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Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems

This document covers the capabilities needed for a logical structure of a Clinical Laboratory Information Management System (CLIMS).



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VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

Preface

In 2001, ASTM Committee E31 decided to restructure its operations, with the intent of focusing on standards-development issues such as security, privacy, and the electronic health record. Part of the reorganization plan was to explore the option of transferring responsibility for nine E31.13 standards to NCCLS.

The NCCLS Area Committee on Automation and Informatics, at its meeting in April 2002, reached a positive assessment of the value of the ASTM standards and encouraged the NCCLS Executive Offices staff to pursue negotiations with ASTM on transferring these standards to NCCLS.

Following this transfer, these nine standards (formerly ASTM E792; E1029; E1238; E1246; E1381; E1394; E1466; E1639; and E2118) have been redesignated as NCCLS standards LIS1 through LIS9.

The Area Committee on Automation and Informatics has assumed responsibility for maintaining the documents and will revise or update each document in accord with NCCLS Administrative Procedures.

This document is the equivalent of ASTM E1639-01 but has been redesignated and is now maintained by NCCLS. This document has been approved as an American National Standard (ANSI/ASTM E1639-01).

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Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems

1. Scope

1.1 This guide covers the capabilities needed for a logical structure of a Clinical Laboratory Information Management System (CLIMS). It was written so that both the vendors or developers of CLIMS and laboratory managers would have a common understanding of the requirements and logical structure of a laboratory data system. This guide will also help answer many of the questions faced by designers of CLIMS and provide more uniformity in the way that requirements are expressed from one laboratory to another. It is therefore applicable to users who are involved with acquiring or operating a CLIMS.

2. Referenced Documents

2.1 ASTM Standards:

- E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (RADT) Systems for Automated Patient Care Information Systems¹
- E 1340 Guide for Rapid Prototyping of Computerized Systems¹
- E 1384 Guide for Content and Structure of the Electronic Health Record (EHR)¹
- E 1460 Specification for Defining and Sharing Modular Health Knowledge Bases (Arden Syntax for Medical Logic Modules)²
- E 1578 Guide for Laboratory Information Management Systems (LIMS)¹
- E 1633 Specification for Coded Values Used in the Electronic Health Record (EHR)¹
- E 1712 Specification for Representing Clinical Laboratory Procedure and Analyte Names¹
- E 1714 Guide for Properties of a Universal Healthcare Identifier¹
- E 1715 Practice for an Object-Oriented Model for Registration, Admitting, Discharge, and Transfer (RADT) Functions in Computer-Based Patient Record Systems¹

2.2 ANSI Standards:

- ANSI X3.172-1990 American National Dictionary for Information Systems³
- ANSI X11.1 M Programming Language³

2.3 NCCLS Standards:

- NCCLS Auto Communications System, Instrument Systems⁴
- NCCLS AUTO3-A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems⁴

2.4 IEEE Standards:⁵

- IEEE 1074 Standard for Developing Software Life Cycle Processes
- IEEE 610.2 Standard Glossary of Computer Applications Terminology
- IEEE 610.5 IEEE Standard Glossary for Information Management Terminology
- IEEE 610.12 Standard Glossary of Software Engineering Terminology
- IEEE 830 Software Requirements Specification
- IEEE 1058 Software Project Management Plans
- IEEE 1362 Guide for Information Technology—System Definition-Concept of Operations

2.5 ISO Standard:

- ISO 11756 M Programming Language³
- ISO 12207 Information Technology—Software Life Cycle Processes³

2.6 Other Document:

- HL7 Health Industry Level 7 Interface Standards Version 2.3⁶

¹Annual Book of ASTM Standards, Vol 14.01.

²Discontinued 1999. See the 1999 Annual Book of ASTM Standards, Vol 14.01.

³Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

⁴NCCLS, 940 West Valley Rd., Suite 1400, Wayne, PA 19087-1898.

⁵Available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.

⁶Health Level 7, 3300 Washtenaw Ave., Suite 227, Ann Arbor, MI 48108.