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Standard Guide for Documenting the Standard Operating Procedures Used for the Analysis of Water[1]

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1. Scope

1.1 This guide addresses the need for each laboratory engaged in the analysis of water and wastewater to develop and maintain an up-to-date written manual that clearly and completely delineates the exact steps followed in performing every test method and procedure used in the laboratory, that is, a manual of their standard operating procedures (SOPs).

1.2 This guide details the practices necessary to provide clear in-house SOPs and a mechanism whereby the normal development and evolution of an analytical test method or procedure can be controlled and properly evaluated for incorporation into the SOP used in that laboratory.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* Specific precautionary statements are given in the note.

2. Referenced Documents

2.1 *ASTM Standards:*[2]
D1129 Terminology Relating to Water

3. Terminology

3.1 *Definitions*—For definitions of terms used in this guide, refer to Terminology D1129.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *procedure*— any process involving sequential steps conducted to achieve a specific objective.

4. Summary of Guide

4.1 This guide describes suggested practices for developing and maintaining a current compilation of the complete and exact analytical test methods and procedures being used in a particular laboratory.

5. Significance and Use

5.1 The exact analytical test methods and procedures used in any laboratory may be unique and affect the usability of their analytical results. A general reference to a book of standard analytical test methods, guides, and practices published by a reputable organization such as ASTM is not sufficient to guarantee acceptable results. As a point of clarification, a procedure may be part of a test method or it may be any other routine process the laboratory personnel must follow, for example, glassware cleaning, quality control, routine maintenance, or data reporting procedures.

5.2 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.

5.3 The manual of SOPs is an important component of any laboratory's quality assurance program. As with all quality assurance activities, the importance of this manual lies in its impact on maintaining uniformity of test method performance and the utility of data generated by the laboratory.

5.4 Each laboratory should develop and maintain a loose-leaf manual containing an exact step-by-step description of how every test method and procedure is performed in the laboratory to help guarantee uniform performance among different analysts using them.

5.5 With adequate documentation of a laboratory's complete and exact analytical test methods and procedures, a laboratory will have improved confidence in its ability to reproduce analytical conditions exactly and thereby general reproducible results. This manual of SOPs is the cornerstone of a laboratory's creditability.

[1] This guide is under the jurisdiction of ASTM Committee D19 on Water and is the direct responsibility of Subcommittee D19.02 on Quality Systems, Specification, and Statistics.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

6. Suggested Steps for Generating a Manual of SOPs

6.1 The manual should begin with specification of the published references from a standard-setting organization or regulatory agency. An adequate written SOP should then be drafted in-house for each test method or procedure performed by the laboratory. A standard format should be used that is appropriate to the SOP and is similar in scope to the formats included in this guide as Annex A1 and Annex A2. All aspects of the test method or procedure as actually applied in the laboratory should be addressed in detail.

NOTE 1—**Caution:** When a laboratory is performing an analytical procedure in a regulatory or legal environment, it is of vital importance that the in-house version be maintained within the technical allowances of the mandated procedure. Technical departures from the mandated procedure may result in a legal liability. One way to demonstrate consistency with the mandated procedure is to copy the standard procedure as published and add footnotes to fully document the specific in-house version.

6.2 The basic structure and elements of a test method are typically present in consensus standards published by groups such as ASTM. But, invariably, these published test methods and procedures must be interpreted for application in each laboratory. Published versions of other test methods and procedures are often very general or completely unavailable.

6.3 In generating a draft SOP, it is often helpful to solicit input from analysts experienced with a test method or procedure who are familiar with its vagaries and pitfalls, and can provide valuable assistance in writing a complete and exact document on how the procedure is done in the laboratory. It is often useful to have all of the analytical staff review the final draft.

6.4 After an initial draft to identify the pertinent details of an SOP, the laboratory should conduct a study to verify its applicability to the sample matrices encountered in that particular laboratory. In addition, the laboratory should verify that it can, at a minimum, obtain results with precision and bias equivalent to those in published references (if available for similar matrices). The precision and bias obtained in the study should be recorded for future use relating to evaluation of quality control (QC) data from the sample matrices studied.

6.4.1 This process of verifying the utility of an SOP for given sample types is called "method validation" and each laboratory needs an SOP detailing how this process is done in that laboratory. It is a process that should be performed whenever a new SOP is first put into practice or whenever an SOP is to be modified or used on new sample matrices.

6.5 When the test method involves the selection of various options depending on the sample matrix, it should be organized into subsections dealing with each of the optional paths. Each optional approach should be treated as a separate SOP. Mechanisms should be established whereby the exact procedures employed to generate a result can be identified at a later time. In cases where subsections of a test method for a single analyte reflect substantially different chemical bases, a completely separate SOP should be generated from each of these subsections.

6.6 The final version should be annotated with an effective date, revision number, page numbers out of total number of pages, and the author(s). The effective date is the date when it was first used to produce actual data. The final version and all subsequent revisions should be approved and signed by the laboratory manager and the quality assurance officer or their designees, and distributed to all analysts for bench use.

7. Centralized Files

7.1 A master copy of the laboratory's SOPs should be kept on-file under the control of the quality assurance officer. Whenever a procedure is modified, the revised version should be documented and the changes highlighted. Copies of the revised SOP should be distributed to the staff to replace the previous version, that they should destroy, and a new effective date for the revision and a revised copy of the SOP should be added to the master file along with an explanation of why the revision was necessary. Out-of-date versions of an SOP should be filed separately by the QA officer for future reference. Through use of such an updating mechanism, the laboratory will be able to identify the exact procedure being followed at the time a particular result was generated.

7.2 A laboratory's SOPs may be managed through the use of electronic documents. Whether through a paper system or electronic files, the key issue is that there is one, and only one, official SOP document at any moment. "Bench" copies of an SOP or analytical practice in the Lab should be referenced to this official document. If electronic or "computerized" SOP documents are employed, they must be adequately controlled with limited access to assure their integrity.

8. Suggested Use and Maintenance

8.1 While performing an SOP, the analyst should have a copy of the current documentation readily at-hand and follow it to the letter. If the SOP allows for multiple options, the option employed should be noted with the final results.

8.2 When an analyst encounters a situation for which no clear direction is provided in the SOP, possible changes should be discussed with a qualified supervisor, and approved and documented before use.

8.3 Records should be maintained of the distribution of the laboratory's SOPs and their revisions.

9. Procedure Audits

9.1 For a variety of reasons, procedures as they are actually applied in the laboratory have a tendency to drift away from the approved written versions. For this reason, the actual performance of each analyst while performing a test method or procedure should be audited by the responsible supervisor or the quality assurance officer, or both, on a periodic basis, ideally not less than once per year and more frequently during analyst's initial training period. Any deviations from the written SOP should be noted and evaluated. The analyst's performance should be corrected or the SOP should be modified to incorporate the deviations. When the deviations are deemed to be inappropriate, the SOP should be annotated to specifically exclude the noted deviation.

10. Responsibility for Improvement

10.1 Analytical methods and procedures are not static, finished products; they are continually modified in response to changing demands or to improve performance or efficiency. Every laboratory should emphasize the responsibility of its professional staff to monitor pertinent scientific publications for new developments relevant to the SOPs under their jurisdiction.

11. Keywords

11.1 analysis; documenting; procedure; standard operating procedure

ANNEXES

(Mandatory Information)

A1. SUGGESTED FORMAT FOR A TEST METHOD SOP

A1.1 *Record of Approval and Update*—Include the following information:

Approvals: Laboratory Manager_____ Date _____
QA Officer _____ Date ____
Revision No. _____ by _____ Effective Date _____
Total Pages _____ Pages Revised _____

A1.2 *Title*—The property, analyte, or class of compounds being measured. It is also useful to include any laboratory codes used to refer to this test method.

A1.3 *Principal Reference(s)*—A published reference(s) that defines the basic analytical method.

A1.4 *Scope of Application*—Types of sample matrices and the analytical range to which this test method can be applied.

A1.5 *Summary of Test Method*—A short description highlighting the definitive chemical and procedural elements of the test method.

A1.6 *Interferences*—A general overview of the kinds of matrices that cause unacceptable performance and the general mechanisms for compensating for them. The specific steps for dealing with interferences should be incorporated in the procedure portion of the test method as options defining a unique method.

A1.7 *Sample Handling*—Itemize any concerns relating to proper handling of samples after they are received for analysis. Specifically indicate holding times, storage procedures, and preservation procedure (applied at or prior to receipt).

A1.8 *Apparatus:*

A1.8.1 *Instruments*—Specify model and make.

A1.8.2 *Labware*—Specify preparation and conditioning, class, assembly instructions, diagrams, etc.

A1.9 *Chemicals and Reagents*—A listing of required chemicals, purity grade; instructions for reagent makeup; standardizing, storing, and disposing of reagents; reagent and chemical shelf life.

A1.10 *Safety*—Identify at each point in the test method where safety precautions are to be observed; reference this section or a safety manual.

A1.11 *Procedure*—A detailed description of each step considered essential to the reproducibility and accuracy of the test method as actually carried out in the laboratory. Include calibration procedures. Re-analysis sample preparation steps should be specified.

A1.12 *Short Hand Procedure*—A condensed version of the test method that can be used for quick reference.

A1.13 *Calculation*—A description of the mathematical steps required to complete the analysis. Include sample calculations and the number of significant figures to report. It is also helpful to include a sample of the analytical bench form.

A1.14 *Data Management*—Specific instructions on how and where data should be reported, and on what, how, and where data should be stored.

A1.15 *Quality Assurance and Quality Control:*

A1.15.1 Itemize desirable and mandatory quality assurance procedures specific to this test method, especially equipment and reagent checks, recalibrations, and other system checks that should be done routinely. This section should be referenced in the procedure section (see A1.11).

A1.15.2 Specify statistical quality control parameters: batch size, reference materials, frequencies, data handling. This should also be referenced in the procedure section (see A1.11).

A1.15.3 *Lowest Reporting Level*—The concentration below which all results are reported as “less than,” based on the specified procedure and sample size. The laboratory should adopt a uniform system for determining this limit.

A1.15.4 *Precision and Bias Statements* —A tabulation of these statistics as determined using this test method in your laboratory, by matrix and concentration level.

A1.16 *References*—A listing of published documents supporting the specifics of this test method.

A1.17 *Appendixes*—Copies of documents, tables, or graphs that would be useful to have appended to the test method.

A2. SUGGESTED FORMAT FOR A NON-TEST METHOD SOP

A2.1 *Record of Approval and Update*—Include the following information:

Approvals: Laboratory Manager_____ Date _____
QA Officer _____ Date _____
Revision No. _____ by _____ Effective Date _____
Total Pages _____ Pages Revised _____

A2.2 *Title*—Should be descriptive of the SOP.

A2.3 *Summary of the SOP*—Should include a statement of its purpose.

A2.4 *Apparatus*—Provide description.

A2.5 *Safety*—Discuss any hazards and how they may be minimized.

A2.6 *Procedure*—A detailed description of each step of the SOP.

A2.7 *Quality Assurance*—Discuss applicable maintenance, performance review, and corrective procedures.

A2.8 *Responsibility*—Identify individuals responsible for significant activities.

A2.9 *References*—A listing of related published documents.

A2.10 *Appendixes*—Copies of related and useful documents, tables, graphs, etc.