



Designation: E 1029 – 01

An American National Standard

Standard Guide for Documentation of Clinical Laboratory Computer Systems¹

This standard is issued under the fixed designation E 1029; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

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, audio tapes, 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 work flow 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 792 Guide for Selection of a Clinical Laboratory Information Management System²
- E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer R-ADT Systems for Electronic Health Record (EHR) Systems²
- E 1246 Practice for Reporting Reliability of Clinical Laboratory Computer Systems²
- E 1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems²
- E 1985 Guide for User Authentication and Authorization²
- E 1986 Guide for Information Access Privileges to Health Information²
- E 1987 Guide for Individual Rights Regarding Health Information²
- E 1988 Guide for Training Persons who have Access to Health Information²
- E 2017 Guide for Amendments to Healthcare Information²
- E 2084 Specification for Authentication of Healthcare Information Using Digital Signatures²
- E 2085 Guide on Security Framework for Healthcare Information²
- E 2086 Guide for Internet and Intranet Security²
- E 2118 Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures²
- E 2147 Specification for Audit and Disclosure Logs for Use in Healthcare Information Systems²

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

¹ This guide is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.13 on Clinical Laboratory Information Management. Prepared in cooperation with the College of American Pathologists (CAP).

Current edition approved Nov. 10, 2001. Published January 2002. Originally published as E 1029–84(1997). Last previous edition E 1029–84(1997).

² Annual Book of ASTM Standards, Vol 14.01.



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

2.4 *Other Standards:*

21 CFR 809.10³

21 CFR 58.81³

IEEE-1362 Concept of Operations

3. Significance and Use

3.1 This guide may be used as a checklist of the subjects that should be covered by the documentation. The level and needed content of the documentation to be acquired, however, varies with the needs of the laboratory and the scope, purpose, and price of the system. Not all laboratories need all the items listed in this guide. The laboratory and the seller need to determine what documentation is required on site for each system, based on the rationales presented in this guide and the procedures outlined in Guide E 792 and Guide E 2118. All laboratories shall obtain at least the minimum amount of documentation that is appropriate and not necessarily only the amount wanted for immediate needs. Proof is important that necessary documentation exists and can be obtained later.

3.2 In this guide, the verb *shall* implies a mandatory requirement, *should* a strong recommendation that may not be appropriate in all situations, and *may* an optional feature or example.

3.3 This guide is primarily concerned with the content of the documentation, and its role in the management of the life cycle model. Presentation of the material in this guide must follow an organizational scheme. The actual documentation produced for any system need not be organized in the same way.

3.4 All documentation shall be prepared with sufficient detail and clarity to make it useful to the intended user.

3.5 Some documentation is best prepared by the system vendor and some by the system purchaser. This section describes who typically prepares the documentation.

3.5.1 The vendor supplied documentation should include all materials needed to:

3.5.1.1 Understand the operation of the equipment and software,

3.5.1.2 Install the system,

3.5.1.3 Verify system operation, engineering performance specifications, and application performance characteristics,

3.5.1.4 Operate the system,

3.5.1.5 Recognize and recover from system problems, including repair procedures,

3.5.1.6 Perform preventive maintenance,

3.5.1.7 Modify laboratory defined parameters, and

3.5.1.8 Enhance or modify the system, based upon understanding of the system design, and still permit the system to be maintained.

3.5.2 The laboratory prepared documentation should include:

3.5.2.1 Policy on system use,

3.5.2.2 Policy on quality assurance procedures,

3.5.2.3 Schedules of activities not already required or suggested by the vendor, such as scheduled times for production of reports,

3.5.2.4 Operation manuals that are specific for individual tasks or personnel positions, and

3.5.2.5 Backup and recovery procedures.

3.5.2.6 Interoperable integration into enterprise architectures.

3.5.3 In particular cases, variances in who prepares the documentation may be in order. This guide can be used as a focus of discussions between vendor and purchaser on not only the need for specific items of documentation, but who shall provide it. Included in this category are training materials.

3.6 Availability of a complete set of documentation is necessary for the continued effective use of the clinical laboratory computer system. Availability is also necessary to satisfy the requirements of Federal Regulation (FDA) 21 CFR 809.10. If the system is used in nonclinical applications, other Federal Regulations may apply (such as (FDA) 21 CFR 58.81 dealing with good laboratory practices). The laboratory may wish to obtain a license or other agreement to maintain such a complete set of documentation on site.

3.7 In most cases it is necessary to distinguish between training and reference documentation. In this context, the training function is defined as a structured activity designed to teach new users how to operate the system in the context of their jobs, or to expand the knowledge and abilities of existing users. Training material presents information in a logical way, often skipping over or reserving for later special cases, options, and fine details. Reference material provides the fullest detail of the system and is usually organized by subject. It is typically used by experienced people to operate and maintain the system. In many cases, the documentation needed for reference is not suitable for structured training and sometimes it is not understandable until the training is complete. The laboratory must decide whether to use only training materials provided by the vendor, supplement vendor training with those prepared in whole or part by the laboratory, or use no special training materials at all. Training materials may exist in any form as described in 1.2.

4. System Overview

4.1 A general description of the system is an important introduction for most readers. It should give the scope of activities handled by the system, a general overview of the functional approach used by the system, a general description of components of the system, and any general instructions needed by the user of the rest of the documentation. The latter might include an explanation of style (such as the technique used to distinguish system response from operator input in examples), use of abbreviations, and a description of the organization and purpose of other manuals. This may include material organized in the format of IEEE-1362.

4.2 Particularly useful is a description of system operating and formatting style conventions, such as screen style conventions, the form for expressing dates, names, and so forth, and how to transmit data from terminals to the computer (that is, the "enter" key on some terminals).

4.3 A glossary of terms should be supplied as a general reference.

³ The Code of Federal Regulations is available from the Superintendent of Documents, US Government Printing Office, Washington, DC 20402.



to understanding the documentation.

4.4 Since many of the system users in a clinical laboratory have little experience with computer systems, special documentation for beginners is desirable.

4.5 When the documentation is extensive, there shall be an aid for locating specific information such as help buttons and screens.

4.5.1 The aid should take the form of an index (preferred), but in some cases may be a detailed table of contents, or equivalent. It should be prepared for every separately identified item of documentation.

4.5.2 In addition, an overall system of cross-indexing, hyperlinks, or equivalent is desirable when documentation exists in different forms and places.

5. Installation

5.1 *Site Requirements*—There shall be a document provided by the system vendor that specifies the site requirements in sufficient detail to allow design and construction of the site, or sites where the system components may be used, and to permit testing of compliance with these specifications. This documentation is typically produced by the original equipment manufacturer and passed on to the user by the system vendor.

5.1.1 The following items may be important:

5.1.1.1 Temperature limits for satisfactory operation and for shipping and storage.

5.1.1.2 Heat generated by the system and air conditioning requirements.

5.1.1.3 Limits on relative humidity at the site.

5.1.1.4 Dust limits, if any.

5.1.1.5 Altitude limits, if any. High voltage breakdown is affected by atmospheric pressure, as is the heat capacity of air which can effect the cooling requirements.

5.1.1.6 Electrical power. This includes the voltage, whether single or three-phase, and power consumption. If separate grounding, filtering, regulation, or other conditioning is required, it too shall be specified.

5.1.1.7 The need for fire alarms, temperature monitoring or alarms, flood detectors, humidity monitors, electrical power monitors, or other site monitoring equipment.

5.1.1.8 The need for special fire extinguishers or other emergency equipment beyond code requirements.

5.1.1.9 The floor and desk space required for the system, including recommended or required access space, desirable or required orientation of equipment modules, and the need for chairs, tables, shelves, racks, cabinets, other equipment, or raised flooring.

5.1.1.10 Dimensions and weight of the supplied equipment.

5.1.1.11 Situations where high acoustic noise may be produced. This is important for equipment in patient areas and when a noise suppression environment is recommended to protect employee working conditions.

5.1.1.12 Requests for communications connecting a mosaic of systems components and external systems.

5.1.2 *Site Compliance*—A method of testing compliance of each site requirement shall be given.

5.1.3 *Site Maintenance*—All procedures needed to maintain the site shall be specified. These may include:

5.1.3.1 Log books, indicating all site problems and their

correction, results of regular checks, scheduled maintenance, and the like.

5.1.3.2 Monitoring equipment (as described in 5.1.1.5) and the procedures for interpreting the results of these monitors.

5.1.3.3 Any special recommendations for the janitorial staff shall be provided. This may include floor cleaning materials and techniques, waste disposal, and other such operations.

5.2 *Assembly*—Documentation from the hardware vendor shall describe how the components of the system are assembled, how the interconnections are made, and how hardware performance can be verified. The documentation should describe such things as switches, jumpers, or other controls or selectable options and give directions for setting them properly. Lastly, checkout procedures and, if needed, methods of calibration or alignment should be presented.

5.3 *Start-Up*—The method of starting system operation after the computer has been powered-up shall be described.

5.3.1 If the procedure is different for restarting the system after an error has caused operations to become disrupted or difficult, the restart procedure should also be described.

5.4 *System Generation*—In most systems, there is an initialization procedure, often called system generation. This procedure sets up the computer operating system to correspond with the exact hardware configuration installed. It can be more or less automatic, but it must be done. It, or an abbreviated form, may be required when new hardware components or laboratory instruments are added, additional memory is installed, or generally when the hardware configuration is changed.

5.4.1 *Device Configuration*—The method of configuring the operating system to support all the I/O devices attached to the computer shall be described.

5.4.2 *Software Options*—Frequently the system will support alternative procedures for specific activities. The method for selecting the desired procedure shall be specified.

5.4.3 If software components are delivered in different forms of machine readable media and require conversion before use, these procedures shall be described together with procedures to verify the proper loading of the software.

5.4.4 *Building the Operating System*—Some operating systems have considerable flexibility and are configured for each installation. Usually these are supplied by the original equipment manufacturer. Documentation shall describe the procedure to produce a working version of the operating system from its various component parts.

5.4.5 *Partition Sizes*—Some systems require that the memory size available to different users be specified. The procedures for doing this shall be described.

5.4.6 *Content of the Database*—Documentation shall be provided describing how to initialize all databases.

5.5 *Acceptance*—Criteria for acceptance are generally negotiated between vendor and purchaser, and the results should become a part of the documentation.

6. Training

6.1 Documentation is required for initial training of users, and as an ongoing effort as new personnel are hired or come into contact with the system.

