



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:

- E 622 Guide for Developing Computerized Systems²
- E 623 Guide for Developing Functional Requirements for Computerized Systems³
- E 624 Guide for Developing Implementation Designs for Computerized Systems³
- E 627 Guide for Documenting Computerized Systems²
- E 919 Specification for Software Documentation for a Computerized System²
- E 1013 Terminology Relating to Computerized Systems²
- E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)²
- E 1578 Guide for Laboratory Information Management Systems (LIMS)²
- E 1639 Guide for Functional Requirements of Clinical

Laboratory Information Management Systems (CLIMS)

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
- 9003 Quality Systems—Model for Quality Assurance in Final Inspection and Test
- 9004 Quality Management and Quality System Elements—Guidelines
- 9004-2 Quality Management and Quality System Elements, Part 2 Guidelines for Services
- 9004-4 Guidelines for Quality Improvements
- 10005 Guidelines for Quality Plans
- 10007 Guidelines for Configuration Management

¹ This guide is under the jurisdiction of ASTM Committee E01 on Analytical Chemistry for Metals, Ores and Related Materials and is the direct responsibility of Subcommittee E01.25 on Laboratory Data Interchange and Information Management.

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² Annual Book of ASTM Standards, Vol 14.01.

³ Discontinued 1994; see 1993 Annual Book of ASTM Standards, Vol 14.01.

⁴ Available from Institute of Electrical and Electronic Engineers, Inc., 445 Hoes Lane, P. O. Box 1331, Piscataway, NJ 08855-1331.

⁵ Available from International Organization for Standardization, 1 rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland.