



Standard Guide for Laboratory Informatics¹

This standard is issued under the fixed designation E1578; 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 helps describe the laboratory informatics landscape and covers issues commonly encountered at all stages in the life cycle of laboratory informatics from inception to retirement. It explains the evolution of laboratory informatics tools used in today's laboratories such as Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebooks (ELN), Scientific Data Management Systems (SDMS), and Chromatography Data Systems (CDS). It also covers the relationship (interactions) between these tools and the external systems in a given organization. The guide discusses supporting laboratory informatics tools and a wide variety of the issues commonly encountered at different stages in the life cycle. The sub-sections that follow describe details of scope of this document in specific areas.

1.2 *High-Level Purpose*—The purpose of this guide includes: (1) helping educate new users of laboratory informatics tools, (2) provide a standard terminology that can be used by different vendors and end users, (3) establish minimum requirements for laboratory informatics, (4) provide guidance for the specification, evaluation, cost justification, implementation, project management, training, and documentation of the systems, and (5) provide function checklist examples for laboratory informatics systems that can be adopted within the laboratory and integrated with the existing systems.

1.3 *Laboratory Informatics Definition*—Laboratory informatics is the specialized application of information technology aimed at optimizing laboratory operations. It is a collection of informatics tools utilized within laboratory environments to collect, store, process, analyze, report, and archive data and information from the laboratory and supporting processes. Laboratory informatics includes the integration of systems, the electronic delivery of results to customers, and the supporting systems including training and policies. Examples of laboratory informatics include: Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebooks (ELNs),

Chromatography Data Systems (CDS), and Scientific Data Management Systems (SDMS).

NOTE 1—Laboratory informatics scope encompasses multiple technical solutions or systems. The division between these system categories continues to soften as functionality continues to be added to each of them. LIMS were originally created to address the laboratories' need to manage laboratory operations and data, provide traceability for all laboratory samples and equipment, and ensure that laboratory procedures are followed. ELNs, on the other hand, were originally created to meet the scientists' need to document their experimental design, execution, and conclusions in an electronic format instead of in a paper notebook. SDMS was created to provide a repository of all scientific data files and results regardless of instrument type. The current definitions of each of these system categories are far more encompassing.

1.4 *Scope Considerations When Selecting and Implementing Laboratory Informatics Solutions*—Many laboratories have determined that they need to deploy multiple laboratory informatics systems to automate their laboratory process and manage their data. Selection of an informatics solution requires a detailed analysis of the laboratory's requirements rather than by choosing a product category. It is important to include representatives from Information Technology (IT) and Subject Matter Experts (SMEs), who understand the needs of the laboratory, to be involved in the selection and implementation of a laboratory informatics system to ensure that the needs of the laboratory are met and that IT can support it. Customers (internal and external) of laboratory information should also be included in the laboratory informatics solution design, to ensure there is full electronic integration between systems.

1.5 The scope of this guide covers a wide range of laboratory types, industries, and sizes. Examples of laboratory types and industries are listed in the following:

1.5.1 *General Laboratories:*

1.5.1.1 Standards (ASTM, IEEE, ISO), and

1.5.1.2 Government (EPA, FDA, JPL, NASA, NRC, USDA, FERC).

1.5.2 *Environmental:*

1.5.2.1 Environmental Monitoring.

1.5.3 *Life Science Laboratories:*

1.5.3.1 Biotechnology, and

1.5.3.2 Diagnostic.

1.5.4 *Healthcare Medical:*

1.5.4.1 Devices,

1.5.4.2 Pharmaceuticals vet/animal,

1.5.4.3 Public health, and

¹ This guide is under the jurisdiction of ASTM Committee E13 on Molecular Spectroscopy and Separation Science and is the direct responsibility of Subcommittee E13.15 on Analytical Data.

Current edition approved Aug. 1, 2013. Published November 2013. Originally approved in 1993. Last previous edition approved in 2006 as E1578-06. DOI: 10.1520/E1578-13.