Designation: E 1579 – 94

AMERICAN SOCIETY FOR TESTING AND MATERIALS
100 Barr Harbor Dr., West Conshohocken, PA 19428

Standard Guide for Ensuring Data Integrity in Highly Computerized Laboratory Operations[1]

This standard is issued under the fixed designation E 1579; 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 covers general requirements for data integrity for computer operations in a laboratory. This guide expands upon the requirements of paragraph 11.7 in Guide E 548 for those laboratories that are highly computerized and is intended to be used in conjunction with Guide E 548 in the assessment of testing laboratories.

1.2 This guide presents requirements that are generally in harmony with and in addition to those in Guide E 548 (ISO/IEC Guide 25); the paragraphs dealing with similar subjects carry similar numbers.

1.3 Additional requirements may be necessary for fields of testing where the computer system(s) are integrated into the test methods themselves. These requirements can normally be found in the test methods.

1.4 In highly computerized laboratories, computers are increasingly being used for:

1.4.1 Direct capture of data from instruments and testing machines;

1.4.2 Automatic control and monitoring of test processes;

1.4.3 Control of critical environmental conditions;

1.4.4 Capture, processing, and display of laboratory quality-control data;

1.4.5 Basic data processing;

1.4.6 Data storage and retrieval;

1.4.7 Generation of test reports;

1.4.8 Scheduling and monitoring of work throughput;

1.4.9 Monitoring and control of inventories;

1.4.10 Equipment inventories, and calibration and maintenance schedules;

1.4.11 Design of statistical experiments; and

1.4.12 Communication between laboratories (and with clients).

1.5 The assessment of the highly computerized laboratory will depend upon the nature of the computer systems and the functions they are intended to perform. This guide may be useful in assessing portions of computer systems in less highly computerized laboratories.[2]

1.6 *This standard does not purport to address all of the safety problems, 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:*

E 548 Guide for General Criteria Used for Evaluating Laboratory Competence[3]

E 1187 Terminology Relating to Laboratory Accreditation[3]

2.2 *ISO Standards:*

ISO/IEC Guide 25: General Requirements for the Competence of Calibration and Testing Laboratories[4]

3. Terminology

3.1 *Definitions*—Basic definitions are those of Terminology E 1178.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *highly computerized laboratory*—one in which computers are employed to perform almost all of the laboratory functions (for example, as identified in 1.4) with staff merely setting up the samples for testing and overseeing the process.

3.2.2 *raw data*—data used as input to a computerized operation in the laboratory: must be defined explicitly for each computer operation. Section 13 further amplifies the meaning.

3.2.3 *software*—written instructions that, when implemented, cause the computer or application program to operate.

4. Significance and Use

4.1 A laboratory is the processor and provider of information. Like other processors and providers of information, laboratories are exploiting the benefits of modern information technology.

4.2 The assessment of a highly computerized laboratory

---

[1] This guide is under the jurisdiction of ASTM Committee E-36 on Laboratory and Inspection Agency Evaluation and Accreditation and is the direct responsibility of Subcommittee E36.10 on Genetic Criteria.

Current edition approved Oct. 15, 1994. Published March 1999.Originally published as E 1579 - 93. Last previous edition E 1579 - 93.

[2] Older laboratory computer systems or less "highly computerized" systems in laboratories may not be capable of conforming to the provisions of this guide due to software or hardware limitations, or both. If conformance to this guide is important to the laboratory's operations, it may be necessary to appropriately upgrade the software or hardware, or both, before it is possible to achieve guide criteria.

[3] *Annual Book of ASTM Standards*, Vol 14.02.

[4] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

using this guide will depend upon the nature of the computer systems and the functions they are intended to perform.

4.3 The output of the laboratory is essentially information: the test report that the laboratory issues reflects the manner in which this information is packaged and delivered to the client, and the test and measurements are intermediate stages through which the raw data are captured and processed.

5. Organization and Management

5.1 The laboratory shall have an organization with management and operations implementing the requirements of this guide at all times and in all aspects of the automated data collection system. The laboratory management shall:

5.1.1 Identify clearly defined responsibilities and the specific individual(s) (responsible person(s)) with authority to continually determine compliance with the documented requirements for the computer system(s). This(se) individual(s) shall ensure that:

5.1.1.1 There are sufficient personnel with adequate training and experience to supervise and operate the computer system(s);

5.1.1.2 The continuing competency of staff who develop or use the computer system(s) is maintained by documentation of their training, review of work performance, and verification of required skills;

5.1.1.3 The computer system(s) has written operating procedures and appropriate software documentation that are complete, current, and available to all staff;

5.1.1.4 There are adequate acceptance procedures for software and software changes and that all significant changes to operating procedures are approved by review and signature;

5.1.1.5 There are procedures to ensure that data are accurately recorded in the computer system(s);

5.1.1.6 Problems with the computer system(s) that could affect data quality are documented when they occur, are subject to corrective action, and the corrective action is documented; and

5.1.1.7 A security risk assessment has been made, points of vulnerability of the system(s) determined, and all necessary security measures have been implemented.

5.2 Ensure that personnel are adequately trained on the computer system(s).

5.3 Receive reports of quality assurance assessments or audits of computers, software, and any computer-resident data and promptly take corrective actions in response to any identified deficiencies. These shall be coordinated with appropriate regulatory requirements.

5.4 Ensure that any deviations from this guide for laboratory computer system(s) are reported to the designated responsible person(s) and that corrective actions are taken and documented.

5.5 Ensure that the laboratory's quality assurance system includes monitoring the computer system(s).

6. Quality System

6.1 Laboratory personnel shall be responsible for monitoring those aspects of testing in which the computer system(s) is extensively used. The laboratory's quality assurance personnel (or other appropriately designated personnel) shall inspect and audit the computer system(s) and the related test information documentation at intervals adequate to ensure the integrity of the testing.

6.1.1 The laboratory's quality assurance personnel shall:

6.1.1.1 Maintain a copy of the written test procedures which include operation of the computer system(s);

6.1.1.2 Perform periodic assessments of the computer system(s) and submit properly signed records of each assessment, the tests included in the assessment, the person performing the assessment, the findings and problems identified, action recommended and taken to resolve existing problems, and any scheduled dates for reassessment. Any problems noted in the computer system(s) that are likely to affect testing integrity found during the course of an inspection shall be brought to the immediate attention of the designated responsible person(s);

6.1.1.3 Determine that no deviations from approved written operating instructions and software were made without proper authorization and sufficient documentation; and

6.1.1.4 Periodically review final data reports to ensure that results produced by the computer system(s) accurately represent the raw data.

6.2 Laboratories using highly computerized system(s) must conduct comprehensive audits of overall system performance, including document review, after a major software/hardware revision, or at least once every year. These audits must be documented and the documentation must be retained for an appropriate period to suit its particular circumstances and comply with any applicable regulations.

7. Personnel

7.1 When the computer system(s) is used in association with or in performance of the testing, all personnel involved in the design or operation of the computer system shall:

7.1.1 Have adequate education, training, and experience to enable those individuals to perform the assigned system functions,

7.1.2 Have a current summary of their computer training, experience, and job description included in their personnel file, and

7.1.3 Be of sufficient number for timely and proper maintenance of the automated data collection system(s).

8. Accommodation, Environment, and Security

8.1 When a computer system(s) is used in performing the testing, the laboratory shall:

8.1.1 Ensure that the facility used to house the computer system(s) has provisions to regulate the environmental conditions, that is, temperature, humidity, electrical requirements, and that these provisions are adequate to protect the system(s) against data loss due to environmental problems; and

8.1.2 Provide adequate storage capability to retain raw data, including archives of computer-resident data.

8.2 When a computer system(s) is used in performing the testing, the laboratory shall evaluate the need for system security. The laboratory shall have procedures that ensure that the computer system(s) is secured if that system:

8.2.1 Contains confidential information that requires protection from unauthorized disclosure; or

8.2.2 Contains data whose integrity must be protected