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Standard Guide for Management Systems in Laboratories Engaged in Analysis of Water[1]

This standard is issued under the fixed designation D3856; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide provides information on consensus good laboratory practices for laboratories that provide services in the sampling and analysis of water. As consensus standards, these are the minimum criteria that all laboratories should consider in establishing their good laboratory practices. This guide may not be applicable to certain types of laboratories (e.g., microbiological).

1.2 This guide is designed to be used by those responsible for the selection, operation, or control of laboratory organizations engaged in sampling and analysis of water.

1.3 This guide presents features of organization, facilities, resources, and operations which affect the usefulness of the data generated.

1.4 This guide presents criteria for selection and control of the features described in 1.3 and also makes recommendations for the correction of unacceptable performance.

1.5 This guide describes methodology and practices intended to be completely consistent with the International Organization for Standardization (ISO) 9000 series of standards and Guide 25 – 1990 (**1**). [2]

1.6 The values stated in inch-pound units are to be regarded as the standard. The values given in parentheses are for information only.

1.7 *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.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

D1129 Terminology Relating to Water
D1193 Specification for Reagent Water
D2777 Practice for Determination of Precision and Bias of Applicable Test Methods of Committee D19 on Water
D3370 Practices for Sampling Water from Closed Conduits
D3694 Practices for Preparation of Sample Containers and for Preservation of Organic Constituents
D4210 Practice for Intralaboratory Quality Control Procedures and a Discussion on Reporting Low-Level Data[4]
D4375 Practice for Basic Statistics in Committee D19 on Water
D4447 Guide for Disposal of Laboratory Chemicals and Samples
D4840 Guide for Sample Chain-of-Custody Procedures
D4841 Practice for Estimation of Holding Time for Water Samples Containing Organic and Inorganic Constituents
D5172 Guide for Documenting the Standard Operating Procedures Used for the Analysis of Water
D5847 Practice for Writing Quality Control Specifications for Standard Test Methods for Water Analysis
E456 Terminology Relating to Quality and Statistics
E548 Guide for General Criteria Used for Evaluating Laboratory Competence[4]

3. Terminology

3.1 For definitions of terms used in this guide, refer to Terminologies D1129, D4375, and E456, Guide E548, and *ASTM MNL 7*(**2**).

[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] The boldface numbers in parentheses refer to the list of references at the end of this guide.

[3] 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.

[4] Withdrawn. The last approved version of this historical standard is referenced on www.astm.org.

4. Summary of Guide

4.1 This guide describes the criteria, guidelines, and recommendations for physical and human resources and data validation for the operation of a laboratory.

4.2 Although, philosophically, this guide is intended to apply to all analyses of water, there may be certain test methods to which parts of this guide are not applicable due to the nature of the samples, for example, microbiological analyses.

5. Significance and Use

5.1 Data on the composition and characteristics of water are frequently used to evaluate the health and safety to humans and the environment.

5.2 Moreover, such data are frequently used for process control or to ascertain compliance with regulatory statutes that place limits on acceptable compositions and characteristics of waters.

5.3 Laboratories that conduct water sampling and generate analytical data, and those persons who have the responsibility for selecting a laboratory to perform water quality studies, need to use criteria, guidelines, and recommendations that have been developed by consensus and are well accepted in making this selection.

5.4 Demonstration and documentation by a laboratory that there was judicious selection and control of organization, facilities, resources, and operations will enhance the credibility of the data produced and promote its acceptance.

6. Organization

6.1 *General*—The production of reliable data is effected through the effort of everyone involved with the service. It is paramount, therefore, that personnel have a clear understanding of their duties and responsibilities and their relationship to the product produced. Management has the responsibility for defining function and goals as applied to the individual. A formal document describing objectives, staff functions and responsibilities, should be distributed and explained to all staff members.

6.1.1 The personnel in a laboratory will vary with the specific functions that are to be served, but minimal qualifications and duties generally will be as described in 7.2 through 7.3.2.

6.2 *Laboratory Director*—Must have a BS or BA degree with a strong chemistry emphasis and with at least 5 years laboratory experience including supervisory roles or equivalent.

NOTE 1—The purpose of the —equivalent‖ requirement is to allow the assignment of persons who have comparable skills obtained through qualified training which did not result in the award of a baccalaureate degree. Interpretation of the term —equivalent‖ will necessarily require careful judgment by the user of these guidelines. Certification by professional boards is to be encouraged.

6.2.1 The laboratory director or manager should be a full-time employee who operates the laboratory with at least the responsibilities outlined below.

6.2.1.1 Establishment of long-term program plans and shorter term work plans and assignments to meet the program objectives.

6.2.1.2 Operation and maintenance of the physical plant (building, equipment, instrumentation, services, etc.).

6.2.1.3 Selection, training, and development of personnel.

6.2.1.4 Overview and approval of methods of sampling and analyses.

6.2.1.5 Oversee development and implementation of a Quality Assurance (QA) program to monitor and maintain the quality of laboratory performance. This includes ensuring staff participation in appropriate interlaboratory quality control activities, intercalibration checks, performance audit programs, etc. Such interlaboratory checks are the most effective measure of comparative performance and should demonstrate the worth of a good QA program to upper management or regulatory agencies. A QA program also provides each laboratory staff member with a copy of the QA plan for the laboratory, which documents responsibilities and kind and frequency of quality control checks. The plan should also specify the monitoring and overview responsibilities of management. This responsibility is implemented by the Quality Assuranace Manager or Coordinator.

6.2.1.6 Establishment of a development and operational performance appraisal system for the staff and an individual career development plan for each staff member. Performance standards should be developed and agreed to jointly by each staff member and their supervisor. The director should be responsible for assuring a periodic review of performance of all staff members by supervisors, for rewarding good quality performance, and for implementing and encouraging on-the-job or offsite training. This joint development of performance standards is key to obtaining an understanding between the worker and the supervisor, as to what is expected for satisfactory performance. It also paves the way for rewarding outstanding performance or identifying unsatisfactory performance. These standards should be used to evaluate performance frequently but informally, and formally on a less frequent (annual or semiannual) basis.

6.2.2 Quality Assurance Manager or Coordinator – Reports directly to the Laboratory Director.

6.2.2.1 Develops and implements the QA Plan as described above.

6.2.2.2 Investigates any quality issues and reviews on a regular basis the quality of all work performed by the laboratory.

6.2.2.3 Hosts third party laboratory assessments and responsible for seeing that all findings are addressed and corrective actions completed.

6.2.2.4 Implement intra- and inter-laboratory QA performance testing programs and evaluate results and taking corrective actions as necessary.

The laboratory shall have one or more of the following staff or persons responsible for multiple roles.

6.2.3 *Senior Staff*——The senior professional staff of the laboratory conduct the difficult and non-routine sampling and analyses, resolve analytical problems, and modify and develop analytical procedures.

6.2.3.1 Senior staff supervise and assist the technical staff in analyses, other laboratory operations and training.

6.2.3.2 Senior staff members should have earned a baccalaureate degree in science or engineering, with a strong chemistry emphasis, from an accredited college or the equivalent (see Note 1) and have at least two years experience at the bench level in a water laboratory.

6.2.4 *Technical Staff*—The technical staff are personnel who perform routine and specialized analyses.

6.2.4.1 Where appropriate, technical staff members should have formal training in the analytical methodology, and quality control, as applied to the specific sample types and concentration levels of analytes which are of interest to the laboratory.

6.2.4.2 Technical staff may be required to satisfactorily complete analytical tests to qualify initially and to periodically re-qualify throughout their work career. Qualification should be based on the generation of analytical results with precision and bias recovery within limits known to be possible for the particular method and which meet the data user's requirements.

6.2.5 *Laboratory Support Staff*—The support staff are nontechnical workers who perform routine field laboratory services in support of the professional and technical staff.

6.2.5.1 In the laboratory, they wash glassware, operate laboratory reagent water systems, autoclaves, drying ovens, and incubators. The support staff also receives, stores, and ships samples, materials, and laboratory equipment.

6.2.6 *Office Support Staff*—The office staff are nontechnical clerical or secretarial personnel who are trained either on the job or by formal schooling in computer programs, filing, recordkeeping, communications by telephone or personal visits, payroll, travel, or some combination thereof.

6.2.6.1 The laboratory or office support staff may be an integral part of the laboratory or may be provided as part of the administrative function in a larger organization.

6.3 *Physical Resources and Related Operating Procedures*:

6.3.1 The laboratory environment can significantly affect the results of water analyses; therefore, the laboratory facility should be carefully designed and periodically inspected and reevaluated. In general, the physical conditions in the laboratory should comply with the applicable U.S. OSHA requirements, and other regulatory safety and legal requirements.

6.3.2 *Equipment and Supplies*—The specific instrumentation, equipment, materials, and supplies needed for the performance of a standard test method are usually described in a written standard operating procedure (SOP). If the laboratory proposes to perform a new analytical procedure, it must be prepared to acquire the necessary instrumentation, supplies and space, and to conduct an appropriate training period prior to its routine use.

6.3.3 *Laboratory Environment*—The laboratory should be kept as free from environmental contamination as possible in order to protect the samples and instrumentation. Specific procedures should be established for assuring the quality of the laboratory reagent water per method specifications or Specification D1193. By doing so, the laboratory ensures the opportunity to produce quality data. The production of valid data not only depends on the collection of representative samples, but also on maintaining such samples as closely as possible to their original condition through careful handling and storage. If the sample cannot be analyzed at once, it should be preserved and stored as required for the analytes of interest. Recommended procedures for collecting, transporting and handling water and wastewater samples are described in this guide or in Practices D3370 and D3694. Recommended chain of custody procedures are described in Guide D4840. Whenever sample holding times must be determined, recommended procedures are described in Practice D4841.

6.3.4 *Ventilation System*—Laboratories should be well ventilated and free of dust, drafts, and extreme temperature changes. Central air conditioning is recommended because: 1) incoming air is filtered, reducing the likelihood of airborne laboratory contamination; 2) uniform temperature is conducive to stable operation of instrumentation and equipment; and 3) low humidity reduces moisture problems with hygroscopic chemicals, samples, and corrosion problems with analytical balances and other instrumentation.

6.3.4.1 In order for the hoods to be effective in removing fumes and aerosols from the laboratory environment, they must be operating at their designed capacity. Proper hood performance cannot be assumed. Hoods should be tested periodically for proper air flow by qualified support staff or a professional maintenance contractor. Hoods should not be located in areas of countervailing drafts, such as between two open doors. Under usual operating conditions, hoods require from 50 to 125 CFM/ft^2 (15 to 38 (m^3 /min)/m^2) of face area. For a more detailed treatment of ventilation consult *Industrial Ventilation—A Manual of Recommended Practice* (4) .

6.3.5 *Facilities*—Ideally, the areas provided for cleaning of glassware and portable equipment should be separated from the laboratory working area but located close enough for convenience.

6.3.5.1 Laboratories conducting trace organic analyses which use organic solvents in extraction and clean-up procedures must separate these activities from analytical instrumentation rooms to avoid contamination and reduce hazards.

6.3.5.2 Laboratories conducting analyses with a wide range of concentrations must take care to avoid cross contamination among samples in storage or analysis. Relatively clean samples, highly polluted samples and reagents should be stored separately from each other in vented cabinets and hoods to avoid cross-contamination.

6.3.5.3 Calibration standards should be stored separately from all samples.

6.3.5.4 *Laboratory Design*—Limited facilities and restricted work space may affect the quality and validity of results. Visitors and incidental traffic should be discouraged in work areas. Through traffic can be prevented by good laboratory design.

6.3.5.5 High standards of cleanliness should be maintained and monitored for contamination in work areas and the laboratory. If there is any doubt about the effects of the surrounding laboratory facility upon the analytical results, blanks that have been protected against the laboratory environment should be compared periodically against sample blanks that have been exposed to the laboratory environment.

6.3.5.6 A complete set of material safety data sheets (MSDSs), or equivalent safety information for all chemicals used in the laboratory, should be on file in a location accessible