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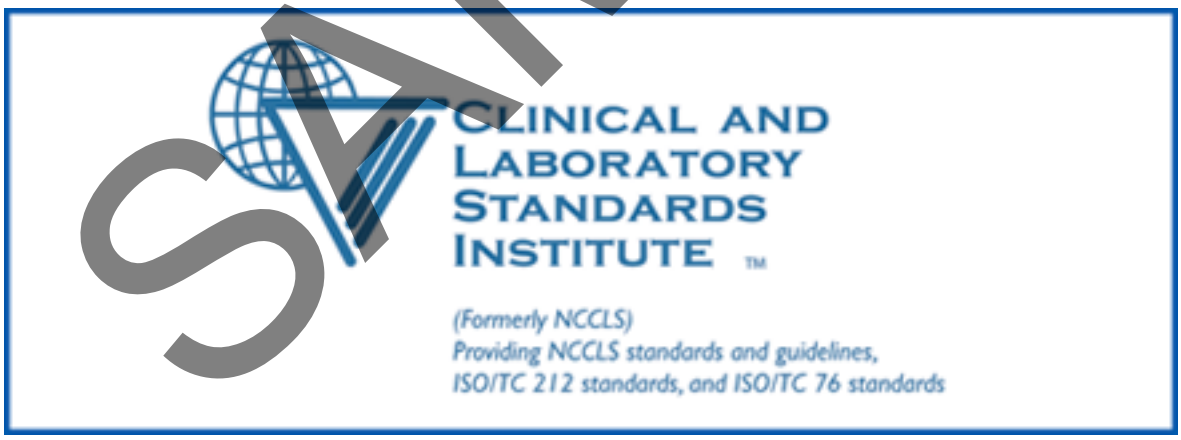
Standard Guide for Documentation of Clinical Laboratory Computer Systems



This document covers documentation for a computer system operating in a clinical laboratory.

NCCLS

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 E1029-01 but has been redesignated and is now maintained by NCCLS. This document has been approved as an American National Standard (ANSI/ASTM E1029-01).

Standard Guide for
Documentation of Clinical Laboratory Computer Systems

1. Scope

1.1 This guide covers documentation for a computer system operating in a clinical laboratory.

1.2 Documentation is defined as the information needed to install, use, maintain, or modify the system. This information shall be in a reusable form, and may exist in other forms as well. These forms may include printed manuals, online help screens, prompts, computer readable text, computer assisted instruction, audiotapes, or equivalent media. As technology and software techniques change, the form of the documentation may also change. It is a central component of the processes by which system life cycles are managed. Hereafter, the term "documentation" shall encompass all such possible forms.

1.2.1 This documentation includes information that explains how the users interact with and operate the system. This may include a terminal operator's guide, training documentation, system operation descriptions, and database and file maintenance instructions.

1.2.2 Documentation also includes reference documents that describe functional and internal characteristics of the system, such as software reference manuals, source code, descriptions of file structures, hardware reference manuals, schematics, and flow charts. Paragraphs 3.1 and 3.6 might apply when some of this information is proprietary.

1.2.3 Documentation includes test procedures to establish whether the system is installed correctly and continues to operate properly. The frequency that the tests are to be performed, the test data sets to be used, and whether the results are to be compared to manual methods should be provided.

1.3 The computer systems under consideration are those designed to assist the general workflow of the laboratory. They typically include some or all of the following features: sample tracking, data gathering, report generation, record keeping, quality assurance, management aids, and hospital communications. They may range from very large to small computer systems. Computers dedicated only to a single instrument are not the primary focus.

1.4 *This standard does not purport to address the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer R-ADT Systems for Electronic Health Record (EHR) Systems [1]

E 1985 Guide for User Authentication and Authorization[1]

E 1986 Guide for Information Access Privileges to Health Information[1]

E 1987 Guide for Individual Rights Regarding Health Information[1]

E 1988 Guide for Training Persons who have Access to Health Information[1]

E 2017 Guide for Amendments to Healthcare Information[1]

E 2084 Specification for Authentication of Healthcare Information Using Digital Signatures[1]

E 2085 Guide on Security Framework for Healthcare Information[1]

E 2086 Guide for Internet and Intranet Security[1]

E 2147 Specification for Audit and Disclosure Logs for Use in Healthcare Information Systems[1]

2.2 *ISO Standards:*

ISO IS 12207 Information Technology-Software Life Cycle Processes

ISO CD 15288 System Life Cycle Processes

2.3 *NCCLS Standards:*

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

NCCLS AUTO4-A Laboratory Automation: Systems Operational Requirements, Characteristics and Information Elements

2.4 *Other Standards:*

21 CFR 809.10[2]

[1] Annual Book of ASTM Standards, Vol 14.01.

[2] The Code of Federal Regulations is available from the Superintendent of Documents, US Government Printing Office, Washington, DC 20402.