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Agency

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Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents

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GUIDANCE FOR THE PREPARATION OF STANDARD OPERATING PROCEDURES FOR QUALITY-RELATED DOCUMENTS

1.0 Purpose of the Standard Operating Procedure

A Standard Operating Procedure (SOP) documents routine or repetitive administrative and technical activities to facilitate consistency in the quality and integrity of the product. The development and use of SOPs for both technical (e.g., measurements) and administrative (e.g., document review/tracking) functions is an integral part of a successful quality system. SOPs facilitate activities that would be managed under a work plan or a Quality Assurance Project Plan (EPA QA/R-5), or Chapter 5 of the EPA Quality Manual.

The development and use of an SOP promotes quality through consistency within the organization, even if there are personnel changes. Therefore, SOPs could be used as a part of a personnel training program. When reviewing historical data, SOPs are valuable for reconstructing project activities when no references are available. Additional benefits of an SOP are reduced work effort, along with improved data comparability, credibility, and defensibility.

This guidance document is designed to assist in the preparation and review of an SOP. To clarify terms for the purpose of this guidance, "protocol" is used to describe the actions of a program or group of activities and should not be confused with an SOP. The terms "shall" and "must" are used when the element mentioned is required and deviation from the specification will constitute nonconformance with the standard. The term "should" indicates that the element mentioned is recommended. The term "may" indicates when the element is optional or discretionary. The terms (shall, must, should, and may) are used as noted in ANSI/ASQC E4-1994.

2.0 Applicability

An SOP is intended to be specific to the organization or facility whose activities are described. For example, if the SOP is written for a standard analytical method, the SOP specifies analytical procedures in greater detail than appear in the published method to ensure that the procedure is conducted in a standard, reliable, and reproducible fashion within the organization. An SOP delineates the specific procedures used to carry out a method and how, if at all, the SOP differs from the standard method.

As noted in ASTM D 5172-91, "A significant part of the variability of results generated by different laboratories analyzing the same samples and citing the same general reference is due to differences in the way the analytical test methods and procedures are actually performed in each laboratory. These differences are often caused by the slight changes or adjustments allowed by the general reference, but that can affect the final results."

Any activities that are classified as "Inherently Governmental Functions" and, as such, must be performed only by EPA employees (or other designated Federal employees), should be so indicated.

3.0 SOP Logistics

The SOP needs to be written by individuals knowledgeable with the activity, the equipment, and the organization's internal structure. The SOP should be written with sufficient detail so that someone with limited experience with or knowledge of the procedure can successfully reproduce the activity or procedure. The experience requirement can be noted in the section on personnel qualifications.

The SOP should be reviewed (that is, validated) by one or more individuals with appropriate training and experience with the process. The final SOP should be approved at least by the immediate supervisor (section/branch chief) and the quality assurance officer, or as described in the organization's Quality Management Plan (QMP).

Whenever procedures are changed, the SOP should be modified and approved as stated above. The revision number and date should be indicated after each modification.

The SOP should be reviewed periodically as defined by the QMP to ensure that the policies and procedures remain current and appropriate. Any SOP that is current does not need to be revised. However, the review date should be added to document that the SOP has been reviewed.

Current copies of the SOPs should be readily available for reference in the work areas of those individuals actually performing the activity. Individuals following these SOPs should note the revision number being used. This is critical when the need for evidentiary records is involved and when the activity is being reviewed.

Each organization should maintain in its files a master list and file of all SOPs, including the date of the current version, in accordance with its approved QMP. Outdated versions need to be maintained in a manner to prevent their continued use and to be available for historical data review. The Quality Assurance Manager (or designee) is responsible for maintaining a file listing all current quality-related SOPs used within the organization. This list may be used when audits are being considered and questions are raised as to practices being followed within the organization.

4.0 General Format

An SOP should be organized to ensure ease and efficiency in use. Development of short and simple SOPs and citation of other available SOPs or documents are highly recommended practices.

4.1 Title Page

The first page of each SOP should be a title page having the following information: a title that clearly identifies the activity or procedure, the name of the applicable agency/group, and the date and signatures of those individuals who prepared and approved the SOP.

4.2 Table of Contents

A Table of Contents is needed only if the SOP is longer than ten pages.

4.3 Control Documentation

Each page of the SOP should have control documentation, as illustrated below, generally in the upper right hand corner. A short title can identify the activity covered by the SOP and serve as a reference designation. The revision number and date are useful in identifying the SOP in use when reviewing historical data. The user can also quickly check if the SOP is complete when the number of pages is indicated. Suggested control documentation format:

Short Title
Rev. #: 0
Date: July 1995
Page 1 of 6

4.4 Text

A well-written SOP has three sections: procedural, QA/QC, and reference. The text of an SOP should be clearly worded so as to be readily understandable by a person knowledgeable with the general concept of the procedure. The procedures should be written in a step-by-step (cookbook) format that clearly describes the steps in chronological order. Use the active voice and present verb tense. The term "you" should not be used, but implied.

An SOP can reference other SOPs. In such a case, cite the other SOP or attach a copy.

5.0 Checklists

Many activities use checklists to ensure that steps are followed in order. Checklists also document completed actions. Any checklists or forms that are included as part of an activity should be referenced at the points in the procedure where they are used; blank and completed copies of the checklists should be attached to the SOP.

In some cases, detailed checklists are prepared specifically for a given activity, as for an inspection. In those cases, the SOP should describe, at least generally, how the checklist is to be prepared, or on what it is to be based. Copies of specific checklists are then maintained in the file with the activity results and/or with the SOP. Remember that the checklist is not an SOP, but a part of one.

6.0 Types of SOPs

An SOP may be written for a repetitive administrative procedure as well as for a technical activity. Examples are: QA procedures for conducting assessments; equipment use; maintenance and calibration; and, collection of samples. General guidance for preparing both Technical and Administrative SOPs follow.

The Agency has prescribed a format for documenting environmental monitoring methods, entitled *EMMC Methods Format* (attached). This methods format is sometimes confused with an SOP, perhaps because methods also include step-wise procedures that are to be followed by an analyst. However, monitoring methods contain information that is not essential to performing a repetitive technical activity, e.g., sections on method sensitivity, method performance, validation data, and pollution prevention.

7.0 Suggested Format for a Technical SOP

7.1 Procedural Section:

After the title page, the following are topics that may be appropriate for inclusion in a technical SOP:

a. Scope & Applicability,
b. Summary of Method,
c. Definitions (acronyms, abbreviations and specialized forms used in the SOP),
d. Health & Safety Warnings (indicating operations that could result in personal injury or loss of life and explaining what will happen if the procedure is not followed or is followed incorrectly; listed here <u>and</u> at the critical steps in the procedure),
e. Cautions (indicating activities that could result in equipment damage, degradation of sample or possible invalidation of results; listed here <u>and</u> at the critical steps in the procedure),
f. Interferences,
g. Personnel Qualifications,
h. Apparatus & Materials (list or specify; note also designated locations where found),
i. Instrument or Method Calibration,
j. Sample Collection,
k. Handling & Preservation,

l. Sample Preparation and Analysis,
m. Troubleshooting,
n. Data Acquisition, Calculations & Data Reduction,
o. Computer Hardware & Software (used to manipulate analytical results and report data), and
p. Data Management & Records Management

7.2 Quality Control and Quality Assurance Section

QC activities are designed to allow self-verification of the quality and consistency of the work. Describe the preparation of appropriate QC procedures (self-checks, such as calibration) and QC material (such as blanks - rinsate/trip/field/method, replicates, splits and spiked samples, and performance evaluation samples) that are required to successfully demonstrate performance of the method. Specific criteria for each should be included. Describe the frequency of required calibration and QC checks and discuss the rationale for decisions. Describe the limits/criteria for QC data/results and actions required when QC data exceed QC limits or appear in the warning zone. Describe the procedures for reporting QC data/results.

Specify and describe any QA procedures that are integral parts of the activity, including performance audits, outside audits or reviews, or other activities. These can be referenced from the organization's QMP. Specify who or what organization is responsible for each QA activity, where or how QA materials are to be procured and/or verified. Assign responsibility for taking corrective action, based on the results of the QA activities.

7.3 Reference Section

Documents or procedures that interface with the SOP should be fully referenced (including version), such as related SOPs and published literature or methods manuals. Citations cannot substitute for the description of the method being followed in the organization. Fully cite all references noted in the body of the SOP and attach any that are not readily available.

8.0 Suggested Format for an Administrative SOP

When auditing, reviewing, and/or inspecting the work of others, the SOP needs to include a number of specific steps aimed at making initial contact with the subject of the activity, coordinating the activity, and reporting. An SOP for a general activity (e.g., a management systems review or laboratory audit) should be covered by SOP guidance tailored to that activity. The SOP guidance should fit within the framework presented here, but can be modified, reduced, or expanded.

8.1 Procedural Section

The following are topics that may be appropriate for inclusion in an administrative SOP:

a. Title,
b. Purpose,
c. Applicability,
d. Summary of Procedure,
e. Definitions,
f. Personnel Qualifications, and
g. Procedure.

Audits or assessments SOPs should specify the authority for the assessment, how auditees are to be selected, what will be done with the results, and who is responsible for corrective action.

8.2 Quality Control and Quality Assurance Section

Describe any control steps and provisions for review or oversight prior to acceptance of the product or deliverable. This can include test plans such as verification and validation plans for software.

8.3 Reference Section

Cite all references noted in the body of the SOP. A copy of any cited references not readily available should be attached to the SOP.

9.0 Suggested References

(1) ANSI/ASQC E4-1994, *Specification and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American National Standard, ASQC, Milwaukee, WI (January 1995).

(2) *EPA Manual for the Certification of Laboratories Analyzing Drinking Water. Criteria and Procedures/Quality Assurance*, U.S. EPA, Washington, DC (Draft 1995).

(3) Garner, Willa Y. and Maureen S. Barge, editors, "Good Laboratory Practices. An Agrochemical Perspective," *ACS Symposium Series 369*, American Chemical Society (1988).

(4) Herron, Nelson R., "Standard Operating Procedures: Developing Useful Procedures. Part 1," Environmental Testing and Analysis, (1994) p. 41-44.

(5) *Standard Guide for Documenting the Standard Operating Procedures Used for the Analysis of Water*, ASTM D 5172-91, American Society for Testing and Materials, Philadelphia, PA (1991).

APPENDIX

These SOPs are not purported to be perfect or complete in content, but are provided merely to illustrate application of the SOP format for both technical and administrative subjects.

Like the G-6 Guidance, the SOPs both take advantage of the "Header" format in Word Perfect. You must use the "VIEW" or "SCREEN" function to see the headers when using electronic formats.

STANDARD OPERATING PROCEDURE (SOP) FOR THE DETERMINATION OF COLOR

DRAFT EXAMPLE - DO NOT QUOTE OR CITE

Prepared by:_____ Date:_____
Chemist

Reviewed by:_____ Date:_____
Section Chief

Approved by:_____ Date:_____
Branch Chief

U.S. ENVIRONMENTAL PROTECTION AGENCY
REGION XI

Procedural Section

1.0 Scope & Application

1.1 The Platinum-Cobalt method is useful for measuring color of water derived from naturally occurring material, i.e., vegetable residues such as leaves, barks, roots, humus and peat materials. The method is not suitable for color measurement on waters containing highly colored industrial wastes.

1.2 Detection limit is 5 color units.

1.3 The range is from 5 to 70 units. Higher values may be measured by dilution of the samples.

1.4 Note: The spectrophotometric and Tristimulus methods are useful for detecting specific color problems. The use of these methods, however, is laborious and unless determination of the hue, purity, and luminance is desired, they are of limited value.

2.0 Summary of Method

2.1 Color is measured by visual comparison of the sample with platinum-cobalt standards. One unit of color is that produced by 1 mg/L platinum in the form of the chloroplatinate ion.

3.0 Health and Safety Warnings

3.1 Standard laboratory protective clothing and eye covering is required.

4.0 Cautions

4.1 Reagent standards must be prepared fresh on the day of analysis.

4.2 Determination must be made within 48 hours of collection and sample stored at 4°C.

5.0 Interferences

5.1 Since very slight amounts of turbidity interfere with the determination, samples showing visible turbidity should be clarified by centrifugation. Alternately, samples may be filtered. If turbidity is removed, the results are reported as "true color" otherwise the results are reported as "apparent color."

5.2 The color value of water may be extremely pH-dependent and may increase as the pH of the water is raised. When reporting a color value, specify the pH at which color is determined.

5.3 Absorption of ammonia by the standards will cause an increase in color.

6.0 Personnel Qualifications

6.1 Technician should be trained at least one week in the method before initiating the procedure alone.

7.0 Apparatus & Materials

7.1 Nessler tubes: Matched, tall form, 50 ml capacity.

7.2 Racks for Nessler tubes.

7.3 Miscellaneous lab glassware.

8.0 Method Calibration

8.1 Chloroplatinate Stock Standard, 500 units: Add 100 ml concentrated HCl to 500 ml reagent grade deionized water. Dissolve 1.246g Potassium Chloroplatinate and 1.0g Cobaltous Chloride Monohydrate in this mixture and dilute to 1000 ml. This may be purchased from Fisher Scientific as Platinum Cobalt Standard and is equivalent to 500 color units.

8.2 Prepare the following series of standards, fresh on the day of the analysis.

mls of standard solution diluted to 50 ml with Reagent Grade Deionized Water	Color in Chloroplatinate Units
0.0	0
0.5	5
1.0	10
1.5	15
2.0	20
2.5	25
3.0	30
3.5	35
4.0	40

4.5	45
5.0	50
6.0	60
7.0	70

9.0 Sample Collection, Preservation and Storage

9.1 Representative samples shall be taken in scrupulously clean containers. Both glass and plastic containers are acceptable.

10.0 Preservation

10.1 Since biological activity may change the sample color characteristics, the determination must be made within 48 hours of collection. Samples should be stored at 4°C.

11.0 Sample Analysis Procedure

11.1 Apparent Color: Observe the color of the sample by filling a matched Nessler tube to the 50 ml mark with the sample and compare with standards. This comparison is made by looking vertically downward through the tubes toward a white or specular surface placed at such an angle that light is reflected upward through the columns of liquid. If turbidity has not been removed by the procedure given in 7.2, report color as "apparent color."

11.2 True Color: Remove turbidity by centrifuging until supernatant is clear; up to one hour may be required. Samples can also be filtered through a Whatman #541 filter paper. Results are reported as "true color" if steps are taken to remove turbidity.

11.3 Measure and record pH of each sample (see SOP C-24).

11.4 Dilute any sample with more than 70 units of color and reanalyze.

12.0 Data Analysis & Calculations

12.1 Calculate the color units by means of the following equation:

$$\text{Color units} = \frac{A \times 50}{V}$$

Where:

A = estimated color of diluted sample.
V = ml sample taken for dilution.

12.2 Report the results in whole numbers as follows:

Color Units	Record to Nearest
1 - 50	1
51 - 100	5
101 - 250	10
251 - 500	20

13.0 Data Management and Records Management

All laboratory records must be maintained in the bound record book designated for the method.

Quality Control and Quality Assurance Section

1.0 There are no QC samples for color at this time.

2.0 Choose one sample per set of analyses and run in triplicate. RSD % should not be greater than 20%.

3.0 Spikes are not applicable to color determination.

References

1. Standard Methods for the Examination of Water and Wastewater, 18th Edition, Supplement

2. Methods for Chemical Analysis of Water and Wastewater Method #110.2

STANDARD OPERATING PROCEDURE (SOP) FOR THE MANAGEMENT SYSTEMS REVIEW INTERVIEW

DRAFT EXAMPLE - DO NOT QUOTE OR CITE

Prepared by:_____ Date:_____
Environmental Scientist

Reviewed by:_____ Date:_____

Approved by:_____ Date:_____
Director

U.S. ENVIRONMENTAL PROTECTION AGENCY
QUALITY ASSURANCE DIVISION

1.0 Purpose and Applicability of the Management Systems Review

Beginning in 1992, EPA declared the documentation of its QA program to be a material weakness under the reporting requirements of the Federal Managers' Financial Integrity Act (Integrity Act). Furthermore, recent audits by the General Accounting Office (GAO) and the Inspector General (IG) indicate that there is substantial uncertainty regarding the quality of environmental data being used for key regulatory and programmatic decisions.

EPA Order 5360.1, Policy and Program Requirements to Implement the Mandatory Quality Assurance Program (April 1984), directs the Office of Research and Development (ORD) to review and approve the implementation of QA programs across the Agency. Under the specifications of EPA Order 5360.1, all EPA organizations conducting "environmentally-related measurements" are required to develop and implement a QA program for their work. In response to the Agency's Integrity Act weakness, all Agency organizations were again directed to complete documentation of their QA programs by submitting Quality Management Plans (QMP) to ORD for review and approval. The QMP describes the policies and procedures, roles and responsibilities, and quality assurance/quality control (QA/QC) activities used to plan, implement, and assess the effectiveness of the QA program applied to the collection and use of environmental data for decision making. In addition, the Assistant Administrator for (the Office of) Research and Development (AA/ORD) is delegated review and approval authority for QMPs as the Senior Quality Management Official for the Agency.

EPA Order 5360.1 also directs the AA/ORD to periodically assess the effectiveness of the QA programs being implemented. In FY 94, the AA/ORD directed the Quality Assurance Division (QAD) to initiate a management assessment program in which all Agency organizations collecting and using environmental data for decision making would be reviewed at least once every three years.

In response to this directive, QAD is employing the management systems review (MSR) process to examine the effectiveness of quality systems applied to Agency environmental programs. The focus of the MSR is on systems. The assessment seeks to determine that a quality system is established and is operating within the organization in a manner such that potential vulnerabilities in environmental data beyond that of inherent error may be detected, prevented, and resolved. This is accomplished by examining the processes used to plan, implement, and assess the effectiveness of the QA/QC applied to environmental data collection activities.

The MSR process may be applied to both organizations and to specific data collection programs involving multiple organizations. The MSR process uses background documentation, file reviews, case studies, and interviews of managers and staff involved in environmental data operations to assess the effectiveness of the quality system relative to its stated objectives in the QMP. The MSR process is not an audit in the traditional sense in that it seeks to recognize

noteworthy accomplishments and to identify needed improvements. Moreover, the MSR process does not judge the quality of any data or the performance of any environmental data collection activities. The results of the MSR are provided only to the principal client, in this case, the AA/ORD, and to the program reviewed. QAD will not distribute copies of the final report or discuss the findings with any other organization.

1.1 Summary of Procedure for MSR Interviews

As noted above, the interview is one component of the MSR process. Within a one-hour session, the interviewer introduces him/herself, checks the name and position of the interviewee, and then asks a series of questions relating to the planning, implementing, and assessment of environmental measurement activities in the organization. The interviewer allows the interviewee to suggest any way that the quality program could be better served by QAD or the Agency, and then thanks him/her for his/her time. Related documentation is examined and relevant copies of documents are collected or arranged to be collected.

1.2 Qualifications for MSR Interviewers

The (EPA employee) interviewer must have good communications skills and complete the QAD two-day MSR course. Some familiarity with Agency QA regulations and current guidance is necessary. In addition, there will be a briefing on the planned MSR by the team leader before beginning a particular review. The organization's QMP and QA Annual Report and Work Plan should be studied and discussed.

1.3 MSR Interview Procedure

1.3.1 Deportment for Interviews

Conduct the interview with a partner. This enables verification of the content of the notes by the report writer. Conduct the interview in a congenial manner to put the interviewee at ease. You may need to remind the interviewee that the information is for internal use, and that this is not an audit. Remember that you are there to **learn** about the QA/QC practices in the organization, not to judge their data or to criticize them. You may, however, impart helpful information about current QA practices, guidance, requirements and training, if it does not interfere with the purpose of the interview.

1.3.2 Opening the MSR Interview

Introduce yourself and your partner and give your organization(s). Verify (write in your notes) the name (check spelling) and organizational unit/position of the interviewee and the date/time of the interview. Ask the interviewee if he/she understands the purpose of the interview. If the response is negative, quickly summarize the material in 1.0.

1.3.3 MSR Interview Questions from QAD Director Memorandum

The following are ten groups of questions referred to in the memorandum from the QAD Director to the organization which are useful as a guide to the interview process:

1. **MANAGEMENT COMMITMENT AND ORGANIZATION**

- Is the organizational structure of your quality system implemented as documented in the QMP?

- Are the duties and responsibilities of the QA Manager (and QA Coordinators, if present), as documented in the QMP, being consistently performed?

- Are the duties and responsibilities of managers and staff members relative to QA/QC understood within the organization? How do managers assure that assigned QA responsibilities are performed?

- Are sufficient resources provided for effective QA/QC, including planning, implementation, and oversight (e.g., FTEs, intramural and extramural funding, travel)?

- Is oversight of extramural or delegated programs conducted relative to quality? Are those responsible for oversight of extramural and delegated programs performing as needed?

2. **QUALITY SYSTEM DESCRIPTION**

- Describe the preparation, review, and internal approval process for your Quality Management Plan (QMP).

- How are managers and staff informed of the requirements in the QMP? Do they understand their roles and responsibilities for QA/QC?

- What QA/QC "tools" (e.g., the DQO process, QA Project Plans, audits) are used routinely to plan, implement, and assess environmental data collection activities?

- How are the QA/QC activities described in the QMP implemented? How is senior management assured that the QMP is being implemented as prescribed?

- Are requirements and guidance documents readily available, understood, and used by staff members?

- How have changes to or replacements for Agency-wide guidance been made in order to "tailor" QA/QC requirements to your mission?

- How do you know that the quality system is working? How do you measure the effectiveness of quality systems for external organizations (e.g., contractors, assistance agreement holders)?

- What is the role of non-EPA personnel (e.g., contractors, assistance agreement holders, other Federal Government employees) in implementing your quality system?

3. PERSONNEL QUALIFICATIONS AND TRAINING

- How do you know that your personnel are qualified to perform the environmental data collection activities needed?

- How does management assure that only qualified personnel perform work affecting the quality of the results?

- What is the process for determining QA-related training needs, providing the training, and measuring its effectiveness? Who is responsible for this?

- What QA-related training is provided to managers and staff, and how often?

- What training do you currently need?

4. PROCUREMENTS AND ACQUISITIONS

- What is your process for specifying QA and QC requirements in procurements, acquisitions, assistance agreements, etc.? What is the role of the QA Manager in this process?

- How do you incorporate QA/QC requirements into work assignments, technical directives, etc.?

- How do you assure that environmental data operations performed by external groups (such as, contractors providing analytical services) satisfy all QA/QC specifications and requirements?

- How do you assure that items and services procured (e.g., consumables, reagent-grade chemicals, analytical services) conform to technical and quality specifications?

5. DOCUMENTS AND RECORDS

- What is your process for identifying and keeping necessary documents and records to support your decisions based on environmental data collection activities?

- How are specific QA and QC records and documents identified? What happens to these records and documents?

6. USE OF COMPUTER HARDWARE AND SOFTWARE

- How do you assure that computer hardware and software configurations perform as required for environmental data operations?

- How do you assure that specialized computer software is developed in accordance with specifications and performs as required for environmental data operations?

- How is the quality of environmental data in computerized data bases and information systems identified and documented?

7. ENVIRONMENTAL DATA COLLECTION - PLANNING

- What is the process used for planning environmental data operations? How is technical expertise in sampling, statistics, analytical services, and QA/QC provided?

- Is the Data Quality Objectives process used in planning environmental data operations? What has been the effect of using the DQO process? What other systematic planning processes are used?

- How is the effectiveness of the planning process for QA/QC determined?

- How are QA Project Plans prepared, reviewed, and approved for environmental data collection performed intramurally?

- How are QA Project Plans prepared, reviewed, and approved for environmental data collection performed by contractors or assistance agreement holders?

8. **ENVIRONMENTAL DATA COLLECTION - IMPLEMENTATION**

- What is the process used for implementing QAPPs or other planning documentation for environmental data operations as prescribed? How do managers assure that such implementation is accomplished?

- How are revisions to QAPPs (and other planning documents) made and maintained? How does management assure that project personnel have access to current documentation?

- How do you know that data compiled from computerized data bases and information systems is of adequate quality for use as intended? How do you develop the criteria for accepting these data?

9. **ENVIRONMENTAL DATA COLLECTION - ASSESSMENT**

- What assessment methods (such as audits, peer reviews, surveillances, readiness reviews, performance evaluations, etc.) are used to examine the effectiveness of the technical and QA/QC activities in a project?

- What is the process for planning, conducting, and reporting the results of assessment activities? Who is responsible for conducting assessments?

- Who assures that corrective actions are implemented in a timely manner? How is the effectiveness of corrective actions measured?

10. **QUALITY IMPROVEMENT**

- What needs to be done to improve QA/QC in your environmental data collection activities?

- What has or has not worked in the past to improve quality?

1.3.4 QA Staff Interviews

The above questions are especially appropriate for QA staff, and they may prepare answers ahead of your visit to facilitate the interview. In addition, listen for innovative strategies employed. Ask about interaction with and support from management. Is there a strategy for ensuring that all data collection activities include QA? Is there consistent participation throughout the organization? Discuss the current status of the QMP. Discuss attendance at national/programmatic QA meetings and courses. Are there resource limitations?

Although not strictly an interview, during the MSR a time is scheduled to meet with the QA staff to examine files. Inspect guidance, training materials, files of QAPPs, logbooks, printouts of tracking programs, reports from audits, assessments, and MSRs. Look for timeliness of reviews, frequency of audits, response to comments, signature blocks. Scan guidance/course material for conformance with QAD guidance (new or old), age, program-specificity.

1.3.5 Intramural Data Collector Interviews

Many of the questions above will not apply to non-QA staffers and they sometimes assume that you do not need to interview them. Furthermore, they may have limited familiarity with "Qaspeak." Repeat questions about QA practices in "plain English" as a check for a lack of understanding of QA jargon. For example, ask the interviewee to describe how projects are planned or begun, even if he/she does not use the DQO process. Ask about his/her awareness of the existence of the QMP and interaction with QA staff.

Planning:

Ask to discuss a current or recently completed data collection activity. Ask who the clients are for the data, and how they participate in planning the objectives. Is a formal (DQO) process used? What decision is being based upon the data? Is it regulatory or enforcement-related? Are QA staffers involved in planning?

Implementation:

Ask what steps are taken to ensure the adequacy/quality of the work. Be aware that many staffers will confuse QA and QC. Ask about their backgrounds relative to QA and their experience with defending their data against legal challenges. What (QA) training have they had? What technical expertise is available to them in QA, experimental design,

statistics, and automated data processing? If they are modelers, how do they ensure the models are of good quality? How do they ensure the quality of the data they are using? Are QA plans written, reviewed, followed, and revised? How often, and who signs off? Are SOPs or checklists used? **Ask for QA plan documentation; check signatures; topics addressed. Ask for example SOP/checklist; check signoff, revision, dates.**

Assessment:

Ask what oversight is exercised? What part do others play in review? What are their qualifications? If there is peer review, how exactly does it work? Who selects the reviewers? What are their areas of expertise? Who sees that comments are addressed? Are resources available to permit adequate training, attendance at professional meetings, oversight/audit of laboratory and field work? Is a final assessment made of whether set objectives were reached? Is the QA plan used in that assessment? Are improvements made based on lessons learned? **Ask to see audit/oversight guidance, checklists, and reports; and reviewed papers with comment/signoff memos.**

1.3.6 Interviewing Project Officers/Work Assignment Managers

The major difference from intramural data collection activities is that there are legal requirements for contractors and assistance agreement holders with respect to QA (40 CFR Parts 30 and 31). Also, because the work is done by others, the project officer (PO) or work assignment manager (WAM) is necessarily responsible for oversight. Try to determine if the PO and/or work assignment manager WAM understands his/her role and responsibilities. Use the same questions as above, with additional resource questions.

Planning:

Ask the same questions as in Section 1.3.5. However, be aware that some funding instruments may be for portions of data collection activities, e.g., contracts or grants for analyses, sampling, or audit gas cylinders only. Therefore, ask about the role of their project in a larger context.

Implementation:

In addition to questions in Section 1.3.5, ask about the award of funds relative to complying with QA requirements. Who writes, reviews and approves the QA plan? How are review comments addressed? When are funds awarded (before or after QA plan approval)? When are plans revised? **Ask to see the QA plan; check signatures and dates; scan topics addressed for coverage of all data collection activities from planning to sampling, analysis, and reporting, etc., as in Section 1.3.5.**

Assessment:

In addition to questions in Section 1.3.5, ask about management and resource support for oversight responsibilities. Is training/guidance provided? Do technical experts perform auditing/data validation and review/interpretation? Are site visits adequate to assess implementation of sampling and analysis plans? Are data bases adequate? **Ask to see audit reports and guidance, etc. as in Section 1.3.5.**

1.3.7 Closing the MSR Interview

Ask the interviewee about any particular topics he/she would like to mention relative to QA. Does he/she have specific needs QAD could address? Close the interview by thanking the interviewee for his/her time. If there are documents to be collected for review, arrange delivery. **Do not detain anyone beyond one hour.** If there are topics that must be discussed further, ask permission to call the person at a later time. Feel free to release staffers who are inappropriately scheduled for interviews, or to release them early if there is little to be discussed.

2.0 Quality Control and Quality Assurance of the MSR Interview

The primary quality assurance measure for the interview is the pairing of interviewers. The report writer uses the two sets of notes of the interview as assurance that the information is accurate. The report writer retains a file of all interviewer notes. Questions about notes can be asked of the interviewers as the draft Findings Report is written. All review team members must review the draft and sign it before it is sent to the organization for its accuracy review. The specific project and/or staff-level organization discussed in the interview is usually mentioned in the report. Because the MSR concerns the quality system rather than individuals, do not quote staffers or mention their names in the text of the report. However, include the complete list of all interviewed staffers with their organizations in the appendix.

When the reviewed organization has returned the draft, the final duty of interviewers is to read the comments and recommend for incorporation any comments that correct statements in the report or reject comments (if they cannot be verified by notes) and discuss rejected comments the writer/leader, who will work with the comment coordinator for the reviewed organization. Be aware that clarifications submitted by the organization after the interview may make the report more complete, but may obscure the lack of understanding of QA issues by the interviewees.

3.0 References

Contact QAD in headquarters (202/260-5763) for current lists of requirements, guidance, and course offerings.

ATTACHMENT

Environmental Monitoring Management Council (EMMC) Methods Format

1.0 Scope and Application

Use a tabular format whenever possible for:

- Analyte list(s)
- Chemical Abstract Service (CAS) numbers
- Matrices
- Method Sensitivity (expressed as mass and as concentration with a specific sample size)

Include a list of analytes (by common name) and their CAS registry numbers, the matrices to which the method applies, a generic description of method sensitivity (expressed both as the mass of analyte that can be quantified and as the concentration for a specific sample volume or size), and the data quality objectives which the method is designed to meet. Much of this material may be presented in a tabular format.

2.0 Summary of Method

Sample volume requirements

- Extraction
- Digestion
- Concentration, and other preparation steps employed
- Analytical instrumentation and detector system(s), and
- Techniques used for quantitative determinations

Summarize the method in a few paragraphs. The purpose of the summary is to provide a succinct overview of the technique to aid the reviewer or data user in evaluating the method and the data. List sample volume, extraction, digestion, concentration, other preparation steps employed, the analytical instrumentation and detector system(s), and the techniques used for quantitative determinations.

3.0 Definitions

Include the definitions of all method-specific terms here. For extensive lists of definitions, this section may simply refer to a glossary attached at the end of the method document.

4.0 Interferences

This section should discuss any known interferences, especially those that are specific to the performance-based method. If known interferences in the reference method are not interferences in the performance-based method, this should be clearly stated.

5.0 Safety

- Above and beyond good laboratory practices
- Disclaimer statement (look at ASTM disclaimer)
- Special precautions
- Specific toxicity of target analytes or reagents
- Not appropriate for general safety statements

This section should discuss only those safety issues specific to the method and beyond the scope of routine laboratory practices. Target analytes or reagents that pose specific toxicity or safety issues should be addressed in this section.

6.0 Equipment and Supplies

Use generic language wherever possible. However, for specific equipment such as GC (gas chromatograph) columns, do not assume equivalency of equipment that was not specifically evaluated, and clearly state what equipment and supplies were tested.

7.0 Reagents and Standards

Provide sufficient details on the concentration and preparation of reagents and standards to allow the work to be duplicated, but avoid lengthy discussions of common procedures.

8.0 Sample Collection, Preservation and Storage

- Provide information on sample collection, preservation, shipment, and storage conditions.

- Holding times, if evaluated

If effects of holding time were specifically evaluated, provide reference to relevant data, otherwise, do not establish specific holding times.

9.0 Quality Control

Describe specific quality control steps, including such procedures as method blanks, laboratory control samples, QC check samples, instrument checks, etc., defining all terms in Section 3.0. Include frequencies for each such QC operation.

10.0 Calibration and Standardization

Discuss initial calibration procedures here. Indicate frequency of such calibrations, refer to performance specifications, and indicate corrective actions that must be taken when performance specifications are not met. This section may also include procedures for calibration verification or continuing calibration, or these steps may be included in Section 11.0.

11.0 Procedure

Provide a general description of the sample processing and instrumental analysis steps. Discuss those steps that are essential to the process, and avoid unnecessarily restrictive instructions.

12.0 Data Analysis and Calculations

Describe qualitative and quantitative aspects of the method. List identification criteria used. Provide equations used to derive final sample results from typical instrument data. Provide discussion of estimating detection limits, if appropriate.

13.0 Method Performance

A precision/bias statement should be incorporated in the section, including:

- detection limits
- source/limitations of data

Provide detailed description of method performance, including data on precision, bias, detection limits (including the method by which they were determined and matrices to which they apply), statistical procedures used to develop performance specifications, etc. Where performance is tested relative to the reference method, provide a side-by-side comparison of performance versus reference method specifications.

14.0 Pollution Prevention

Describe aspects of this method that minimize or prevent pollution that may be attributable to the reference method.

15.0 Waste Management

Cite how waste and samples are minimized and properly disposed.

16.0 References

- Source documents
- Publications

17.0 Tables, Diagrams, Flowcharts and Validation Data

Additional information may be presented at the end of the method. Lengthy tables may be included here and referred to elsewhere in the text by number. Diagrams should only include new or unusual equipment or aspects of the method.