II

CALCULATION OF DATA QUALITY INDICATORS (Cont.)

%R = percent recovery

C_m = measured concentration of SRM

C_{SRM} = actual concentration of SRM

- Completeness (statistical)

Defined as follows for all measurements:

$$\%C = 100\% \times \left(\frac{V}{n} \right)$$

%C = percent completeness

V = number of measurements judged valid

n = total number of measurements **necessary to achieve a specified statistical level of confidence in decision making**

- Method detection limit

Defined as follows for all measurements:

$$MDL = t_{(n-1, 1-\alpha = 0.99)} \times S$$

MDL = method detection limit

S = standard deviation of the replicate analyses

$t_{(n-1, 1-\alpha = 0.99)}$ = Students' t-value appropriate to a 99% confidence level and a standard deviation estimate with n-1 degrees of freedom

For more information, see
"Preparation Aids..." Category II, Section 9.0

Category II

CORRECTIVE ACTION

Q. What exactly is a "corrective action" plan?

A. It's a contingency plan spelled out in IF...THEN... statements. ("IF this happens, THEN we will do the following.")

For each measurement critical to the success of your project, discuss the following:

- **Trigger points**

What pre-specified conditions will automatically require corrective action?

- **Personnel**

Who initiates, approves, implements, evaluates, and reports corrective action?

- **Response**

What specific procedures will you use when corrective action is needed?

For more information, see
"Preparation Aids....," Category II, Section 10.0

QUALITY CONTROL REPORTS TO MANAGEMENT

Q. What is the main purpose of this section?

A. It helps you do several things: (1) identify the individuals responsible for reporting; (2) describe the form and contents of all anticipated reports; and (3) present QC data so that management can monitor your data quality effectively.

Here are some things to describe:

- Individuals preparing and receiving reports
- Type of report
 - Written or oral, frequency
 - Interim or final (QA/QC reporting is required in Final Reports)
- Content of various reports
 - Changes in QA Project Plan
 - Summary of QA/QC programs, training, and accomplishments
 - Results of technical systems and performance evaluation audits
 - Significant QA/QC problems, recommended solutions, and results of corrective actions
 - Data quality assessment in terms of precision, accuracy, representativeness, completeness, comparability, and method detection limit
 - Discussion of whether the QA objectives were met, and the resulting impact on decision making
 - Limitations on use of the measurement data

For more information, see
"Preparation Aids...", Category II, Section 11.0

Category II

REFERENCES

Q. *Are references mandatory, and must they be placed in a separate section?*

A. No to both questions. You can also cite references in the body of the text or as footnotes. If any reference is not readily available, attach a photocopy to your QA Project Plan.

Wherever you put the references, make sure they include the following information:

- Author
- Title
- Source, date, edition
- Volume, page, year
- Document number

For more information, see
"Preparation Aids...", Category II, Section 12.0

Category II

OTHER ITEMS

Q. *What else is needed?*

A. A technical editor to ensure that your document is ready to be submitted for review.

Make sure your document has the following items:

- A signed QA Project Plan approval form
- Title page, table of contents, and distribution list, including subcontractors when applicable
- EPA-approved document control format as shown below, in the upper right-hand corner of each page:

Section No.:	5.0
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- A good, clear, writing style with correct grammar and spelling
- Inclusion of all appendices, attachments, and figures cited

~REMEMBER~

Your QA Project Plan explains YOUR requirements to the sampling team, analytical laboratory, management, and all other interested parties. Make sure it is well organized and complete to do this critical job effectively.

Category III

PROJECT DESCRIPTION

Q. How detailed should the description be?

A. A technical person unfamiliar with your project must be able to understand what you've written.

Be sure to include:

- **General overview**
 - Statement of the decision to be made or the question to be answered
 - Description of the site, facility, process, or operating parameters to be studied
 - Anticipated uses of the results
 - Consequences of incorrect decisions or conclusions based on these results

- **Experimental design features**
 - List of all measurements, differentiating the critical measurements (i.e., process and analytical measurements essential to achieving project objectives) from the non-critical measurements
 - Summary table covering the following for each sampling location:
 - Total number of samples (Including primary, quality control, and reserve)
 - Type of sample (air, water, soil, etc.)
 - All measurements planned for each sample

- **Project start-up and ending dates, including preliminary studies and field and laboratory activities**

(Continued)

For more information, see
"Preparation Aids...", Category III, Section 1.0

Category III

PROJECT DESCRIPTION (Cont.)

- Project responsibilities
 - Identification of all key technical and QA/QC personnel of contractor and subcontractors
 - Designation of an independent QA/QC coordinator

- Communication procedures
 - Procedures for monitoring subcontractors
 - Communicating within and across project areas of responsibility
 - Reporting to EPA

For more information, see
"Preparation Aids..." Category III, Section 1.0

Category III

QUALITY ASSURANCE OBJECTIVES

Q. What's the most common reason for a QA Project Plan getting a NOT APPROVED rating?

A. Inadequate treatment of QA objectives. These QA objectives must be defined in terms of project requirements, not in terms of the capabilities of the test methods used.

Make sure you cover the following for each critical measurement and each matrix:

- Summary table of quantitative QA objectives
 - Method detection limit
 - Precision, both within and between samples
 - Accuracy
 - Completeness
- Discussion of qualitative QA objectives
 - Representativeness
 - Comparability
 - Others, as applicable
- Discussion of how not meeting the QA objectives will affect decision making

For more information, see
"Preparation Aids...", Category III, Section 2.0

SITE SELECTION AND SAMPLING PROCEDURES

Q. *How important is this section?*

A. Very important, because collecting representative samples in both time and space is crucial to subsequent decision making. Obtaining good analytical results on non-representative samples is dangerous because such results could lead to incorrect decisions.

Your QA Project Plan must describe the following:

- **Sampling site selection**
 - Scientific objectives for sampling, including analyte concentrations of interest
 - Statistical method or scientific rationale for choosing sampling sites and/or process sampling points, and sampling frequencies
 - Extent to which the site selection and/or process sampling points will affect the validity of the resulting data and the project objectives

- **Sampling site description**
 - Chart, map, process diagram, etc., showing sampling sites
 - Critical process measurements.

(Continued)

For more information, see
"Preparation Aids...", Category III, Section 3.0

Category III

SITE SELECTION AND SAMPLING PROCEDURES (Cont.)

- Sampling procedures
 - List of analytes and sample volumes to be collected
 - Sampling methods (composite, grab, etc.)
 - EPA-approved or other validated standard methods—cite by reference
 - Non-standard or modified methods—describe fully
 - Preparation and cleaning of sampling equipment, containers, reagents, and supplies
 - Calibration of equipment
 - Preservation, transportation, and storage
 - Holding times of samples, before and after extraction, as applicable
 - Whenever possible, include standard operating procedures (SOPs) to fulfill the above requirements.

- Sample custody concerns
 - Names of sample custodians
 - Procedures for transferring samples from field to lab, within lab, and among contractor and subcontractors
 - Whenever possible, include SOPs to fulfill the above requirements

For more information, see
"Preparation Aids..." Category III, Section 3.0

Category III

ANALYTICAL PROCEDURES AND CALIBRATION

Q. *What factors are critical in selecting analytical methods?*

A. The methods must be appropriate for all analytes in the specific matrix at the anticipated concentrations. They require validation to show that they meet your QA objectives.

Include the following in your QA Project Plan:

(Note: Use a summary table whenever possible.)

- EPA-approved or other validated, standard methods
 - Reference sample preparation and analysis methods for both critical and non-critical measurements for all matrices to be studied.
 - Cite by reference if method validation data are appropriate for your critical measurements.
 - Describe your data validation plans for all critical measurements if existing validation data are inappropriate.
- Non-standard or modified methods
 - Include sample preparation and analysis methods for all measurements for all matrices to be studied.
 - Describe data validation plans for all critical measurements.
 - Whenever possible, include SOPs to fulfill the above requirements.
- Calibration procedures
 - Reference EPA-approved or standard methods.
 - Describe non-standard or modified methods fully.
 - List standards, including source, traceability, and purity checks.
 - Describe frequency of calibration checks.
 - Define acceptance criteria for all calibration measurements.

For more information, see
"Preparation Aids...", Category III, Section 4.0

Category III

DATA REDUCTION, VALIDATION, AND REPORTING

Q. What's the main purpose of this section?

A. You want to collect good data. This section shows how you plan to maintain good data quality throughout data reduction, transfer, storage, retrieval, and reporting.

Here are topics to discuss:

- Data reduction
 - Names of individuals responsible
 - Summary of data reduction procedures
 - Summary of statistical approach for reducing data, including units and definitions of terms
 - Examples of data sheets
 - Description of how results on blanks will be treated in the calculations

- Data validation
 - Names of individuals responsible
 - Procedures for determining outliers and flagging data

- Data reporting
 - Names of individuals responsible
 - Flowchart of the data handling process, covering all data collection, transfer, storage, recovery, and processing steps, and including QC data for both field and laboratory

For more information, see
"Preparation Aids...", Category III, Section 5.0

Category III

INTERNAL QUALITY CONTROL CHECKS

Q. What determines which QC checks are needed?

A. The QA objectives for your project and the anticipated uses of your results. QC checks apply to both field and laboratory activities. State the type and number of QC checks, including acceptance criteria.

Here are some QC checks to consider:

(Note: Use a summary table whenever possible.)

- Samples*
 - Collocated, split, replicate
- Spikes*
 - Matrix spikes and matrix spike duplicates
 - Spiked blanks
 - Surrogates and internal standards
- Others
 - Standard reference materials
 - Blanks (field, trip, method, reagent, instrument)
 - Zero and span gases
 - Mass tuning for mass spectral analyses
 - Confirmation with second column for gas chromatographic analyses
 - Control charts
 - Calibration standards
 - Proficiency testing of analysts
 - Any additional checks required by the special needs of your project

***Identify all stages in the sampling and analytical process where the QC activity will occur.**

For more information, see
"Preparation Aids...", Category III, Section 6.0

Category III

PERFORMANCE AND SYSTEMS AUDITS

Q. What information is most important here?

A. A schedule of all planned performance evaluation audits and technical systems audits.

Be sure to include:

- Schedule of all contractor-planned audits
- Schedule for any interlaboratory performance evaluation studies

For more information, see
"Preparation Aids...", Category III, Section 7.0

Category III

CALCULATION OF DATA QUALITY INDICATORS

Q. What tells me if my data quality is "good enough"?

A. Detailed planning of data assessment procedures as summarized here, including statistical treatment planned, equations, units, and assessment frequency. Make sure everything agrees with the QA objectives. You and other data users can then make the needed comparisons.

Here's how to calculate your results:

- Precision

If calculated from duplicate measurements:

$$RPD = \frac{(C_1 - C_2) \times 100\%}{(C_1 + C_2) / 2}$$

RPD = relative percent difference

C_1 = larger of the two observed values

C_2 = smaller of the two observed values

If calculated from three or more replicates, use relative standard deviation (RSD) rather than RPD:

$$RSD = (s/\bar{y}) \times 100\%$$

RSD = relative standard deviation

s = standard deviation

\bar{y} = mean of replicate analyses

(Continued)

For more information, see
"Preparation Aids...", Category III, Section 8.0

Category III

CALCULATION OF DATA QUALITY INDICATORS (Cont.)

Standard deviation, s , is defined as follows:

$$s = \sqrt{\sum_{i=1}^n \frac{(y_i - \bar{y})^2}{n - 1}}$$

s = standard deviation

y_i = measured value of the i th replicate

\bar{y} = mean of replicate measurements

n = number of replicates

● Accuracy

– For measurements where matrix spikes are used:

$$\%R = 100\% \times \left(\frac{S - U}{C_{sa}} \right)$$

$\%R$ = percent recovery

S = measured concentration in spiked aliquot

U = measured concentration in unspiked aliquot

C_{sa} = actual concentration of spike added

– For situations where a standard reference material (SRM) is used instead of or in addition to matrix spikes:

$$\%R = 100\% \times \left(\frac{C_m}{C_{srm}} \right)$$

(Continued)

For more information, see
"Preparation Aids..." Category III, Section 8.0

Category III

CALCULATION OF DATA QUALITY INDICATORS (Cont.)

%R = percent recovery

C_m = measured concentration of SRM

C_{SRM} = actual concentration of SRM

- Completeness (sampling and analytical)

Defined as follows for all measurements:

$$\%C = 100\% \times \left(\frac{V}{T} \right)$$

%C = percent completeness

V = number of measurements judged valid

T = total number of measurements

- Method detection limit

Defined as follows for all measurements:

$$MDL = t_{(n-1, 1-\alpha = 0.99)} \times S$$

MDL = method detection limit

S = standard deviation of the replicate analyses

$t_{(n-1, 1-\alpha = 0.99)}$ = Students' t-value appropriate to a 99% confidence level and a standard deviation estimate with n-1 degrees of freedom

For more information, see "Preparation Aids...", Category III, Section 8.0

Category III

CORRECTIVE ACTION

Q *What exactly is a "corrective action" plan?*

A. It's a contingency plan spelled out in IF...THEN... statements. ("IF this happens, THEN we will do the following.")

For each measurement critical to the success of your project, discuss the following:

- **Trigger points**

What pre-specified conditions will automatically require corrective action?

- **Personnel**

Who initiates, approves, implements, evaluates, and reports corrective action?

- **Response**

What specific procedures will you use when corrective action is needed?

For more information, see
"Preparation Aids...", Category III, Section 9.0

Category III

QUALITY CONTROL REPORTS TO MANAGEMENT

Q. What is the main purpose of this section?

A. It helps you do several things: (1) identify the Individuals responsible for reporting; (2) describe the form and contents of all anticipated reports; and (3) present QC data so that management can monitor your data quality effectively.

Here are some things to describe:

- Individuals preparing and receiving reports
- Type of report
 - Written or oral, frequency
 - Interim or final (QA/QC reporting is required in Final reports)
- Content of various reports
 - Changes in QA Project Plan
 - Results of technical systems and performance evaluation audits
 - Significant QA/QC problems, recommended solutions, and results of corrective actions
 - Data quality assessment in terms of precision, accuracy, representativeness, completeness, comparability, and method detection limit
 - Discussion of whether the QA objectives were met, and the resulting impact on decision making
 - Limitations on use of the measurement data

For more information, see
"Preparation Aids...", Category III, Section 10.0

Category III

REFERENCES

- Q.** *Are references mandatory, and must they be placed in a separate section?*
- A.** No to both questions. You can also cite references in the body of the text or as footnotes. If any reference is not readily available, attach a photocopy to your QA Project Plan.

Wherever you put the references, make sure they include the following information:

- Author
- Title
- Source, date, edition
- Volume, page, year
- Document number

For more information, see
"Preparation Aids...", Category III, Section 11.0

Category III

OTHER ITEMS

Q. What else is needed?

A. A technical editor to ensure that your document is ready to be submitted for review.

Make sure your document has the following items:

- A signed QA Project Plan approval form
- Title page, table of contents, and distribution list, including subcontractors when applicable
- EPA-approved document control format as shown below, in the upper right-hand corner of each page:

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- A good, clear writing style with correct grammar and spelling
- Inclusion of all appendices, attachments, and figures cited

~ REMEMBER ~

Your QA Project Plan explains YOUR requirements to the sampling team, analytical laboratory, management, and all other interested parties. Make sure it is well organized and complete to do this critical job effectively.

Category IV

PROJECT DESCRIPTION

Q. How detailed should the description be?

A. A technical person unfamiliar with your project must be able to understand what you've written.

Be sure to include:

- General overview
 - Statement of the question to be answered
 - Description of the site, facility, process, or operating parameters to be studied
 - Anticipated uses of the results
 - Consequences of incorrect decisions or conclusions based on these results

- Experimental design features
 - List of all measurements, differentiating the critical measurements (i.e., process and analytical measurements essential to achieving project objectives) from the non-critical measurements
 - Summary table covering the following for each sampling location:
 - Projected number of samples (including primary, quality control, and reserve)
 - Type of sample (air, water, soil, etc.)
 - All measurements planned for each sample

- Project start-up and ending dates, including preliminary studies and field and laboratory activities

- Project responsibilities
 - Identification of all key technical and QA/QC personnel of contractor and subcontractors

For more information, see
"Preparation Aids..." Category IV, Section 1.0

Category IV

QUALITY ASSURANCE OBJECTIVES

Q. What's the most common reason for a QA Project Plan getting a NOT APPROVED rating?

A. Inadequate treatment of QA objectives for precision, accuracy, and limits of detection needed for each critical measurement. These QA objectives should be defined in terms of project requirements, not in terms of the capabilities of the test methods used.

Make sure you cover the following for each critical measurement and each matrix:

- Summary table of quantitative QA objectives
 - Method detection limit
 - Precision
 - Accuracy
- Discussion of qualitative QA objectives
 - Sample acceptance/rejection criteria
 - Representativeness
 - Comparability
 - Others, as applicable
- Discussion of how not meeting the QA objectives will affect decision making

Note: Category IV projects are allowed a wide latitude in defining the specific QA objectives and methods involved. The important thing to remember here is that project-specific QA objectives and methods must be established.

For more information, see
"Preparation Aids...", Category IV, Section 2.0

Category IV

SAMPLING AND ANALYTICAL PROCEDURES

Q. *What factors are critical in selecting the procedures?*

A. The sampling procedures must be appropriate for the collection of a representative sample and the analytical methods must be appropriate for all analytes in the specific matrix at the anticipated concentrations. Analytical methods may be non-standard or state-of-the-art, but must be validated to show that they meet your QA objectives.

Include the following in your QA Project Plan:

(Note: Use a summary table whenever possible.)

- Sampling procedures
 - List of analytes and sample volumes to be collected
 - Sampling methods (composite, grab, etc.)
 - Preparation and cleaning of sampling equipment, containers, reagents, and supplies
 - Preservation, transportation, and storage
 - Holding times of samples, before and after extraction, as applicable
 - Whenever possible, include SOPs to fulfill the above requirements.
- EPA-approved or other validated standard methods
 - Reference sample preparation and analysis methods for both critical and non-critical measurements for all matrices.

(Continued)

For more information, see
"Preparation Aids...", Category IV, Section 3.0

Category IV

SAMPLING AND ANALYTICAL PROCEDURES (Cont.)

- Non-standard or modified methods
 - Include sample preparation and analysis methods for both critical and non-critical measurements for all matrices.
 - Describe data validation plans for all critical measurements.
 - Whenever possible, include SOPs to fulfill the above requirements.

- Calibration procedures
 - Reference EPA-approved or standard methods.
 - Describe non-standard or modified methods fully.
 - Describe frequency of calibration checks.
 - Define acceptance criteria for all calibration measurements.

For more information, see
"Preparation Aids....," Category IV, Section 3.0

Category IV

APPROACH TO QA/QC

- Q. What is important in planning a good approach to quality assurance and quality control for a project?*
- A. You want to collect good data, and you want to be able to evaluate how good your data are. In this section, you show how you plan to (1) maintain good data quality during the calculation and reporting of results, (2) perform the specific internal QC activities needed to evaluate the quality of the data, and (3) calculate the data quality indicators for precision, accuracy, and method detection limit.*

Here are topics to discuss:

- Calculation of results
 - Summary of statistical approach for reducing data, including units and definitions of terms
 - Procedures for determining outliers and flagging data
- Internal QC checks (Use a summary table if possible. Identify the frequency and at what stage in the analytical process each QC activity will occur.)
 - Collocated, split, or replicate samples
 - Matrix spikes and matrix spike duplicates
 - Spiked blanks
 - Surrogates and internal standards
 - Standard reference materials
 - Blanks (field, trip, method, reagent, instrument)
 - Zero and span gases
 - Mass tuning for mass spectral analyses
 - Control charts
 - Calibration standards
 - Any additional checks required by the special needs of your project

(Continued)

For more information, see
"Preparation Aids...", Category IV, Section 4.0

Category IV

APPROACH TO QA/QC (Cont.)

● Calculation of data quality indicators

– Precision

If calculated from duplicate measurements:

$$\text{RPD} = \frac{(C_1 - C_2) \times 100\%}{(C_1 + C_2) / 2}$$

RPD = relative percent difference

C_1 = larger of the two observed values

C_2 = smaller of the two observed values

If calculated from three or more replicates, use relative standard deviation (RSD) rather than RPD:

$$\text{RSD} = (s/\bar{y}) \times 100\%$$

RSD = relative standard deviation

s = standard deviation

\bar{y} = mean of replicate analyses

Standard deviation, s , is defined as follows:

$$s = \sqrt{\sum_{i=1}^n \frac{(y_i - \bar{y})^2}{n - 1}}$$

(Continued)

For more information, see
"Preparation Aids...", Category IV, Section 4.0

Category IV

APPROACH TO QA/QC (Cont.)

s = standard deviation

y_l = measured value of the l th replicate

\bar{y} = mean of replicate measurements

n = number of replicates

– Accuracy

For measurements where matrix spikes are used:

$$\%R = 100\% \times \left(\frac{S - U}{C_{sa}} \right)$$

%R = percent recovery

S = measured concentration in spiked aliquot

U = measured concentration in unspiked aliquot

C_{sa} = actual concentration of spike added

For situations where a standard reference material (SRM) is used instead of or in addition to a matrix spike:

$$\%R = 100\% \times \left(\frac{C_m}{C_{srm}} \right)$$

%R = percent recovery

C_m = measured concentration of SRM

C_{srm} = actual concentration of SRM

(Continued)

For more information, see
"Preparation Aids...", Category IV, Section 4.0

Category IV

APPROACH TO QA/QC (Cont.)

- Method detection limit

Defined as follows for all measurements:

$$\text{MDL} = t_{(n-1, 1-\alpha = 0.99)} \times S$$

MDL = method detection limit

S = standard deviation of the replicate analyses

$t_{(n-1, 1-\alpha = 0.99)}$ = Students' t-value appropriate to a 99% confidence level and a standard deviation estimate with n-1 degrees of freedom

<p>For more information, see "Preparation Aids...", Category IV, Section 4.0</p>
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Category IV

REFERENCES

Q. Are references mandatory, and must they be placed in a separate section?

A. No to both questions. You can also cite references in the body of the text or as footnotes. If any reference is not readily available, attach a photocopy to your QA Project Plan.

Wherever you put the references, make sure they include the following information:

- Author
- Title
- Source, date, edition
- Volume, page, year
- Document number

For more information, see
"Preparation Aids...", Category IV, Section 5.0

Category IV

OTHER ITEMS

Q. What else is needed?

A. A technical editor to ensure that your document is ready to be submitted for review.

Make sure your document has the following items:

- A signed QA Project Plan approval form
- Title page, table of contents, and distribution list, including subcontractors when applicable
- Inclusion of all appendices, attachments, and figures cited

- REMEMBER -

Your QA Project Plan explains YOUR requirements to the sampling team, analytical laboratory, management, and all other interested parties. Make sure it is well organized and complete to do this critical job effectively.

NOTES
