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

## Part 2: Elements of a QA Project Plan

# A few words about Part 2 . . .

This training is designed to be used in various ways:

1) The slides provide an overview of the information that should be included in a QAPP.

2) The slides can be downloaded and used as a workbook when you are planning the project.

**QAPP Writing Tip: Write down as much as you can while you're planning the project.**

3) Speaker notes can also be viewed for additional information on the topic.

# Planning your project and writing the QAPP

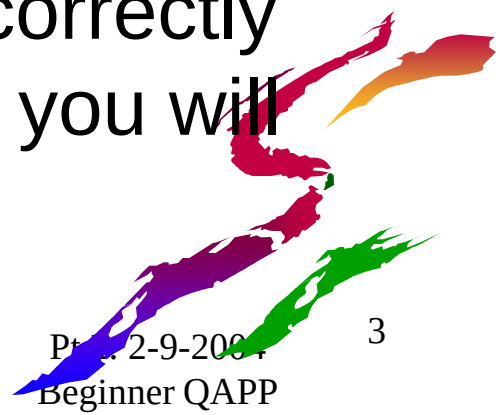
As you learned in Part I of the QAPP Training, EPA requires that you plan and document certain aspects of your project including:

1) **Project Management** - how you will organize and run the project

2) **Data Generation** - how you will collect and report data

3) **Assessment and Oversight** - how you will check that all activities are completed correctly

4) **Data Review and Usability** - how you will review and interpret the data

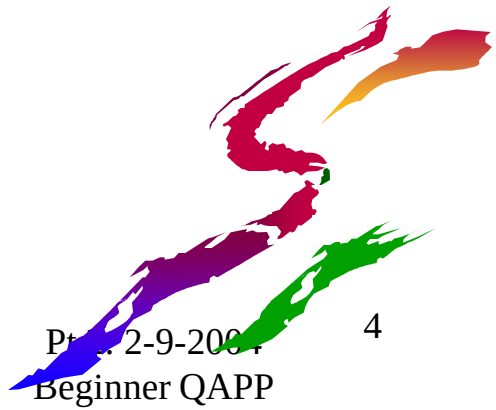


# 1. Project Management

The elements of this section include:

1. Title and Approval Page
2. Table of Contents and Page Header
3. Distribution List
4. Project/Task Organization
5. Problem Definition/Background
6. Project/Task Description
7. Quality Objectives and Criteria
8. Special Training/Certification
9. Documents and Records

**QAPP writing tip: To avoid rewriting project information, use excerpts from the previously written grant application or work plan.**



# Title & Approval Page

First, create a "Title and Approval Page" that includes:

-Title of the project

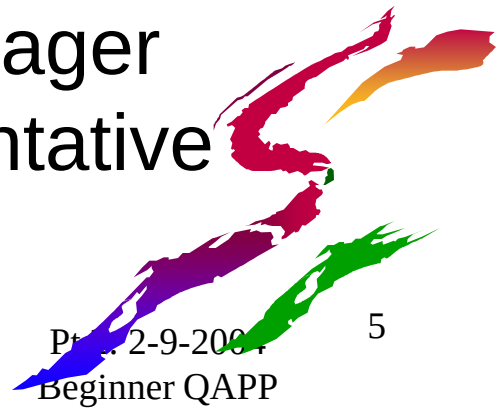
-Name of the organization receiving EPA funding

-Name of person who prepared the plan

-Effective date of the plan and revision number

-Names, titles, signature, and dates for approving officials including:

- Your organization's Project Manager
- Your organization's QA representative
- EPA Project Officer
- EPA QA Manager



# Title and Approval Page

_____

*Document Title*

_____

*EPA Grant Number*

_____

*Grantee's Organization*

_____

*Preparer's Name and Organizational Position* *Preparation Date (Day/Month/Year)*

*Organization's Program Manager Signature/Date:*_____

*Printed Name/Title:*_____

*Organization's QA Officer Signature/Date:*_____

*Printed Name/Title:*_____

**EPA New England QAPP Approval (Both PO and RQAM Approvals are required)**

*EPA Project Officer Signature/Date:*_____

*Printed Name:*_____

*EPA Quality Assurance Manager Signature/Date:*_____

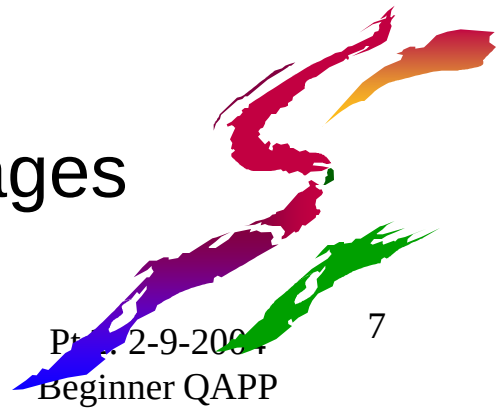
*Printed Name:__Gerry Sotolongo (or authorized QAU Representative)*_____

# Table of Contents and Page Header

✓ Create a table of contents and list the sections, figures, photographs, maps, tables, appendices and attachments contained in the QAPP with corresponding page numbers.

✓ Use header format (see example on previous slide) to provide the following information:

- Abbreviated QAPP Title
- Revision number
- Date
- Page number <u>of</u> total number of pages

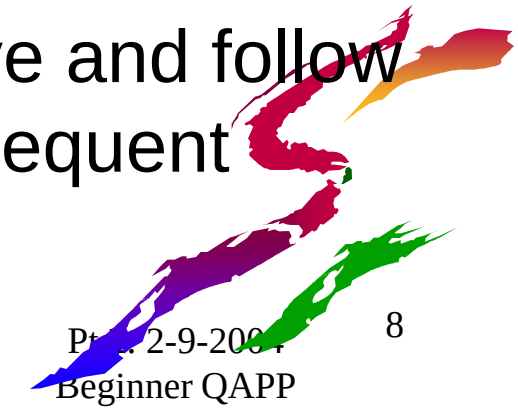


# Distribution List

- ✓ Identify personnel in all organizations who will receive a copy of the approved QAPP, subsequent QAPP revisions, addenda and amendments.

- ✓ Create a table that includes the name of the recipient, their title, organization and contact information including telephone number, address, and email address.

- ✓ Include a sentence that explains how you will ensure that all critical project personnel will receive and follow applicable sections of the QAPP and subsequent revisions.

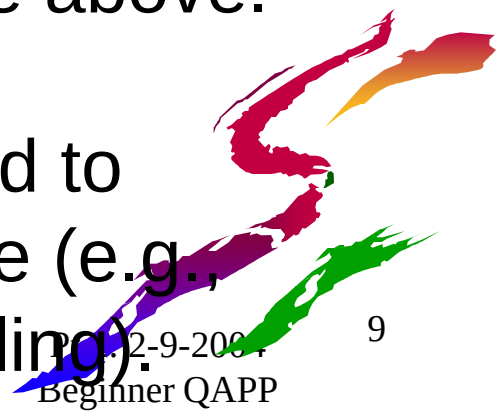


# Project/Task Organization

- ✓ List key project personnel (managers, laboratory personnel, QA personnel, volunteer monitors) and describe their roles and responsibilities for the project.
  1) Identify who is in charge of the entire project
  2) Identify who is in charge of each activity (sampling, laboratory analysis, data reporting, etc.)

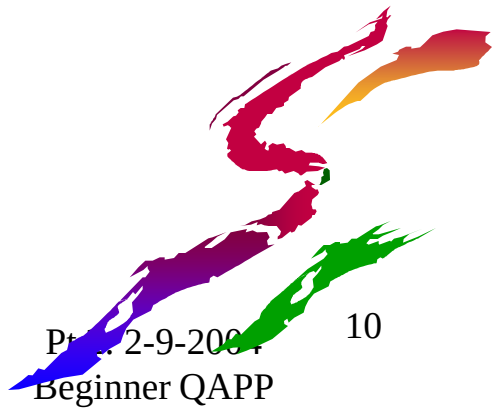
- ✓ Attach an organizational chart and indicate lines of communication and authority for all of the above.

- ✓ Describe critical instructions that will need to be communicated and person responsible (e.g., person who will initiate storm water sampling).



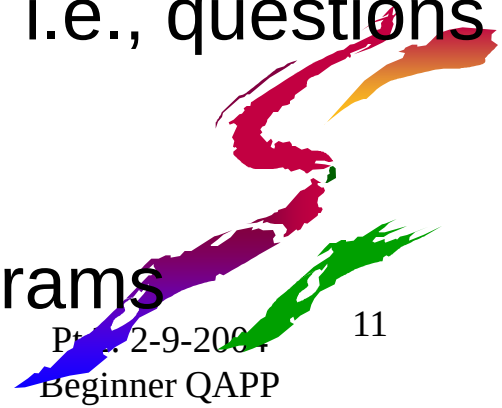
# Problem Definition/Background

- ✓ Describe the environmental problem to be studied.
- ✓ Provide background information from an historic, scientific, and/or regulatory perspective.
- ✓ Summarize the known information/data including environmental parameters of concern and magnitude of contamination.
- ✓ Define the objectives of the project.



# Problem Definition/Background (cont.)

- ✓Describe how data will be used (exploratory, extent of contamination, comparison to regulatory limits, etc.) and who will use the data.
- ✓ Identify what decisions will be made with the data. Cite any regulatory standards or criteria that data will be compared against.
- ✓ Identify information/data that are needed, i.e., questions that must be answered during the study.
- ✓ Include (or reference) historic maps, diagrams and summary data.



# Project/Task Description

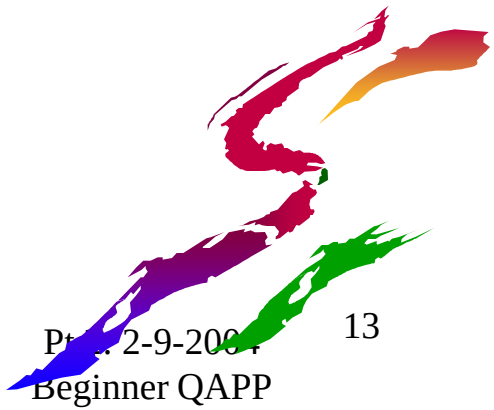
- ✓ Summarize tasks that will be performed, the data that will be collected, and the reports that will be generated.
- ✓ Define the boundaries of the study including geographical, budgetary or seasonal.
- ✓ Provide maps and/or tables to identify geographic locations of field tasks.
- ✓ Provide timeline, either graphical or tabular, of scheduled activities and delivery of reports.

# Quality Objectives and Criteria

- ✓ Describe how "good" the data (data quality) need to be to support the scientific conclusions and/or decisions for your project.

- ➢ Data quality is defined in terms of the degree of precision, accuracy/bias, sensitivity, representativeness, comparability, and completeness needed for your study. Refer to EPA New England QA Glossary for definitions website: http://epa.gov/ne/lab/qa/index.html

- ➢



# Quality Objectives and Criteria (cont.)

- ✓ Provide a table of QC samples and tasks for each environmental parameter and the performance criteria that must be met for precision and accuracy/bias.

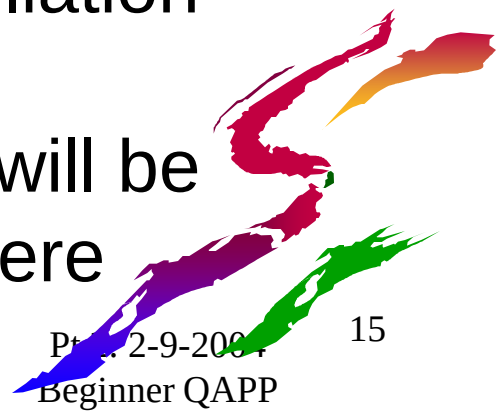
- ✓ Determine the level of sensitivity you must achieve to assess whether contamination exists at a critical level. Provide a table of quantitation limits for each environmental parameter. Make sure your laboratory can achieve these limits.

**Remember:** If you need assistance in determining the level of quality needed for your project, contact the Region 9 EPA QA Unit.

# Special Training/Certifications

- ✓ List any special or non-routine training or certifications needed by personnel to conduct project activities. Provide information in a table with the following headings:
  - -Project Activity
  - -Specialized Training Title of Course (or description)
  - -Training provided by
  - -Training date
  - -Personnel/Groups receiving training (e.g. volunteer monitors) and their organizational affiliation

- ✓ Describe how and by whom this training will be provided and documented and indicate where the records will be kept.



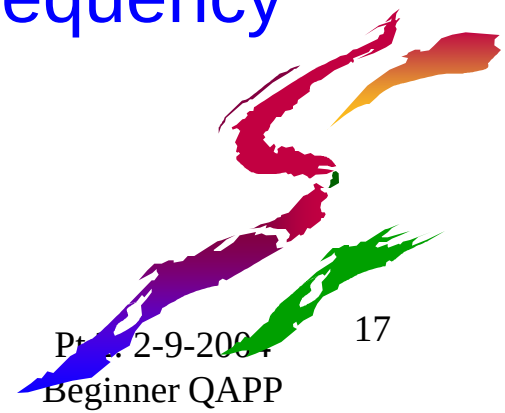
# Documents and Records

- ✓ List all the records and documents that will be created during the project and describe which ones will be kept, how long they will be kept, and where they will be kept.
- ✓ Itemize the contents of the laboratory report package. It should include:
  - ✓ field samples results
  - ✓ QC samples results (blanks, spikes, duplicates, etc.)
  - ✓ description of data qualifiers that laboratory applies to sample results
  - ✓ narrative describing issues and problem resolution during analysis
  - ✓ chain-of-custody records
  - ✓ raw data, copies of logbook information

# 2. Data Generation and Acquisition

The elements of this section include:

1. Sampling Process Design
2. Sampling Procedures
3. Sample Handling and Custody
4. Analytical Procedures
5. Quality Control
6. Instrument/Equipment Testing, Inspection and Maintenance
7. Instrument/Equipment Calibration and Frequency
8. Inspection/Acceptance of Supplies
9. Secondary Data
10. Data Management



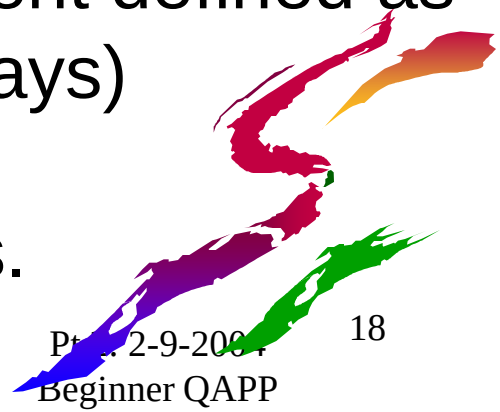
# Sampling Process Design (Experimental Design)

✓ Explain why the sampling locations, environmental parameters and matrices were chosen.

✓ Describe the sampling design for the project including:

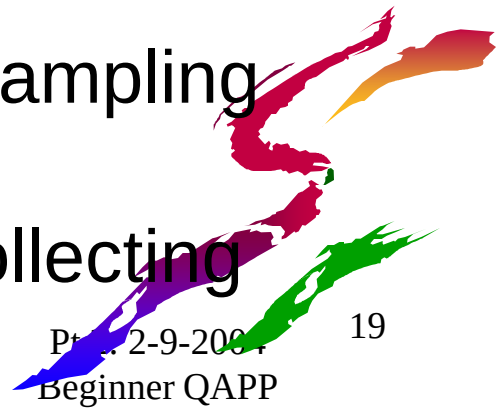
- sampling locations and directions to them
- frequency of sampling at each location
- matrices to be sampled
- environmental parameters of interest in each matrix
- any design assumptions (e.g. storm event defined as "X" inches of rain after "Y" number of dry days)

✓ Include maps that detail sample locations.



# Some things to consider in developing your sampling design:

- What are the standards or action levels against which the data will be compared? For example, do you need to determine whether water quality criteria are exceeded?
- Is the sampling matrix homogenous or heterogeneous? For example, are you sampling a well-mixed stream?
- Do you care about average contamination levels, hot spots, or the proportion of site contaminated?
- Will composite samples or grab samples be collected?
- Are you looking for trends over time?
- Are you using a statistical or judgmental sampling design?
- Will there be a reference site? Are you collecting background samples?



# Sampling Procedures

- ✓ Describe procedures, or include written SOPs as attachments to the QAPP, for:
  - -sample collection including preparation of sample containers, sample volumes, preservation and holding times
  - -sample packaging, labeling and shipping
  - -equipment preparation
  - -decontamination and disposal of waste by-products

- ✓ Describe how problems (lost samples, broken equipment, inaccessible sampling locations, etc.) will be resolved and documented.

# A word about Standard Operating Procedures (SOPs)

- Written SOPs describe an organization's procedure for doing a specific task. Unlike published methods, SOPs are specific to one organization.
- EPA R9 strongly encourages the development of SOPs because they provide consistency from one user to the next and, once written, can be used by the organization for multiple projects.
- When referencing SOPs always cite the title, revision date and/or number, author, organization, and indicate if, and how, the SOP will be modified for the project.

- See Speaker Notes for guidance on writing SOPs

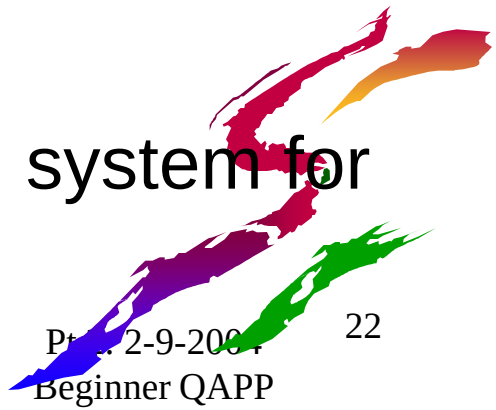
# Sample Handling and Custody

✓ Describe how samples will be handled in the field, during transport and in the lab. Identify responsible persons.

✓ Specify chain-of-custody (C-O-C) procedures that will be used to ensure samples don't get lost, mixed up, or tampered with. Provide examples of a sample label and C-O-C forms
and other documentation.

✓ Describe sample numbering/identification system for field samples and laboratory.

✓Attach applicable SOPs.



# Analytical Procedures

- ✓ Describe sample preparation and analytical procedures for field techniques and laboratory methods. Reference standard methods and attach SOPs. Detail any project-specific modifications to analytical methods and SOPs.

- ✓ List laboratory quantitation limits (reporting limits) to ensure project sensitivity requirements will be met.

- ✓ Include the Laboratory QA Manual.

- ✓ Describe how problems (lost samples, inability to meet required quantitation limits, holding time exceedances, etc.) will be resolved and documented.

# Quality Control - *Field*

✓ Provide a table listing the QC samples for each sampling matrix (e.g., water, soil) and environmental parameter (pH, phosphorus, etc.). The table should include:

- Type of QC sample (field duplicates, split samples, Performance Evaluation Samples, and trip, equipment and cooler temperature blanks) Refer to EPA New England QA Glossary for definitions:

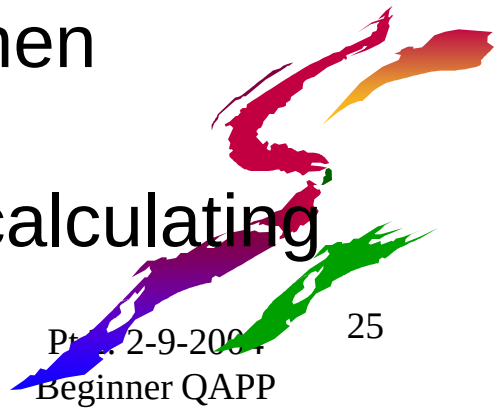
  website: http://epa.gov/ne/lab/qa/index.html

- Frequency
- Acceptance criteria (control limits)
- Corrective actions that will be done when acceptance criteria are exceeded

✓ Include procedures and formulas for calculating QC data.

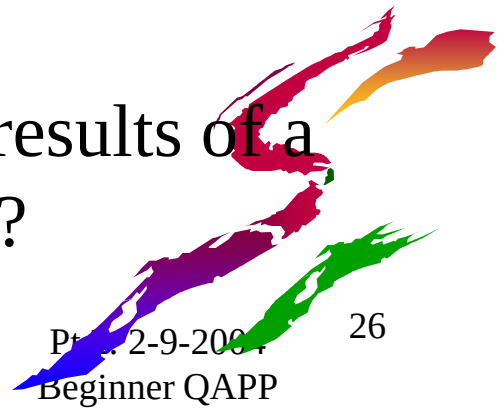
# Quality Control – *Field Measurement/Laboratory*

- ✓ Provide a table listing the QC samples for each analytical method, for each matrix and for each measurement parameter. The table should include:
  - Type of QC sample (lab duplicates, matrix spikes, Performance Evaluation Samples, method blanks, surrogates, etc.) Refer to EPA NE QA Glossary for definitions: http://epa.gov/ne/lab/qa/index.html
  - Frequency
  - Acceptance criteria (control limits)
  - Corrective actions that will be done when acceptance criteria are exceeded.
- ✓ Describe procedures and formulas for calculating QC data.



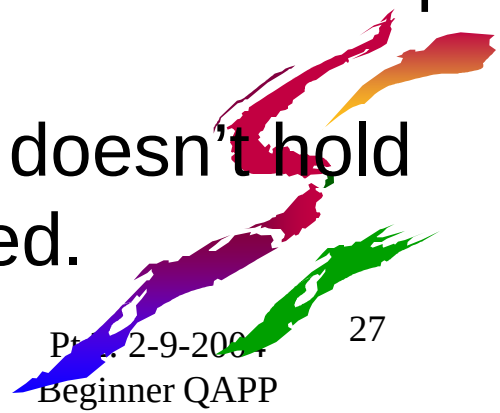
# Some things to consider when reviewing QC sample results:

- What will you do if contaminants are found in a “blank” sample?
- What will you do with sample results that do not compare with previously collected data and appear to be incorrect?
- What will you do with sample results if the instrument was not calibrated correctly?
- What will you do when duplicate sample results aren’t comparable? What will you consider the range of comparable results to be?
- What will you do with sample results when a spiked compound is not recovered? Or the results of a performance evaluation sample are inaccurate?



# Instrument/Equipment Testing, Inspection, Maintenance and Calibration

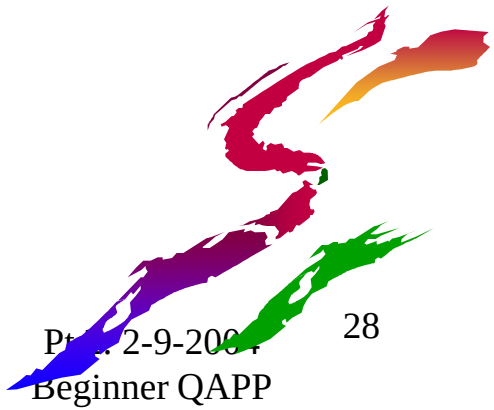
- ✓ Identify equipment and instrumentation (both field and laboratory) requiring calibration and periodic maintenance, inspection and testing.
- ✓ Describe how often the instrument needs to be calibrated and maintained and who will perform and document these tasks.
- ✓ Describe the calibration and testing procedures and acceptance criteria (control limits) for operation.
- ✓ List the spare parts needed to be kept on hand to keep the instrument operational.
- ✓ Describe how problems (e.g., instrument doesn't hold calibration) will be resolved and documented.
- ✓ Attach applicable SOPs.



# Inspection/Acceptance for Supplies

- ✓ Itemize all supplies that may directly or indirectly affect the quality of the data you are collecting (e.g., sample containers, collection devices).

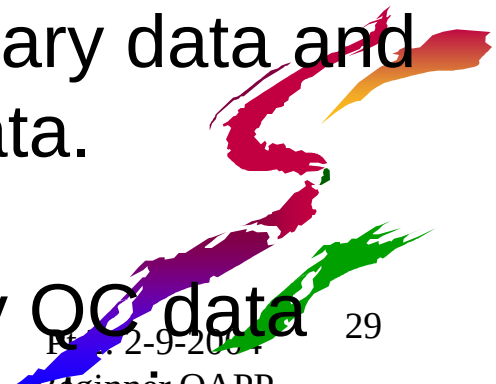
- ✓ Identify the project personnel responsible for inspecting and accepting project supplies.



# Secondary Data
## (a.k.a Non-Direct Measurements)

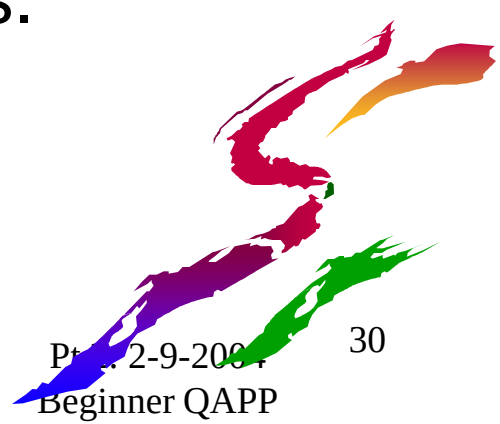
- ✓ List the types of secondary data (data generated for another project or purpose) that that will be used for your project:
  - -historical data or studies
  - -compliance data
  - -information from public databases
  - -photographs
  - -literature files
  - -weather data
- ✓ Describe the intended use of the secondary data and discuss any limitations on the use of the data.

- ➢ Minimally, discuss whether there are any QC data associated with the secondary data to characterize



# Data Management

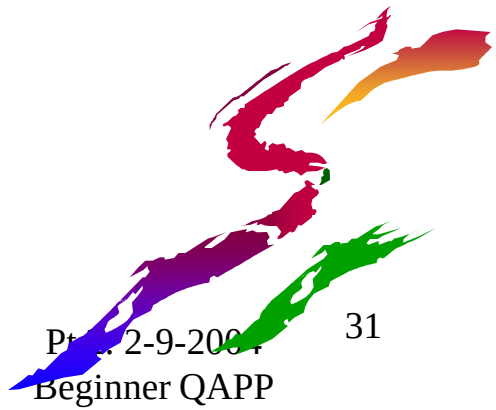
- ✓ Describe how data (both hard-copy and electronic) will be managed from the time they are generated in the field to final report and storage.
- ✓ Discuss methods and equipment for detecting/correcting errors, and preventing data loss. Describe how computer outputs will be checked.
- ✓ Identify who's responsible for these tasks.
- ✓ Attach applicable SOPs.



# 3. Assessment and Oversight

The elements in this section include:

1. Assessments and Corrective Actions
2. Project Reports



# Assessments and Corrective Actions

- ✓ Discuss how you plan to ensure that the project will be conducted as described in the QAPP.

- ✓ Describe any oversight activities and/or assessments that will be performed, approximate timeframe, and person responsible.

- ✓ Identify who will receive a report of the findings and who will be responsible for corrective actions and follow up.

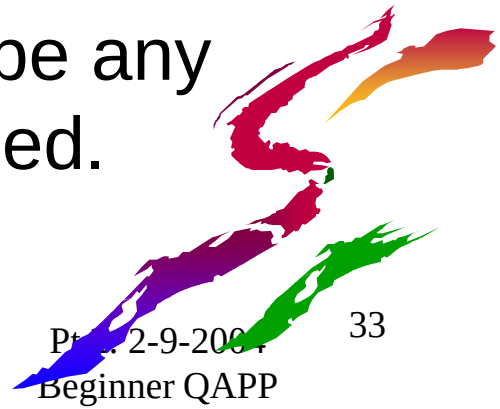
- ➢ Minimally, the Project Manager should schedule one review of field activities at the beginning of the project to ensure that all personnel are trained and that the right equipment is in place.

# Project Reports

- ✓ Describe the type and number of reports that will be generated for the project.

- ✓ Identify who is responsible for preparing the reports and the recipients for each report.

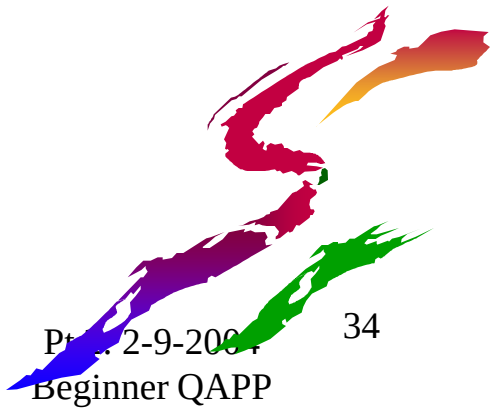
- ➢ Minimally, a ***final project report*** should be written and provided to the EPA Project Officer. This report should analyze and interpret data, present observations, draw conclusions, identify data gaps, and describe any limitations in the way the data should be used.



# 4. Data Review and Evaluation

The elements in this section include:

1. Step 1: Verification
2. Step 2: Validation Procedures
3. Step 3: Evaluating Data in Terms of User Needs



# Review Step 1: Verification

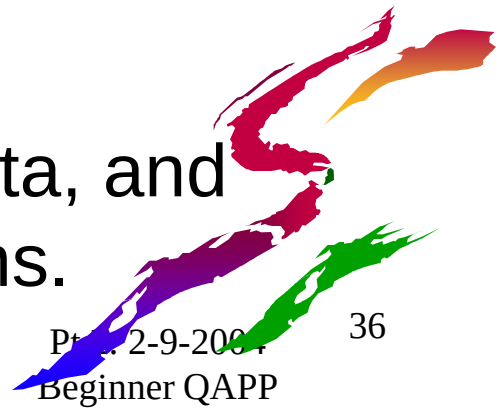
- ✓ Describe how data will be checked to ensure that they are complete and were generated according to the methods and procedures specified in the QAPP.

- ✓ Describe steps taken by the laboratory to qualify sample results. Include qualifiers that the laboratory will apply when data do not meet laboratory QC acceptance limits.

- ✓ Discuss how issues will be resolved, documented and reported and the personnel responsible for these tasks.

# Review Step 2: Validation Procedures

- ✓ Describe how sample results will be accepted, rejected or estimated based on quality control acceptance criteria.
- ✓ Define the data qualifiers that will be applied to the data (e.g., U=not detected, J=estimated, R=rejected).
- ✓ Attach or refer to written data validation procedures, if used.
- ✓ Identify the individuals who will review data, and resolve and document data quality problems.

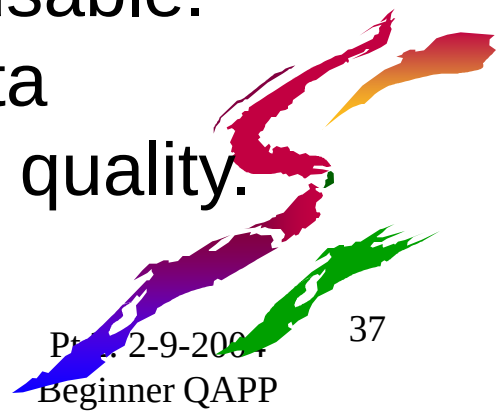


# Step 3: Evaluating Data in Terms of User Needs

- ✓ Describe how the results of the study will be analyzed and evaluated to determine whether the needs of your project were met and then reported.

- ✓ Include mathematical and statistical formulae that will be used to calculate precision, accuracy/bias, completeness, comparability of the project data.

- ✓ Describe what will happen if data are unusable. Remember, anything that compromises data representativeness ultimately impacts data quality.

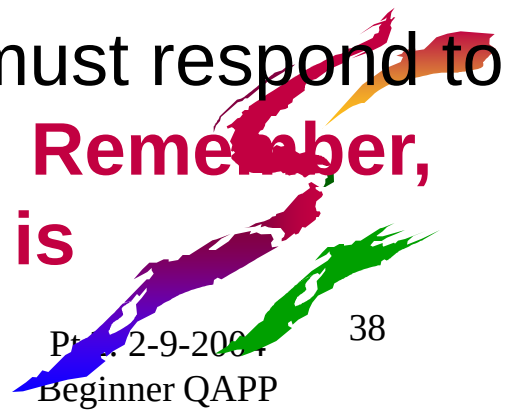


# Once I finish writing my QAPP what should I do?

- ✓ Have someone else in your organization review the QAPP for accuracy and content.

- ✓ At least 30 days in advance of sampling, submit one copy of the QAPP (electronic or hard copy) to each of the following:
  1. Regional QA Manager
  2. EPA Project Officer

- ➢ If EPA has comments on the QAPP, you must respond to the comments before it can be approved. **Remember, sampling cannot begin until the QAPP is approved by EPA.**



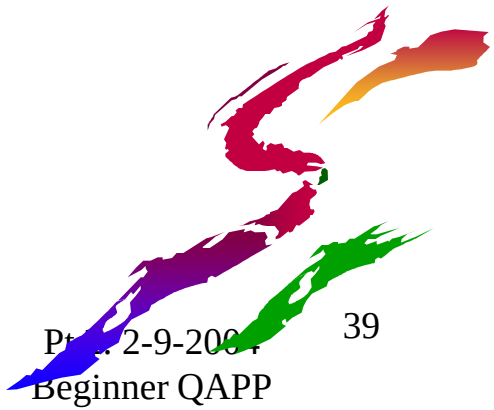
# Once my QAPP is approved can I modify it?

- **Yes.** If major modifications must be made in order to meet the objectives of the project, then amendments to the QAPP should be submitted to the EPA Regional QA Manager and EPA Project Officer for review and approval prior to the change being made. (e.g., change in scope of sampling design and analytical methods).

- Approvals for minor changes are not required.

- If you are unsure if a change constitutes a major or minor modification, contact the QA Unit.

- For on-going projects, the project manager may obtain verbal approval for changes from EPA and then document the change in a follow up letter.



# My project will continue for more than one year. Do I need to write a new QAPP every year?

**No.** Your QAPP will be approved for the length of time stated in the QAPP, for up to five years.

However, the QAPP should be reviewed annually and this review should be documented in a letter to the EPA Region 9 QA Manager and EPA Project Officer.

# I've finished this training, is this all I need to know about QAPPs?

**Not necessarily.**

This training was designed to provide the beginner with an overview of the information they'll need to include in the QAPP. However, just as each project is different, each QAPP will be different too. For some projects, you may need to refer to other QAPP guidance documents for additional information.

And don't forget to give the EPA New Region 9 QA Unit a call if you have any questions!