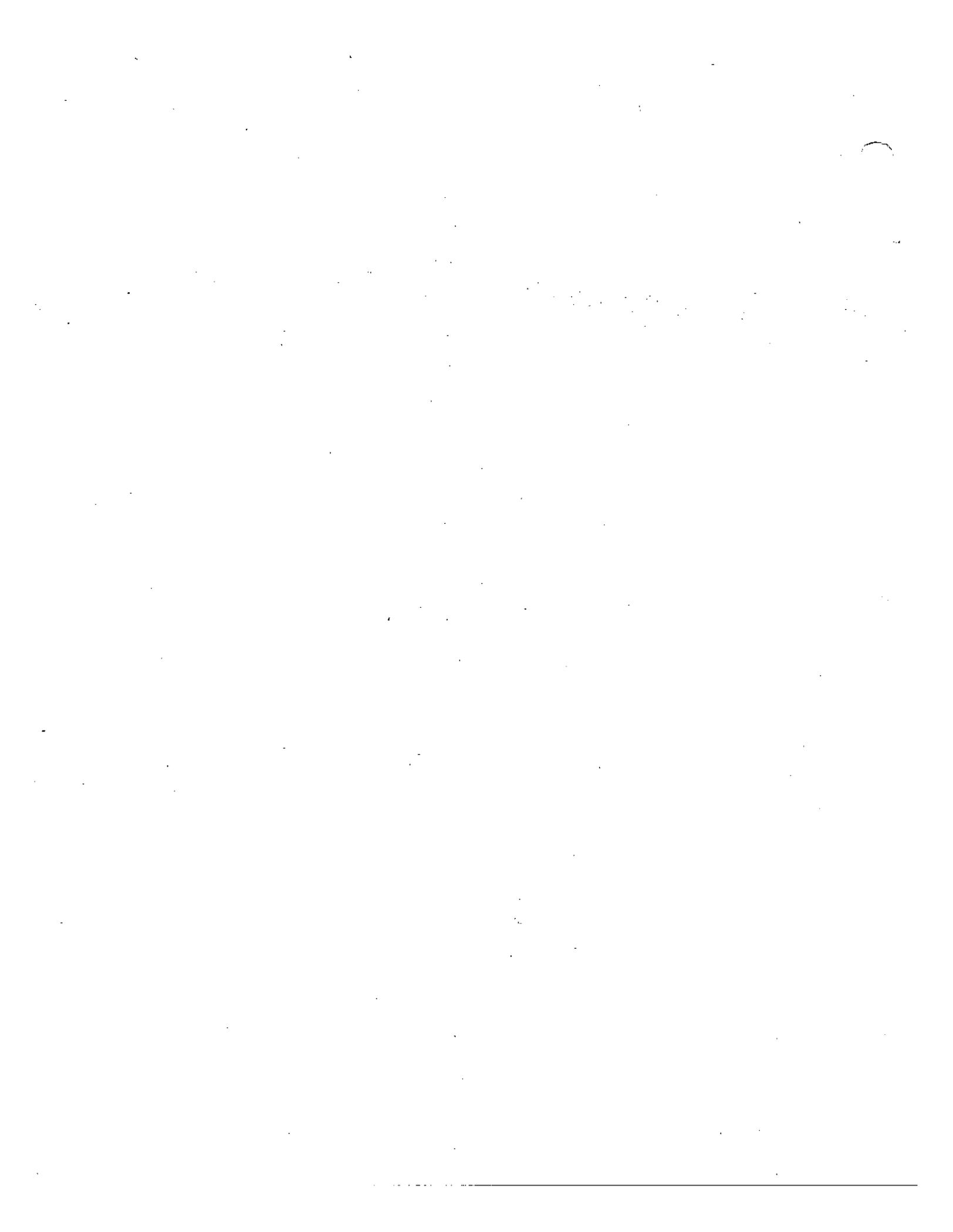




Quality Assurance Handbook for Air Pollution Measurement Systems

**Volume I: A Field
Guide to Environmental
Quality Assurance**



**Quality Assurance Handbook
for
Air Pollution Measurement Systems**

**Volume I – A Field Guide to
Environmental Quality Assurance**

1993

**by
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Office of Research and Development
Atmospheric Research and Exposure Assessment Laboratory
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OVERVIEW OF THE INTERIM EDITION OF VOLUME I

The Quality Assurance (QA) Handbook is comprised of five volumes: Volume I (Principles), Volume II (Ambient Air Methods), Volume III (Stationary Source Methods), Volume IV (Meteorological Measurements), and Volume V (Precipitation Measurement Systems). Much of the material in Volumes II, III and V are out-of-date and some portions of these volumes have long been out-of-print.

EPA is now preparing an updated version of the QA Handbook series which will be available in September 1995. To meet the needs of the user community until the updated version is available, EPA has published Interim Editions of Volumes I, II, III, IV and V. Each volume of the Interim Editions, is being issued as a complete unit with out-of-date sections either deleted or modified using addendum sheets and handwritten notations in the text.

This volume and the other four volumes of the Interim Edition of the QA Handbook are available at no charge from:

USEPA/ORD
Center for Environmental Research Information
26 West Martin Luther King Drive
Cincinnati, Ohio 45268

Since this volume was updated in 1993, only minor changes will be done to it in the updating process. The updated version will be available in September 1995.

The user of the QA Handbook is cautioned to bear in mind that the information provided in the handbook is for guidance purposes only. EPA regulations are published in the Code of Federal Regulations (CFR). When information in the CFR conflicts with information in the QA Handbook, the CFR shall be considered the authoritative and legally bonding document.

William J. Mitchell
Chief
Quality Assurance Support Branch

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This completely new version of Volume 1 of the *Quality Assurance Handbook for Air Pollution Measurement Systems* was prepared by Dr. Monica Nees under three affiliations. First, as a chemist enrollee of the Senior Environmental Employment program of NCBA and the U.S. Environmental Protection Agency (EPA), she developed the initial drafts under the direction of Dr. Bill Mitchell, Chief, Quality Assurance Support Branch, Atmospheric Research and Exposure Assessment Laboratory, U.S. EPA, Research Triangle Park, North Carolina. Then, as a senior scientist at ManTech Environmental Technology, Inc., Research Triangle Park, North Carolina, she completed work for publication under the direction of Kenneth J. Caviston, Supervisor, Quality Assurance and Other Support, under EPA contract 68-DO-0106 .

DISCLAIMER

This document has been reviewed in accordance with the U.S. Environmental Protection Agency's peer review policy and has been approved for publication. Mention of trade names or commercial products does not constitute EPA endorsement or recommendation for use.

FOREWORD

Throughout the world, air quality is a critical concern. In the United States and Canada, air monitoring is not the responsibility of just the federal governments. States and provinces, local governments, private industries, and environmental organizations are also participating. Elsewhere, especially in those countries in which air quality is beginning to be addressed, national governments are the principal monitors.

The purpose of these monitoring efforts is not to collect data, because data are only the beginning, not the end, of environmental investigations. Data should not be stored and forgotten, but should be used to make informed decisions affecting the health and well-being of planet Earth. Application of the principles of quality assurance allows decision makers to know the quality of the data on which their actions are based.

William Zinsser in his book *On Writing Well* calls the instructional manual "one of the most forbidding swamps in the English language." I hope that this field guide is not. It focuses on the fundamentals that transcend national borders, academic disciplines, and even specific environmental media. Like a field guide used in birdwatching, it does not tell everything, but only the most important things. It is designed to be used in the field or laboratory, not stored on a shelf. And, although the examples are chosen from air monitoring, the principles can readily be applied to any type of environmental monitoring.

This field guide does *not* give detailed instructions for preparing a quality assurance plan. Instead, it emphasizes the thought processes and rationales for designing any good data collection program with quality assurance as an integral part. Once this occurs, preparing a quality assurance plan using the format specified by any sponsoring organization will be straightforward.

Monica Nees
1993

HOW TO USE THIS FIELD GUIDE

This field guide replaces *Volume I, Principles*, of the *Quality Assurance Handbook for Air Pollution Measurement Methods*, first published in the late 1970s and updated in 1984. Using a common-sense approach, it explains the unifying concepts underlying all environmental quality assurance, in about one-tenth the number of pages of its predecessors.

Such a massive reduction was possible by the elimination of duplication of numerous definitions, examples, appendices, and details also found in Volumes II through V of the handbook. Then the basic principles could be revealed and studied. Once the user understands the principles, he or she can consult the other volumes for necessary details. *Volume II, Ambient Air Specific Methods*, for instance, includes both a lengthy introductory chapter on quality assurance for ambient air methods and detailed guidance on nearly a dozen individual test methods.

By design, the field guide covers only the "Big Picture." Written for a broad audience, it is intended for use both by field and laboratory personnel and by their managers in planning all aspects of environmental data collection. Its sections cover all phases of the life cycle of any such project, from planning through final report writing. Throughout, the importance of planning is stressed again and again. Each section is self-contained, for ease in future reference. The best way to use the field guide, however, is first to read it completely to get an overview and then to consult individual sections as needed.

By applying the principles described in the field guide to his or her own projects, the user will make certain that all data collected will meet project needs. Because that data will be of known and documented quality, others will be able to use it with confidence too. And that is what quality assurance is all about.

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SECTION 1

PLANNING AND ORGANIZATION

Projects brilliantly conceived will not be brilliantly executed without good planning and organization. Project success depends on the leadership and organizational skills of the project manager. The manager not only must know what needs to be done, but also must share that knowledge so that all staff members understand precisely how they fit into the "Big Picture."

1.1 PROJECT DESCRIPTION

A detailed project description forms the basis for all other planning and organizational activities. The critical personnel and resource needs should arise from the project description – and not the other way around.

The project manager and other key personnel jointly develop the project description, which must contain the following six components.

- **What is going to be done**
- **Why it is necessary to do it**
- **Who will do it**
- **How it will be accomplished**
- **Where it will be done**
- **When it will be carried out**

Unless all six are addressed in test and quality assurance (QA) plans, the project description is incomplete and subject to misinterpretation. Section 2 describes these components in more detail, in the context of reports required before, during, and after data collection.

1.2 ORGANIZATIONAL CHART

A clearly presented organizational chart is one of the most important products of the planning process because it names all key individuals in charge of every major activity of the project. Figure 1-1 shows a simple organizational chart. If possible, the names of all team members should be included; those of all supervisors must be.

All subcontractors must be listed too, with clear lines of reporting, to prevent the all-too-common "floating subcontractor syndrome."

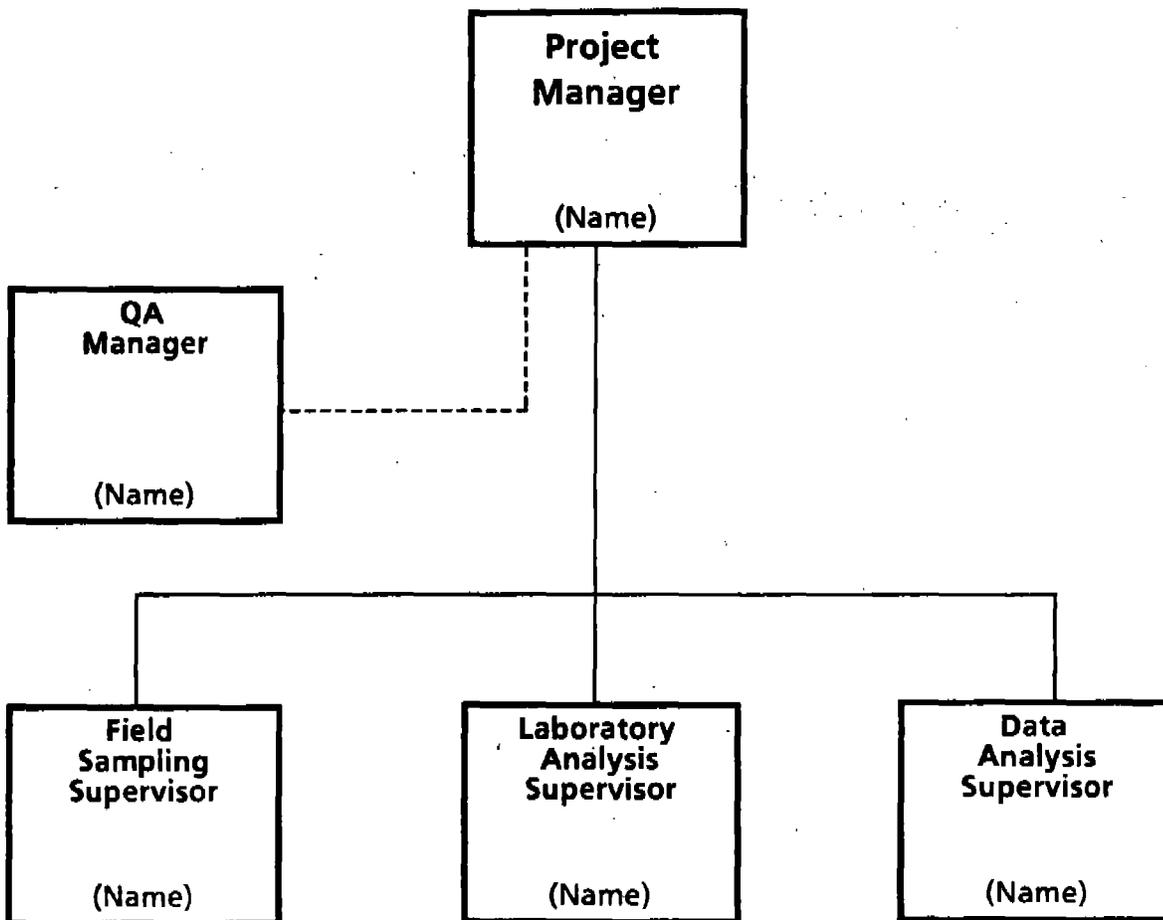


Figure 1-1. Example of Organizational Chart

Because the QA manager must be able to give completely unbiased advice on data quality to the project manager, he or she should be organizationally independent of the project manager and all other data collection and handling personnel. This special relationship is shown by a dotted line on the organizational chart.

1.3 JOB DESCRIPTIONS

Rather than list job responsibilities for each and every conceivable position, this section examines the responsibilities of only two, the project manager and the QA manager, in some detail. Not every project will have a laboratory supervisor, for

instance, because it may entail only analysis of data already collected. But every project will have a manager and a QA manager, even if they are one and the same person on small projects.

1.3.1 Project Manager

Like the captain of a ship, the project manager is ultimately responsible for everything that happens in his or her project, including the QA necessary to achieve the data quality required by the project's sponsor. The manager's primary responsibilities are liaison with the sponsor, planning, budgeting, staffing, and overall coordination and review. Just as no one would expect a ship's captain to perform every operation on board, no one expects the project manager to do everything single-handedly. That is why a staff is hired. Frequently, the project manager appoints a QA manager for assistance in developing and implementing the QA/quality control (QC) needed to achieve the required data quality. The ultimate responsibility for QA/QC, however, as for any other project function, still resides with the project manager.

1.3.2 Quality Assurance Manager

Two definitions will help in understanding the duties of the QA manager:

QUALITY CONTROL is everything **YOU** do to make certain that your project is performing "up to specs."

QUALITY ASSURANCE is everything you have **SOMEONE ELSE** do to assure you that your QC is being done "according to specs."

Thus, if the same individual who performs the work also does the checking for quality, that checking is quality *control*. Running duplicate samples in the laboratory is a common QC procedure. If a *different* individual does the checking, that is an example of quality *assurance*. A project review by auditors from another company is a typical QA activity.

A review, however, need not be performed by a different company; more commonly, it is done by the QA manager within the same organization but completely independent of the data-collecting staff. The QA manager protects the project manager from poor quality data that do not fulfill project needs. Thus, anything that affects data quality comes under the purview of the QA manager.

Most of the activities of a QA manager involve the review of project activities and the preparation or review of reports. The mix depends on the wishes of the

project manager. Frequently, the QA manager is assigned to prepare the QA plan, review all other documents generated during the project, and carry out other tasks specified by the project manager.

The following sections describe various project functions in detail: reports; standard operating procedures (SOPs); preventive maintenance; sample collection, handling, and analysis; data collection and handling; audits; and corrective action. Because all impact on data quality, all must be addressed by the QA manager.

Not addressed in these sections, however, is one other important function often assigned to the QA manager, that of training coordinator. Everyone must be trained well enough to produce the highest quality of data needed by the project.

A common mistake is to provide training only for field and laboratory personnel, while neglecting the clerical staff and managers. Anything that affects data quality is a suitable topic for training. Thus, the clerical staff must be trained continuously to take full advantage of the ever-changing enhancements in word processing systems and managers need training on topics ranging from financial information systems to handling personnel problems.

Hiring staff with appropriate formal education is only the first step in building a competent team. Next comes on-the-job training under the guidance of a knowledgeable mentor who teaches the skills and nuances specific to the particular task and organization. Short courses, both on-site and off-site, develop well-defined sets of skills in a specific area. Formal courses at a college or university give a more in-depth mastery of a subject.

A combination of training activities will be needed for most projects. Some form of training will be needed for someone throughout the life of the project.

SECTION 2

PLANS AND REPORTS

Anyone "allergic" to writing anything on paper will not thrive in environmental data collection. Sponsors and supervisors require a steady stream of reports, from before a project begins until after it is completed. Writing a good report is not that much different from writing a good newspaper article. Both processes concentrate on the six key principles of **Who, What, Where, When, Why, and How**, but the relative emphasis given to each depends on where the report fits into the life cycle of the project.

Rare, indeed, is the project that spawns only one report; instead, many different types are usually produced. The beginning of data collection in the field or laboratory is the benchmark. Planning documents are written before data collection begins, progress reports while it is under way, and final reports after it is completed. Nobody wants to read a report that is too long and incoherent. Applying the six principles can prevent such a report from ever being written. The best "mix of the six" depends on whether the report comes before, during, or after data collection.

2.1 BEFORE DATA COLLECTION

The most important project reports are those written before the first piece of data is collected. These planning documents include all six principles, but the most important are **Who, What, and How**. They specify, by name, **Who** is in charge of **What** part of the project and **How**, in detail, the work will be accomplished. Each and every part must be included because success of the project depends on how well all of the parts fit together. A simple organizational chart is mandatory. If the relationships are difficult to draw, they will be even more difficult to execute.

Examples of typical planning documents include the following.

- Data quality objectives reports
- Work or test plans
- Quality assurance plans
- Site selection, sampling, and analytical procedures (if not included in the work plan)
- Standard operating procedures

- Data handling protocols
- Corrective action plans
- Others, as necessary

Although **Who**, **What**, and **How** predominate, **Where**, **When**, and **Why** cannot be neglected. Geographical location (the **Where**) can be a critical variable in field work. The **When** includes not only the specific hours, days, months, or years of project duration but also such important topics as seasonal and diurnal variations.

Although the **Why** is more subtle than the other principles, knowing **Why** the data have to be collected is critical to the success of any project. The reason is quite simple: data must be collected for a purpose. Different purposes require different data collection plans. Project planners can devise the best one only if they know the end uses of the data. Planning documents must clearly state the purposes behind data collection, so that both current and future users understand the limitations on using the data for decision making. They also establish the competence of the project team to do the job right the first time, on time, and within budget. They describe what is anticipated and thus serve as yardsticks by which to measure progress.

The QA manager reviews and approves the QA plans, which include key sections from many other planning documents, but the project manager must sign off on all documents. Although each staff member is responsible for the quality of his or her part of the project, the project manager is responsible for the quality of the entire undertaking.

2.2 DURING DATA COLLECTION

Progress reports, the most commonly written reports during the data collection phase of a project, continuously answer the question, "How are we doing?" The standards used are the ones previously stipulated in the planning documents. Audit reports and corrective action reports are also prepared in this phase. Audits, whether performed internally or by outside organizations, assess **What** is being done and **How** well. Whenever corrective action is taken, the report describes **What** the problem was and **How** it was solved.

2.3 AFTER DATA COLLECTION

If planning and progress reports are well prepared, writing the final report should not be an overwhelming burden. Its purpose is to summarize and analyze –

to say **What** happened and **Why**, but not to meditate on every single data point. Appendices and references to earlier reports can take care of that.

The final report, which frequently mirrors the test or work plan in sequence and approach, covers all six principles. It is also a self-audit, assessing **How** well the standards spelled out in the planning documents were met, and clearly explaining any limitations on data use for both present and future users. This careful analysis in a final report for one project may also serve as a springboard to a new one in which currently unresolved problems may be solved.



SECTION 3

STANDARD OPERATING PROCEDURES

When should a manager decide that an SOP needs to be written? The answer is deceptively simple: as soon as the procedure becomes standardized – and not before. The argument that no procedure is ever standardized, however, is used all too frequently only to avoid putting anything on paper.

Although the time and effort spent in preparing an SOP can be significant, there are important long-term benefits. No longer will the same procedure have to be described again and again in test plans, QA project plans, audits, and other reports. Instead, it can be incorporated by reference, with a copy attached to the report. But saving data, not merely saving time, is the main reason for preparing an SOP. Data collected using fully documented procedures have much higher credibility and defensibility. Because well-written SOPs focus on routine operations, their users can concentrate primarily on nonroutine problem solving.

3.1 PURPOSE

An SOP is written so that the procedure will be performed consistently by everyone, every time. Deciding whether a particular procedure is a candidate for an SOP is helped by answering two questions:

- Does the procedure significantly affect data quality?
- Is the procedure repetitive or routine?

Preparing an SOP is indicated if the answer to both questions is YES.

Targeting the proper audience can be the most difficult task. Obviously, the SOP should be written at a level of detail appropriate to the end users. If backgrounds of the users are unknown, target the SOP for a "new hire," a technician with at least two years of college and one year of experience in the appropriate field. This approach usually ensures that the SOP has enough detail without becoming overwhelming.

Few routine laboratory or field projects can be described completely in just one SOP. Several will be needed, and deciding how best to divide the topics will take careful planning. In general, an SOP for each of several smaller segments is much better and easier to write than one large SOP for an entire operation.

3.2 CONTENTS

Table 3-1 shows a suggested format for an SOP, including numerous examples of items that could be included in each section. The examples shown are only a few of the many that could be covered, depending on the particular procedure. Occasionally, deciding whether an item belongs in one section or another can be a problem. The important thing is to put it somewhere, rather than leave it out.

TABLE 3-1. SUGGESTED FORMAT FOR A FIELD OR LABORATORY STANDARD OPERATING PROCEDURE

A. TECHNICAL SECTIONS	
Section	Typical Examples
1. Scope and Application	Overview outlining purpose, range, sensitivity, acceptance criteria
2. Summary of Method	Overview describing sampling criteria and analytical methods, method and instrumentation detection limits, reasons for deviations from <i>Federal Register</i> methods
3. Definitions	All acronyms, abbreviations, specialized terms
4. Interferences	Sources of contamination
5. Personnel Requirements	Educational level and training of intended SOP users, number of operators required
6. Facilities Requirements	Mobile analytical laboratory, air conditioning, types of electricity, fume hood
7. Safety Precautions	Types of respirators, carbon monoxide monitors, special handling procedures; hazard warnings, placed immediately BEFORE relevant part of text
8. Apparatus	Larger items such as a meteorological tower, audit device, pH meter, gas chromatograph
9. Reagents/Materials	<i>All</i> chemicals used, including distilled or deionized water; grades of reagents; materials include smaller items such as filter paper, boiling chips, tubing, electrical wiring

(continued)

TABLE 3-1. SUGGESTED FORMAT FOR A FIELD OR LABORATORY STANDARD OPERATING PROCEDURE (Continued)

A. TECHNICAL SECTIONS	
Section	Typical Examples
10. Samples/Sampling Procedures	Sample preparation, collection, storage, transport, and data sheets
11. Calibration/Standardization	Preparation of standards and standard curves, frequency and schedule of calibrations
12. Analysis Procedures	Standard and custom-tailored methods for all analytes in all matrices
13. Calculations	Data reduction, validation, and statistical treatment, including confidence levels and outliers
14. Data Reporting	Selection criteria, format, equations, units
15. Corrective Action	Criteria for initiation; individuals responsible
16. Method Precision and Accuracy	Tabular or narrative summary
B. QUALITY CONTROL SECTIONS	
Section	Typical Examples
1. QC Checks	Precision, accuracy, repeatability, reproducibility, blanks, spikes, replicates, selection criteria, and frequency summarized in tables
2. QC Controls	Audits, notebook checks, blind samples; control charts and graphs; actions to be taken when QC data approaches or exceeds QC limits
C. REFERENCE SECTION	
Standard reference methods, reports, SOPs, journal articles; avoid citing unpublished documents	

3.3 HOUSEKEEPING DETAILS

Once an organization commits to SOPs, many new SOPs will be prepared in the same length of time it took to do the first one. And, as refinements become available, older SOPs will need to be updated, preferably without having to rekey the entire text. A tracking system is a must in handling this ever-increasing workload.

Initially, a simple system shown in Table 3-2 will be sufficient. The title should be as specific as possible; generic titles such as "Atmospheric Monitoring" usually are too broad to be truly descriptive of the SOP.

TABLE 3-2. TRACKING SYSTEM FOR STANDARD OPERATING PROCEDURES

General Information	Specific Example
SOP Number	SOP-25
Title	Site Selection Criteria for Meteorological Monitoring at Heavily Forested Areas
Date	July 1, 1992

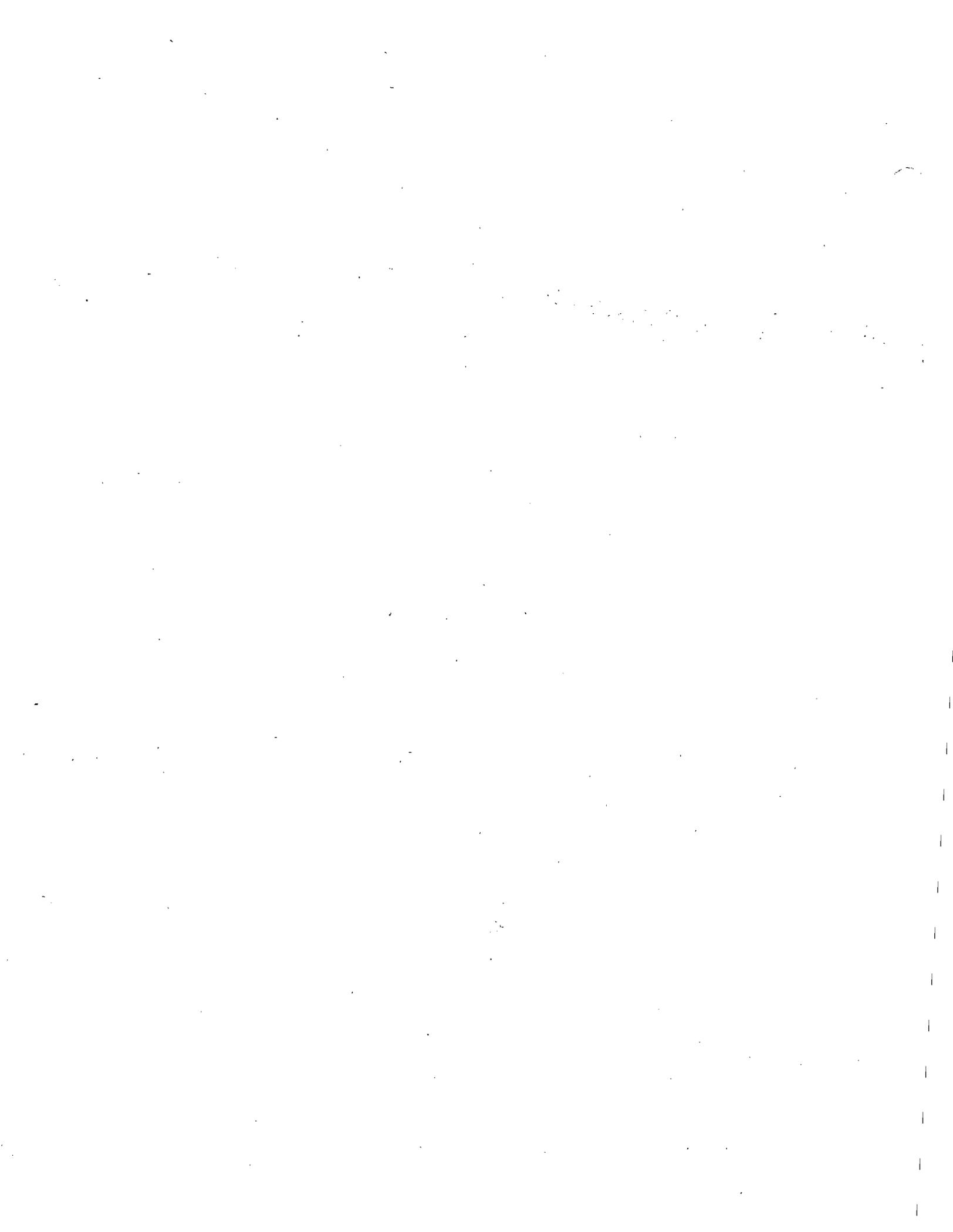
To accommodate later revisions, however, a more detailed "document control format" is frequently used for tracking documents from the very beginning of the SOP program. The information shown in Table 3-3 is placed on the upper right-hand corner of each page.

TABLE 3-3. DOCUMENT CONTROL FORMAT

General Information	Specific Example
SOP Number	SOP-25
Section Number	Section 3
Revision Number	Revision No. 1
Date of Issue	July 29, 1992
Page _____ of _____	Page 5 of 12

The original version is always labeled as Revision 0. If, for example, page 5 of Section 3 needs to be updated, the changes are made and issued as Revision 1, together with instructions to replace page 5 of Revision 0 with the new page 5 of Revision 1. Thus, the value of a ring-binder format becomes obvious.

A complete set of SOPs is stored for reference in one place, usually the office of the QA manager. The most important copies, however, are the dog-eared, coffee-stained ones in the field and laboratory; SOPs are meant to be used, not just filed.



SECTION 4

PREVENTIVE MAINTENANCE

Because breakdowns and repairs use up the time needed for preventive maintenance, buying reliable equipment is the best way to guarantee enough time for planned maintenance. Reliable equipment, which does the job right (almost) every time, has fewer breakdowns and requires less time for troubleshooting.

Several steps are involved in getting reliable equipment.

- Procurement: Ordering the "right stuff"
- Inspection: Checking that everything came in
- Control: Knowing its whereabouts at all times
- Testing: Proving it does what it should do
- Training: Teaching the operators how to use it

Once these steps are carried out, the equipment and the project should run smoothly, with little downtime for repairs.

Merely setting up a detailed schedule of preventive maintenance is not enough; actually *following* it is the critical step. Auditors pay particular attention to whether planned maintenance activities were indeed performed. Because individual air pollution and meteorological monitoring methods include detailed descriptions of required preventive maintenance, this section focuses only on features common to all methods.

4.1 EXAMPLES

Many types of preventive maintenance are needed to achieve good data quality. The following are only a few examples.

- Clean the sample manifold
- Replace vacuum pump filters
- Lubricate pump box blower motors
- Change data tape

Each activity by itself may seem insignificant, but, when coupled with dozens of others, the net result is a program with more reliable data, less downtime, and much less cost in dollars, time, and grief.

4.2 REQUIREMENTS

A good preventive maintenance program must include the following items.

- Short description of each procedure
- Schedule and frequency for performing each procedure
- Supply of critical spare parts on hand, not merely on a list
- List of maintenance contracts for instruments used in critical measurements
- Documentation showing that maintenance has been performed as required by the maintenance contract, QA project plan, or test plan

For convenience, summarize as much of this information as possible in tables.

SECTION 5
SAMPLE COLLECTION, HANDLING, AND ANALYSIS

At first glance, covering sample collection, handling, and analysis in one section sounds like a tall order. But because sampling and analysis share so many characteristics – calibration, contamination, and sample custody, to mention only a few – considering them as a unit is logical. Because other sections of the QA Handbook describe individual methods in greater detail, this one can examine the underlying principles common to all. These principles are first summarized in Table 5-1, then discussed briefly in the following sections.

**TABLE 5-1. PRINCIPLES OF SAMPLE COLLECTION,
HANDLING, AND ANALYSIS**

-
1. Select Sampling Sites Based on Data Quality Needs
 2. Understand the Reasons Behind the Procedures
 3. Use the Same Conditions for Standards and Samples
 4. Use Quality Control Checks and Standards
 5. Know Where the Samples Are and Be Able to Prove It
-

5.1 SELECT SAMPLING SITES BASED ON DATA QUALITY NEEDS

Although convenience and previous use are attractive features of any sampling site, the driving force behind site selection must be the data quality needs of the project. If a site cannot provide suitable samples, it is useless for the project. Once project needs are specified, a statistician should be consulted for help in site selection; sampling strategy; and the type, frequency, and number of samples required to attain the desired level of confidence in the results.

5.2 UNDERSTAND THE REASONS BEHIND THE PROCEDURES

All procedures should explain *why* certain steps are used, not just *how* to perform them. For example, here are only a few of many precautions taken to prevent contamination during the cleaning and handling of air monitoring equipment and samples: glass fiber, quartz, or Teflon filters are handled with

tweezers, not bare hands; clean cotton gloves, not surgical rubber gloves with potentially contaminating powder, are also used to handle the filters; dedicated or disposable glassware is used for standards; and glassware for anion analysis is not cleaned with soap, which could leave a residue containing anionic contaminants, but with multiple rinsings of deionized water. Similar explanations should be a part of all procedures, especially SOPs. The more reasons that are given, the more likely the procedure will be understood, appreciated, and followed.

5.3 USE THE SAME CONDITIONS FOR STANDARDS AND SAMPLES

Simple as this admonition sounds, it goes unheeded all too frequently in both field and laboratory. For example, suppose the expected concentration of an analyte is around 200 ppm. Even a careful calibration in the 0 to 20 ppm range is meaningless at the 10-fold higher concentration. Calibrations must be made over the full span of expected concentrations. Gas cylinders and regulators need to equilibrate for at least 24 hours to adjust for changes in temperature and altitude before being calibrated and used. Leak checks must be made under the same pressure to be used during data collection. Only when standards are subjected to the same treatment as the samples can meaningful data be obtained.

5.4 USE QUALITY CONTROL CHECKS AND STANDARDS

Quality control checks and standards show when the system is out-of-control and corrective action is needed. High-quality precision and accuracy data are derived from blanks, replicates, spikes, standards, and other QC checks. Calibration standards, which should be verified regularly, are also used throughout sampling and analysis. To avoid the possibility of being precise but not accurate, QC check samples should not be the same ones used for calibration standards.

5.5 KNOW WHERE THE SAMPLES ARE AND BE ABLE TO PROVE IT

Proof is especially important for high visibility projects where litigation is a distinct possibility. Strict sample custody procedures protect against losses, mixups, accidental contamination, and tampering. Although good sample labels, custody seals, and tracking sheets are essential for maintaining sample integrity, dedicated sample custodians are the most important factors. Chain-of-custody forms must be used for all sample transfers, not only between field and laboratory, but also from one field (or laboratory) group to another. Projects of lesser visibility also benefit from similar, though less stringent, procedures.

SECTION 6
DATA COLLECTION AND HANDLING

Entire books have been written on data collection, validation, reduction, analysis, storage, and retrieval, yet this chapter covers the same topics in only a few pages. How? By focusing on the fundamental principles common to many of these steps in the data-gathering process. These principles are first summarized in Table 6-1, then discussed briefly in the following sections.

TABLE 6-1. PRINCIPLES OF DATA COLLECTION AND HANDLING

-
1. Know Why the Data Must Be Collected
 2. Document Everything Thoroughly
 3. Calibrate Instruments and Test Software
 4. Preserve the Original Data
 5. Use Only Validated Data
 6. Use Tables or Graphs to Present Summary Statistics
 7. Leave Sophisticated Data Handling Techniques to the Statisticians
 8. Beware of Using Data Collected for Another Purpose
-

6.1 KNOW WHY THE DATA MUST BE COLLECTED

How data will be used dictates how they must be collected. Consider, for example, just a few of the many questions to be answered before beginning air monitoring studies: How many sites? Are all sites equally important, or are some more important than others? Will sampling be continuous or episodic? Over what time period? How many samples are needed? Statistical expertise is required to answer questions like these and to design a cost-effective data collection program that will yield data good enough for confident decision making.

6.2 DOCUMENT EVERYTHING THOROUGHLY

From data collection through data use, the motto is "Write it down!" Nothing enhances the credibility of a data collection program more than thoroughly detailed documentation. Data usability, for future as well as present applications, depends on how well all of the details are recorded.

6.3 CALIBRATE INSTRUMENTS AND TEST SOFTWARE

Improperly calibrated instruments frequently cause poor results. All calibrations must be directly traceable to a standard of recognized accuracy, such as those from the National Institute of Standards and Technology. All calibrations must also include a zero-span check covering the full range of concentrations expected during data collection. Linearity of instrumental response must be demonstrated, not assumed. Software, too, must be tested thoroughly, to verify that it is performing as planned. If not, data collection, validation, reduction, and analysis can be jeopardized.

6.4 PRESERVE THE ORIGINAL DATA

Whatever is done in data processing, especially in data reduction, the original data must be preserved and all derivative data must be directly traceable to them. All data transformations must also be preserved. Back-up files, whether computer or manual, are mandatory. Only protected data allow a second chance for analysis if critical problems arise on the first attempt.

6.5 USE ONLY VALIDATED DATA

To catch data errors and biases at the earliest possible stage, data validation is used to compare each data point against prespecified criteria. Whether performed by humans or computers, during or after data collection, it asks the question "Is this specific piece of data reasonable?" Only validated data can proceed to the next step. Abnormally high or low values cannot be discarded automatically. Instead, they must be examined statistically to determine if they truly fall outside the expected range. They may be real values on the tails of a distribution curve or they may be invalid as shown by standard tests. Or, as sometimes happens, their occurrence is simply unexplainable. Decisions to use or discard suspect data can be made only after these validity checks.

6.6 USE TABLES OR GRAPHS TO PRESENT SUMMARY STATISTICS

Air monitoring studies, particularly those with multiple stations and automatic recording devices, produce vast quantities of data impossible to comprehend in the raw state. Trends become apparent only after data are reduced and tables or graphs are used to present summary statistics. Graphs are frequently more informative than tables for presenting numerical data because patterns and magnitudes are easier to comprehend. Statistics used most often are the number of observations, means, and standard deviations, with others included as needed. Presenting numerical data in narrative form throughout a report is a poor alternative because the interrelationships among scattered data are easily lost.

6.7 LEAVE SOPHISTICATED DATA HANDLING TECHNIQUES TO THE STATISTICIANS

Amateur statistics can be nearly as dangerous as amateur surgery. Powerful software packages are widely available for data validation and analysis, but using them without a thorough understanding of their limitations and underlying statistical assumptions almost guarantees severe over- or under-interpretation of the data. Key topics such as graphical display of data, identification of outliers, regression analysis, analysis of variance, and how to handle zero or nondetected data require advanced statistical techniques. To extract the maximum information from a data set, statisticians must participate in the design phase too, rather than just the data analysis.

6.8 BEWARE OF USING DATA COLLECTED FOR ANOTHER PURPOSE

The temptation to use existing data rather than collect new data is especially strong when budgets are tight. Succumbing to that temptation can be disastrous, unless all of the restrictions applicable to the previous data are known and documented.



SECTION 7

STATISTICAL TERMS AND DATA QUALITY INDICATORS

Previous sections have discussed data qualitatively. This section summarizes how data are described quantitatively by statistical terms and data quality indicators. Definitions and equations are accompanied by brief descriptions of the conditions when the specific terms should or should not be used. For ease in reference, the equations are numbered at the right of the page.

7.1 STATISTICAL TERMS

In Volume 1, Principles, of the first edition of the *Quality Assurance Handbook for Air Pollution Measurement Systems*, there were almost 200 pages dealing with statistics. Here they have been condensed to less than 6, which no doubt will cause consternation to some. But this is a field guide, and a field guide covers only the most important things.

7.1.1 Arithmetic Mean

Whenever data plots show a roughly symmetrical (bell-shaped or normal) distribution, the average value is called the arithmetic mean. It is simply the sum of the individual values divided by the number of values in the data set:

$$\bar{X} = \frac{1}{n} \sum X_i \quad (1)$$

where

\bar{X} = arithmetic mean

n = number of values

X_i = individual data values

Calculating the arithmetic mean without first plotting the data to verify a symmetrical distribution can lead to faulty data interpretation. See Section 7.1.3 for a discussion of when the arithmetic mean is particularly inappropriate.

7.1.2 Standard Deviation and Variance

The standard deviation, used to measure the dispersion or spread of data, is defined as follows:

$$s = \sqrt{\frac{\sum X_i^2 - (\sum X_i)^2/n}{n-1}} \quad (2)$$

where

- s = standard deviation
- X_i = individual data values
- n = number of values

The square of the standard deviation, called the variance, is another frequently used measure of data dispersion.

Programmable calculators require only that the raw data be entered in a specified manner. All computations are then performed automatically. Thus, in actual practice, it is no longer necessary to manually compute the tedious squarings required by Equation 2.

7.1.3 Geometric Mean

Plots of air monitoring data frequently show a skewed, nonsymmetrical distribution. For these cases, the geometric mean rather than the arithmetic mean is a better measure of the average value. The geometric mean is defined as the antilog of the average of the logarithms of the data values:

$$\bar{X}_g = \text{antilog}_b \left(\frac{1}{n} \sum \log_b X_i \right) \quad (3)$$

where

- \bar{X}_g = geometric mean
- n = number of values
- $\log_b X_i$ = logarithms of individual data values

Either common logarithms (\log_{10}) or natural logarithms (\log_e) can be used to calculate the geometric mean. The necessary tables of logs and antilogs are found in mathematics and statistics textbooks and in standard reference books such as the *Handbook of Chemistry and Physics*. Software programs are also available.

7.1.4 Geometric Standard Deviation

The geometric standard deviation, used when data are distributed lognormally rather than normally, is defined as follows:

$$s_g = \text{antilog} \sqrt{\frac{\Sigma (\log X_i)^2 - \frac{(\Sigma \log X_i)^2}{n}}{n - 1}} \quad (4)$$

where

- s_g = geometric standard deviation
- $\log X_i$ = logarithm of individual data values
- n = number of values

7.2 DATA QUALITY INDICATORS

"How good are the data?" Because project success depends on the answer, data quality is used as an indicator of project performance. Six terms frequently used to describe data quality are precision, accuracy, completeness, method detection limit, representativeness, and comparability. Each is defined in the following sections, but, as shown there, the definitions are not always quantitative or universally accepted. Nevertheless, the definitions do provide a common ground for discussions on data quality.

7.2.1 Precision

Precision is a measure of agreement among two or more determinations of the same parameter under similar conditions. Two terms used to describe precision are relative percent difference (RPD) and relative standard deviation (RSD) (also called the coefficient of variation), depending on whether two or more than two replicates are used.

If precision is calculated from duplicate measurements, use

$$RPD = \frac{100 (X_1 - X_2)}{(X_1 + X_2)/2} \quad (5)$$

where

- RPD = relative percent difference
- X_1 = larger of the two values
- X_2 = smaller of the two values

If precision is calculated from three or more replicates, use RSD rather than RPD:

$$RSD = 100 (s/\bar{X}) \quad (6)$$

where

RSD = relative standard deviation

s = standard deviation (see Equation 2)

\bar{X} = mean of replicate analyses

For two replicates, $RSD = RPD/\sqrt{2}$

7.2.2 Accuracy

Accuracy is the degree of agreement between a measured value and the true, expected, or accepted value. It is frequently expressed in terms of percent recovery (%R) whether Standard Reference Materials (SRMs) or spiked samples (known concentrations of test materials added to samples) are used.

If SRMs are used, accuracy is expressed as follows:

$$\%R = 100 (C_M/C_{SRM}) \quad (7)$$

where

$\%R$ = percent recovery

C_M = measured concentration of SRM

C_{SRM} = actual concentration of SRM

When spikes are added to samples, %R is calculated as follows:

$$\%R = 100 (C_s - C_u)/C_{sa} \quad (8)$$

where

$\%R$ = percent recovery,

C_s = measured concentration in spiked aliquot

C_u = measured concentration in unspiked aliquot

C_{sa} = actual concentration of spike

When measurement systems for ambient air monitoring are audited, accuracy is expressed as follows:

$$RPD = 100 (C_m - C_a) / C_a \quad (9)$$

where

- RPD = relative percent difference
- C_m = measured value of audit standard
- C_a = actual value of audit standard

7.2.3 Completeness

Completeness is a measure of the amount of valid data obtained compared with that expected to be obtained under normal operating conditions. It is defined as follows for all measurements:

$$\%C = 100 (n_v / n) \quad (10)$$

where

- $\%C$ = percent completeness
- n_v = number of valid measurements
- n = total number of planned measurements

The above equation is a simplified definition. In actuality, $\%C$ must be tied to the specific statistical level of confidence needed for decision making. Obviously, a decision needing, say, a 99% confidence level needs more valid data than one requiring only an 80% level. A statistician should be consulted for guidance on this topic.

7.2.4 Method Detection Limit

The method detection limit (MDL), the lowest concentration of an analyte that can be measured by a given procedure, is as much a statistical as an analytical concept, and there are numerous definitions. One definition favored by statisticians is as follows:

$$MDL = st_{(n-1, 1-\alpha = 0.99)} \quad (11)$$

where

- MDL = method detection limit
- s = standard deviation of the replicates at the lowest concentration
- $t_{(n-1, 1-\alpha = 0.99)}$ = Student's t-value appropriate to a 99% confidence level and a standard deviation estimate with $n-1$ degrees of freedom

Field and laboratory personnel frequently use a much simpler version:

$$MDL = (N)(s) \quad (12)$$

where

MDL = method detection limit

N = a multiplier between 3 and 10

s = standard deviation

7.2.5 Representativeness

Representativeness expresses how closely a sample reflects the characteristics of the substance for which it is a surrogate. Ideally, the representativeness of the sample would be 100%; practically, however, the quantitative value is rarely known. Every effort is made to ensure that the sample is truly representative, by using such techniques as thorough mixing to obtain homogeneity, duplicate analyses, and such. Problems with uniformity are not so great with air samples as with liquids or solids because of the nature of the air media.

7.2.6 Comparability

Comparability refers to how confidently one data set can be compared with another. Ideally, all data would be completely comparable, so comparability would be 100%. Practically, because the data were collected under different conditions and for different purposes, comparing data sets must be done very cautiously. See Section 6.8 for more details.

SECTION 8

AUDITS

Managers need to know how well things are going on their projects. Is a particular project performing according to specifications? An audit, a management tool used to answer that question, is a formal, detailed study of one or more aspects of a project by independent auditors. The project is not audited at random, but against specific criteria previously determined by the manager to be critical to project success. Many audits are held shortly after the project has become operational, to detect and correct problems before they affect data quality adversely.

A cooperative effort of auditors and auditees (to gather the needed information efficiently and completely) gives the best results. There is no room for "Gotcha!" in any audit.

The audit report describes any problems found and may suggest appropriate corrective actions. Equally important, it also covers those aspects that were operating as specified. Thus, the manager learns what is going well, not just what needs attention.

An audit focuses on one or more of the following components of a project.

- People
- Procedures
- Equipment
- Data
- Documentation

The success of any project depends on how well the people follow procedures, operate equipment, collect and interpret data, and carefully document their activities.

8.1 DOCUMENTATION

A poor paper trail can lead to even poorer audit results. During their on-site visit, auditors can observe only the current operations first hand; for previous ones, they must depend on written documentation. Verbal assurances from the auditees

are not enough to convince the auditors that proper procedures had, indeed, been followed. Only clear, complete, written documentation can do that.

8.2 AUDIT TYPES

The QA project plan is the basis for all four audit types described in the following sections. Although the audit is used to determine whether criteria stipulated in the plan are being met, any additional findings are also included in the report.

8.2.1 Technical Systems Audit

The technical systems audit, a qualitative on-site evaluation of an entire measurement system, is used frequently in an air monitoring program. It looks at everything – all facilities, equipment, systems, record keeping, data validation, operations, maintenance, calibration procedures, reporting requirements, and QC procedures. Findings from this global review can then be used to focus efforts on specific parts of the measurement system that need attention to obtain the desired data quality. Systems audits are normally done immediately before, or shortly after, measurement systems are operational, and should also be performed on a regularly scheduled basis throughout the lifetime of the project.

8.2.2 Performance Evaluation Audit

The performance evaluation audit, also used frequently in air monitoring studies, is a quantitative evaluation of a part or parts of a measurement system, including all associated data acquisition and reduction procedures. It involves the analysis of a reference material of known value or composition and critical to the success of the project. The reference material is usually disguised as a typical project sample so that the operator or analyst will not give it any undue special attention. Long-term projects require regularly scheduled performance audits. Although a performance audit may show that a system is out-of-control, a systems audit may be needed to pinpoint the cause and target the corrective action.

8.2.3 Audit of Data Quality

An audit of data quality exhaustively evaluates the methods used to collect, interpret, and report data quality. The following criteria are evaluated against the QA project plan and other pertinent guidelines:

- Recording and transfer of raw data
- Calculations, including equations used for presentation of data
- Documentation of data-handling procedures
- Selection and discussion of data-quality indicators, including precision, accuracy, representativeness, comparability, and completeness

8.2.4 Management Systems Audit

A management systems audit (or review) examines the structures and processes used by management to achieve the desired data quality. Broad in scope, it frequently covers multiple projects within a larger program. Laboratory and field personnel rarely participate directly in this type of audit.

8.3 AUDIT PROCEDURES

Detailed planning is the essence of any good audit. Without it, the resulting chaos causes short tempers and sloppy work; with it, the ensuing cooperation fosters harmony and success. In addition to auditor and auditee, a third party, the sponsor, plays a key role. As commonly occurs in government and industry, a sponsor funds the project and requests the audit. The following sections describe critical interactions among these three parties. If only auditor and auditee are involved, the audit procedure is simpler because the auditor assumes the functions of the sponsor.

8.3.1 Preaudit Activities

Decisions made by the sponsor in the preaudit planning phase determine the course of the audit. As shown in the following summary, all three parties communicate extensively to ensure that there will be no hidden agendas and no surprises.

A. RESPONSIBILITIES OF THE SPONSOR

The sponsor's project manager and QA manager decide on the following audit details.

- (1) Intent, scope, cost, and frequency of auditing activities
- (2) Parts of project to be audited
- (3) Audit schedule
- (4) Qualifications needed for auditors

- (5) Action to be taken by auditors if they discover out-of-control situations
- (6) Potential for organizational conflict of interest between auditors and auditees
- (7) Selection of proposed auditors

Of these items, (5) is the most critical. Out-of-control situations can arise in the field, the laboratory, or in data handling operations. What should the auditors do? Correct the problem immediately and cite it in the report? Take no corrective action and cite the problem in the report? Use some other approach? Whatever the answer, it must be spelled out and agreed upon by all parties *before* the audit can begin. The sponsor's project manager then notifies the auditee of the purpose and scope of the audit and requests comments on the following items.

- (8) Acceptability of preceding points (1) through (7)
- (9) Actual or perceived, current or potential, conflicts of interest
- (10) Necessity for a preaudit, face-to-face meeting of auditor, auditee, and sponsor
- (11) Location, date, and time of meeting, if requested in item (10)

B. RESPONSIBILITIES OF THE AUDITEE

The auditee or the sponsor's project manager then sends the following information to the auditor.

- (1) Details of project operation (SOPs, site locations, QA project plan, operator proficiency and training, sampling schedule, etc.)
- (2) Name of person to contact for additional information

C. RESPONSIBILITIES OF THE AUDITOR

The auditor responds by sending the following information to the auditee.

- (1) Standard operating procedures to be used in the audit
- (2) Parts of the project to be audited, and by whom
- (3) Qualifications of the auditors

- (4) Name of person to contact for additional information
- (5) Authority and responsibility of the auditors to take action if a problem is found

Note: All parties must address all of the above points and come to an agreement on them before the audit begins.

8.3.2 Conducting the Audit

The audit should proceed smoothly because of the preaudit agreements. Steps in the actual audit are as follows.

- A. The audit is conducted according to the preaudit agreements. If any party feels that changes are needed, it must then notify all other parties and gain approval before deviating from the agreements.
- B. Auditor informs auditee (on site or by phone/fax/E-Mail, as appropriate) of preliminary audit findings and recommendations for corrective action.
- C. Auditor tries to resolve any disagreements before leaving the site.
- D. If disagreements between auditee and auditor cannot be resolved, auditor contacts sponsor's project manager, QA manager, or the auditee's project manager, depending on the preaudit agreements.
- E. In the audit report, the auditor includes the outcome of this postaudit discussion and identifies still unresolved disagreements.

8.3.3 Preparation of the Audit Report

An audit report is the last step in the auditing process. As shown in the sequence below, the auditee has significant input.

- A. Auditor briefs sponsor's project manager and QA manager on the audit findings.
- B. Auditor prepares draft audit report and submits it, and all supporting data, to the QA manager.
- C. The QA manager determines if the report meets the sponsor's guidelines for clarity, accuracy, completeness, etc. (If not, the report is returned for revision.)
- D. Once the draft report is accepted by the QA manager, it is sent to both the sponsor's project manager and to the auditee.

- E. The sponsor's project manager and the auditee send their written comments to the QA manager, not to the auditor.
- F. After reviewing the comments, the QA manager discusses them with the auditor, and, if necessary, arranges a meeting of all appropriate parties. If disagreements remain, the QA manager will recommend to the sponsor a course of action such as
 - (1) Repeat the part of the audit in question;
 - (2) Issue the audit report, but include a statement that the auditee has questioned a particular audit finding; or
 - (3) Delete the item(s) under question from the report.

If disagreements still remain, the sponsor's project manager receives the final report only after the sponsor has approved the proposed course of action. If there are no disagreements, the QA manager releases the final report to the sponsor's project manager, with a copy to the sponsor and the auditee.

8.3.4 Postaudit Report Activities

The audit report is not the end of the audit. If major problems were discovered, the auditee must institute corrective action (see Section 9). If the problems were critically compromising to data quality, a special follow-up audit might be necessary to verify that the corrective action was adequate to allow data collection to resume. Corrective actions for minor problems are checked at the next regularly scheduled audit.

SECTION 9

CORRECTIVE ACTION

Few projects run perfectly; fewer still automatically correct the many problems, large and small, that inevitably arise. For that, competent, responsible people are required. Both assigning and accepting responsibility are critical to the success of any corrective action plan.

9.1 ROUTINE MEASUREMENTS

Many corrective action plans are already embedded in the QC checks used for all routine measurements. Acceptance criteria or tolerance limits are contingency plans that state that "If this happens, then *WE* will do the following:". The "*WE*" cannot be left unspecified in the corrective action plan; a person or persons (chemical analyst, stack sampling operator, etc.) must be designated by title or function, and, if possible, by name. A statement such as "If this measurement activity is out of control, all sampling will be stopped" is unacceptable because it does not indicate who is responsible for making that decision.

Field and laboratory personnel will be able to make most of the corrective actions needed. They must then document these actions in the appropriate notebooks or logbooks so that a record exists of the problems encountered and the solutions discovered.

9.2 MAJOR PROBLEMS

Sometimes, however, problems occur that field and laboratory staff members are unable to solve, despite their best efforts. These problems can arise during routine operations or as a result of performance evaluation and technical systems audits. Staff members must immediately bring these major problems to the attention of their supervisor or other individuals designated in their test or QA project plans to handle the problem. Because many individuals could become involved in the corrective action, the notification is best done by a standard corrective action form, a copy of which is shown in Figure 9-1.

CORRECTIVE ACTION FORM

Project Title _____ Project No. _____

I. REQUEST FOR ASSISTANCE

To: A Date: _____
From: B Signature: _____

Problem: (1) Nature _____

(2) Suspected Cause _____

II. PROPOSED CORRECTIVE ACTION

To: B Date: _____
From: A Signature: _____

Suggestion: _____

III. RESULTS OF PROPOSED CORRECTIVE ACTION

To: A Date: _____
From: B Signature: _____

Results: _____

Figure 9-1. Corrective Action Form.

The form has three parts:

- Request for Assistance
- Proposed Corrective Action
- Results of Proposed Corrective Action

A three-part, no-carbon-required, corrective action form is highly recommended, especially for field use, where photocopiers are rarely available. Space is provided for signatures and a brief outline of the problem, the proposed solution, and the results. Each person signing the form should feel free to attach any other needed material, but must also keep a copy of the complete packet in his or her own files for ready access should a similar problem arise.



SECTION 10
BIBLIOGRAPHY

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Detailed description and flow charts of the entire auditing process.

2. **Dixon, W.J. and F.J. Massey, Jr.** 1969 *Introduction to Statistical Analysis*, Third Edition. New York, NY: McGraw-Hill, Inc.

A clearly written basic textbook, still a standard for statistical analysis.

3. **Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans.** QAMS-005/80. U.S. Environmental Protection Agency, Washington, DC. 1980.

The ancestor of all U.S. EPA guidance documents for preparing QA project plans. Still the standard, but will be replaced in 1993 by a completely new document consistent with recommendations of the American Society for Quality Control and the American National Standards Institute.

4. **Porter, L.F.** *Guideline for Design, Installation, Operation, and Quality Assurance for Dry Deposition Monitoring Networks.* EPA/600/3-88/047. U.S. Environmental Protection Agency, Research Triangle Park, NC. 1988. 500 + pp.

Practical guidance on the design of monitoring projects and associated QA/QC. Lengthy and detailed, but a readable format. Covers all phases from design to installation to implementation of monitoring networks.

5. **Simes, G.F.** *Preparing Perfect Project Plans: A Pocket Guide for the Preparation of Quality Assurance Project Plans.* EPA/600/9-89/087. U. S. Environmental Protection Agency, Cincinnati, OH. 1989. 62 pp.

A companion document to those listed in item (6) below. Uses four-category approach to project classification and associated QA. For each category, provides hints and checklists for preparing QA project plans.

6. **Simes, G.F.** *Preparation Aids for the Development of Category I (II, III, IV) Quality Assurance Project Plans.* EPA/600/8-91/003, EPA/600/8-91/004, EPA/600/8-91/005, EPA/600/8-91/006. U. S. Environmental Protection Agency, Cincinnati, OH. 1991. 65, 63, 57, 35 pp., respectively.

Companion documents to that listed in item (5) above. Uses a four-category approach to project classification and associated QA. For

each category, gives more detail than the Pocket Guide. Includes many examples of summary tables for presenting QA requirements.

7. **Quality Assurance Handbook for Air Pollution Measurement Systems.** U.S. Environmental Protection Agency, Research Triangle Park, NC. Dates variable.

Volume I Now: A Field Guide to Environmental Quality Assurance. 1993. Replacement for: Principles. EPA-600/9-76-005, 1976.

Volume II Ambient Air Specific Methods. EPA-600/4-77-027a, 1977.

Volume III Stationery Source Specific Methods. EPA/600/4-77-027b, 1977.

Volume IV Meteorological Methods. EPA/600/4-90/003, 1989.

Volume V Manual for Precipitation Measurement Systems. EPA-600/4-82-042a & b, 1983.

A large 5-volume compendium of all things related to ambient air measurements, including, but not restricted to, test methods, sampling, analysis, and QA. Individual methods revised occasionally since 1976, but many are both out of date and out of print. Use the EPA document numbers shown above to obtain the most recent updates if available. Major revisions are planned for the entire Handbook. Those for Volume I are completed with publication of this field guide. Work on Volumes II and III has begun. Volumes IV and V, published more recently, will be addressed later. Pending funding, the target for completing all revisions is the mid-1990s.

8. **Quality Assurance Project Plan for the Atmospheric Research and Exposure Assessment Laboratory.** U.S. Environmental Protection Agency, Research Triangle Park, NC. 1990.

Example of a broad guidance document for an entire laboratory rather than a single project. Emphasizes job descriptions, QA oversight requirements, and protocols for the preparation and review of a wide variety of documents. Other U.S. EPA laboratories have similar plans tailored to their special needs.

