



Standard Guide for Validation of Laboratory Information Management Systems¹

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1. Scope

1.1 This guide describes an approach to the validation process for a Laboratory Information Management System (LIMS).

1.2 This guide is for validation of a commercial LIMS purchased from a vendor. The procedures may apply to other types of systems, but this guide makes no claim to address all issues for other types of systems. Further, in-house developed LIMS, that is, those developed by internal or external programmers specifically for an organization, can utilize this guide. It should be noted that there are a number of related software development issues that this guide does not address. Users who embark on developing a LIMS either internally or with external programmers also should consult the appropriate ASTM, ISO, and IEEE software development standards.

1.3 This guide is intended to educate individuals on LIMS validation, to provide standard terminology useful in discussions with independent validation consultants, and to provide guidance for development of validation plans, test plans, required standard operating procedures, and the final validation report.

2. Referenced Documents

2.1 ASTM Standards:²

E622 Guide for Developing Computerized Systems (Discontinued 2000) (Withdrawn 2000)³

E623 Guide for Developing Functional Requirements for Computerized Systems (Withdrawn 1994)³

E624 Guide for Developing Implementation Designs for Computerized Systems (Withdrawn 1994)³

E627 Guide for Documenting Computerized Systems (Discontinued 2000) (Withdrawn 2000)³

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.

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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.

³ The last approved version of this historical standard is referenced on www.astm.org.

E919 Specification for Software Documentation for a Computerized System (Discontinued 2000) (Withdrawn 2000)³

E1013 Terminology Relating to Computerized Systems (Withdrawn 2000)³

E1384 Practice for Content and Structure of the Electronic Health Record (EHR)

E1578 Guide for Laboratory Informatics

E1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems (Withdrawn 2002)³

2.2 IEEE Standards:⁴

100 Standard Dictionary of Electric and Electronic Terms

610 Standard Glossaries of Computer-Related Terminology

729 Glossary of Software Engineering Terminology

730.1 Standard for Software Quality Assurance Plans

730.2 Guide for Software Quality Assurance Plans

828 Standard for Software Configuration Management Plans

829 Standard for Software Testing Documentation

830 Guide for Software Test Documentation

1008 Standard for Software Unit Testing

1012 Standard for Software Verification and Validation Plans

1016 Recommended Practice for Software Design Descriptions

1028 Standard for Software Reviews and Audits

1042 Guide to Software Configuration Management

1058-1 Standard for Software Project Management Plans

1063 Standard for Software User Documentation

1074 Standard for Developing Software Life Cycle Processes

1228 Standard for Software Safety Plans

2.3 ISO Standards:⁵

9000 Quality Management and Quality Assurance Standards – Guidelines for Selection and Use

9000-3 Guidelines for Application of ISO 9001 to Development, Supply, and Maintenance of Software

9001 Quality Systems—Model for Quality Assurance in Design, Production, Installation, and Servicing

9002 Quality Systems—Model for Quality Assurance in Production and Installation

⁴ Available from Institute of Electrical and Electronics Engineers, Inc. (IEEE), 445 Hoes Ln., P.O. Box 1331, Piscataway, NJ 08854-1331, <http://www.ieee.org>.

⁵ Available from International Organization for Standardization (ISO), 1 rue de Varembe, Case postale 56, CH-1211, Geneva 20, Switzerland, <http://www.iso.ch>.