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Standard Guide for Laboratory Information Management Systems (LIMS)[1]

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1. Scope

1.1 This guide describes computer systems used to manage laboratory information. The term Laboratory Information Management Systems (LIMS) describes this class of computer systems.

1.2 This guide covers LIMS ranging from small laboratories with simple requirements to large multi-site laboratories with complex requirements. The elements of the LIMS guide may be selected based on specific laboratory requirements.

1.3 The audience of this document includes: (*1*) end users of LIMS, (*2*) implementers of LIMS, (*3*) LIMS vendors, (*4*) instrument vendors, and (*5*) individuals who must approve LIMS funding.

1.4 The purpose of this guide includes: (*1*) help educate new users of Laboratory Information Management Systems (LIMS), (*2*) provide standard terminology that can be used by LIMS vendors and end users, (*3*) establish minimum requirements for primary LIMS functions, (*4*) provide guidance for the specification, evaluation, cost justification, implementation, project management, training, and documentation, and (*5*) provide an example of a LIMS function checklist.

1.5 Information contained in this guide will benefit a broad audience of people who work or interact with a laboratory. New LIMS users can use this guide to understand the purpose and functions of LIMS. The guide can help prospective LIMS users in understanding terminology, configurations, features, design, and costs. Individuals who are purchasing a LIMS can use this guide to identify functions that are recommended for specific laboratory environments. LIMS vendor Research and Development staffs can use the guide as a tool to evaluate, identify, and correct areas that need improvement. LIMS vendor sales staffs can use the guide to accurately represent functions of their LIMS product to prospective customers. This guide does not define laboratory instrument interfaces.

1.6 This guide can be used by laboratories of all sizes. The guide addresses complex issues that impact primarily large LIMS implementations. Small laboratories should review issues that may impact their environments. The implementation times and recommendations listed in this guide are directed at medium and large laboratories.

2. Referenced Documents

2.1 *ASTM Standards:*

E 622 Generic Guide for Computerized Systems[2]
E 625 Guide for Training Users of Computerized Systems[2]
E 627 Guide for Documenting Computerized Systems[2]
E 730 Guide for Developing Functional Designs for Computerized Systems[2]
E 731 Guide for Selection and Acquisition of Commercially Available Computerized Systems[2]
E 792 Guide for Computer Automation in the Clinical Laboratory[2]
E 919 Specification for Software Documentation for a Computerized System[2]
E 1013 Terminology Relating to Computerized Systems[2]
E 1029 Guide for Documentation of Clinical Laboratory Computer Systems[2]
E 1340 Guide for Rapid Prototyping of Computerized Systems[2]
E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems[2]
E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems[2]

2.2 *IEEE Standards:*

100—Standard Dictionary of Electrical and Electronic Terms[3]
610—Standard Glossaries of Computer-Related Terminology[3]
729—Glossary of Software Engineering Terminology[3]
730.1—Standard for Software Quality Assurance Plans[3]
730.2—Guide for Software Quality Assurance Plans[3]
828—Standard for Software Configuration Management Plans[3]
829—Standard for Software Test Documentation[3]
830—Guide to Software Requirements Specifications[3]
1008—Standard for Software Unit Testing[3]
1012—Standard for Software Verification and Validation Plans[3]
1016—Recommended Practice for Software Design Descriptions[3]
1028—Standard for Software Reviews and Audits[3]

[1] This guide is under the jurisdiction of ASTM Committee E-49 on Computerized Systems and Chemical and Material Information and is the direct responsibility of Subcommittee E49.07 on Laboratory Information Management Systems (LIMS).

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[2] *Annual Book of ASTM Standards*, Vol 14.01.

[3] Available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.

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