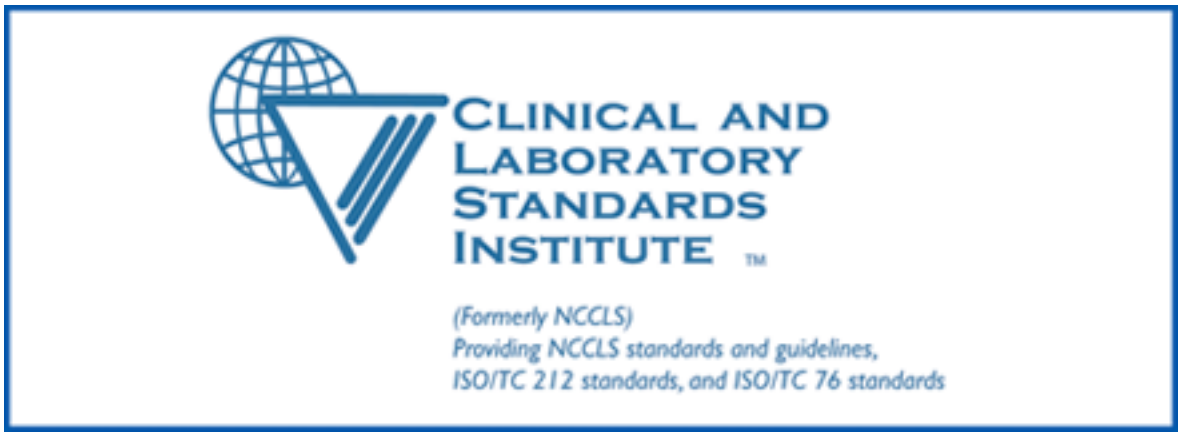
LIS4-A
Vol. 23 No. 10
Formerly ASTM E1029-01

Standard Guide for Documentation of Clinical Laboratory Computer Systems



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

NCCLS

NCCLS...

Serving the World's Medical Science Community Through Voluntary Consensus

NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

An NCCLS document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate (i.e., "tentative") consensus level.

Proposed An NCCLS consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Tentative A tentative standard or guideline is made available for review and comment only when a recommended method has a well-defined need for a field evaluation or when a recommended protocol requires that specific data be collected. It should be reviewed to ensure its utility.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

NCCLS standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following NCCLS's established consensus procedures. Provisions in NCCLS standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the NCCLS committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

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 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).

Suggested Citation

(NCCLS. *Standard Guide for Documentation of Clinical Laboratory Computer Systems.* NCCLS document LIS4-A [ISBN 1-56238-492-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.)

Published
April 2003

ISBN 1-56238-492-9
ISSN 0273-3099

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.

21 CFR 58.81[2]
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 NCCLS documents LIS3 and LIS9. 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 aid 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.

6.2 Training documentation may be external to the application system (for example, printed materials, or online multimedia instruction containing slides and movies).

6.3 Training documentation may also exist as online prompts and help functions produced by the computer on demand. This form is highly desirable for training and a training configuration of the system may be available in addition to the operational system. Such information is immediately available when one needs help during work sessions and does not require locating and then searching through extensive printed material. The information is also more easily maintained, with the latest version always available.

6.3.1 If the online help feature is supported by the computer system, it is recommended that help messages be made available for all input requirements beyond user sign-on.

6.3.2 The help messages are initially written by the vendor, but the user may have the option of configuring the text to suit local preferences and vocabulary, either on-site or with the assistance of the vendor. Changes to the prompts or help text can adversely affect the vendor support system.

6.3.3 Help text should be aimed at the intended user and should use appropriate language.

7. System Operators Documentation

7.1 This portion of the documentation is intended for those people who are running the system. It shall include directions for operating the various hardware components, operating the software, and recognizing and correcting problems. Much of this information must come from the vendor. There may also be a portion outlining laboratory and hospital policy, and scheduled activities.

7.2 Hardware operating instructions shall be included for each device. For example:

7.2.1 Turning the system on and off,

7.2.2 Changing ribbons and paper in printers and terminals, and

7.2.3 Mounting tapes and disks in mass storage devices.

7.3 Software and system operating directions shall be included, for example:

7.3.1 Starting or restarting the system,

7.3.2 Interrupting a running system,

7.3.3 Dealing with a catastrophic failure,

7.3.4 Running operator utilities, and

7.3.5 Recognizing and correcting other problems.

8. System Management Documentation

8.1 A set of information is needed by those individuals who must manage day-to-day operations.

8.2 Some systems are designed so the laboratory can select or reject features or set parameters to better tailor the system to the particular installation. An example would be the ability to change formats of reports or allow views of certain screens that depend upon user role. Documentation shall list all of these options and describe the procedures required to make the permitted changes.

8.3 Procedures for security and user control shall be described. These include the mechanism for giving new users permission to use the system and its designated functions for deleting users, and for changing the authorization of individuals to use various functions. Documentation of security procedures shall be available only to authorized people.

8.4 Many systems contain files of relatively fixed information needed for daily operation. These include such things as descriptions of laboratory personnel, lists of authorized physicians, lists of available beds, descriptions of tests, normal values for tests, and billing charges for various services. Procedures for maintaining the current state of this information shall be described.

8.5 In some systems, it is necessary to run special programs from time-to-time to maintain or check satisfactory operation or conduct certain laboratory management functions. The purpose of these programs and how to run them shall be described. Also, the schedule or criteria that indicates when the routines should be run shall be explained. As an example, some disk filing systems periodically require running a cleanup program to reorganize the information on the disk and recover more usable file space.

9. Information for Other User Categories

9.1 A user is an authorized person who interacts with the computer or its peripherals, uses the results, or supplies data for the system.

9.1.1 This documentation is written for users with different backgrounds. Each user guide has two parts. One part deals with the mechanical operation of the I/O equipment such as terminals, light pens, printers, and barcode readers. Included is general protocol, with such items as the functions of special keys, error recovery, sign-on procedures, and the general operating philosophy or format of the screen or key command sequences. This part is common to all guides.

9.1.2 The second part is specific for each type of job function. It includes related instructions and policy appropriate for each function for normal operation and for backup procedures. These depend upon the enterprise environment (see LIS9). Separate manuals may be prepared for the following functions:

9.1.2.1 Admission-discharge-transfer function (see Guide E 1239),

9.1.2.2 Test ordering function,

9.1.2.3 Sample collection function,

9.1.2.4 Sample allocation function,

9.1.2.5 Work scheduling at workstations,

9.1.2.6 Result entry function,

9.1.2.7 Result verification and quality assurance functions,

9.1.2.8 Result reporting/posting function,

9.1.2.9 Result inquiry function, and

9.1.2.10 Administrative functions.

9.1.3 Depending on enterprise and laboratory policy, the categories in 9.1.2 may be organized differently, or additional functions may exist.

9.1.4 One way to facilitate initial and ongoing training is to carefully prepare the user function documentation described in this section.

9.1.5 Online web-based instruction may be prepared for any of the described conventions.

10. Policy Manual

10.1 The institution normally has a policy manual available in each work center that contains general laboratory policy, specific departmental policy, and the like. This shall be revised to reflect the new methods and responsibilities when an information system is installed. This is often prepared by the laboratory. This policy documentation is either written separately or included as appropriate in other places. The following topics should be considered:

10.1.1 Regular schedule of activities, which may involve:

10.1.1.1 Normal report printing time,

10.1.1.2 Specimen draw list generation time,

10.1.1.3 Normal dumps and backup times,

10.1.1.4 Regular file maintenance activities,
10.1.1.5 Hardware maintenance schedules, and
10.1.1.6 Schedule of management reports.
10.1.2 Quality assurance procedures.
10.1.3 Personnel responsible for various functions and operations.
10.1.4 Security and privacy restrictions (see NCCLS document LIS8 and ASTM Guides E 1985, E 1986, E 1987, E 1988, E 2017, E 2084, E 2085, E 2086, E 2147).
10.1.5 Service procedures and responsibilities.
10.1.6 Procedures for reporting workload statistics and other clinical laboratory management information.
10.1.7 Accounting procedures.
10.1.8 Interfaces to other computers, such as hospital information systems.
10.2 In addition to normal procedures, an important part of the policy documentation concerns backup procedures. Backup procedures often are manual or require manual steps.
10.2.1 Procedures for receiving test orders and specimens, performing tests, and reporting results when the computer system is down or performance is degraded shall be given.
10.2.2 In addition, procedures shall be described for the uncompleted tests that were in the system when a system failure occurred.
10.2.3 Backup plans for various partial system failures should also be described.
10.2.4 Policy procedures for dealing with special circumstances and unexpected occurrences should be stated. An example might be the policy followed if unusual or odd test requests are received.
10.2.5 If backup procedures are not explicitly included in the work station policy or user function documentation, there shall be a separate reference in that documentation to where backup information exists.
10.3 Documentation shall be prepared to define the procedures in the event of a site failure. Such failures include fire or flood, loss of electricity, or a breakdown of the air conditioning system. This is likely to be laboratory written since it involves questions of policy. Often this policy might simply dictate that the procedure is to call someone else with authority to perform service.

11. Hardware Devices

11.1 The documentation in this section is normally prepared by the hardware device manufacturer or the system supplier, as appropriate.
11.2 There shall be a section on operator procedures for each hardware device. This section should give a brief statement of the function of the device, tell how to start and stop the unit, perform other operations, and give instructions for dealing with common problems and contingencies. The criteria for identifying proper operation should be specified. This may involve indication of the expected time for a given task, or indicator light or sound patterns (or both), or system messages that should occur. Any special procedures or operations required to verify proper operation after routine service or correction of common problems shall be stated.
11.3 There shall be a statement of essential specifications for each device, such as the physical size and site requirements, performance specifications, electrical power and other facilities needed, and recommended environment conditions. See 5.1.
11.4 An installation guide shall be provided for each device. See 5.2.
11.5 An interface specification shall be provided. It should state the connector type, pin definitions, and electrical specifications of the signals available or required at each connector pin. It is desirable to also give the data format in use and all critical timing constraints. Lastly, the format and content of the messages that move through these interconnections should be specified, insofar as they are determined by the hardware. (The software documentation described in Section 12 calls for a specification of message format that is based on software decisions or constraints.)
11.5.1 An interface specification shall be provided for every laboratory instrument that is connected to the computer system, including point-of-care services. Obtaining documentation for existing instruments may be the responsibility of the owner.
11.5.2 An interface specification shall be provided for each end of any computer-to-computer connections.
11.6 A preventive maintenance section shall provide a schedule when routine service is required and a description of how the various maintenance steps are carried out.
11.7 A troubleshooting and repair document shall be provided. It may be written in two levels if some maintenance is permitted by laboratory employees under the terms of the warranty or service contract, and some only by vendor representatives. The documentation should indicate who is permitted to perform each aspect of maintenance. In particular, it is important to give the on-site staff enough information so they can try to correct the problem. If vendor maintenance is required, the user staff must be instructed what information to collect so that the

vendor has the best chance of quickly identifying the failed component, and is able to bring a set of likely replacements.

11.7.1 The maintenance document should include a functional block diagram, a written statement of the theory of operation, and a written or graphical representation of the sequence of events.

11.7.2 It should include a flowchart or other guide to help service personnel isolate the source of problems from observed symptoms.

11.7.3 The operation of any diagnostic procedures shall be described. This may include continuous monitoring for certain faults, specific routines or procedures that are used from time-to-time to check operation (such as verification programs or a switch that turns on all lights so one can see if any are burned out), and procedures that are used to isolate problems when improper operation has been detected.

11.7.4 The documentation shall describe the physical location of basic component parts and test points. In addition, instructions for disassembly and reassembly of cabinetry and other parts to gain access to these test points and components may be required (depending on whether that process is obvious or not).

11.7.5 Any precautions in handling circuit boards or other components shall be stated.

11.7.6 A set of schematic diagrams that identifies each component, specifies the source of the component, and how it is connected in the circuit shall be provided.

11.7.7 A list of recommended spare parts should be provided.

11.7.8 A list of servicing and diagnostic equipment needed by the user to perform maintenance should be provided.

11.8 All system devices must meet legislated standards. It is recommended that all devices have Underwriters Laboratory or Canadian Standards Association labels, or equivalent. Any devices in primary care areas must also be tested and certified to NFPA standards. In addition, there may be local certification labels required. A method of insuring compliance with all appropriate standards shall be described or referenced. The responsibility for obtaining this information may be negotiated between seller and buyer.

12. Software

12.1 The software documentation is intended for those who maintain, alter, or enhance the software.

12.2 The documentation may be in two parts if the system is designed to permit some programming by customer personnel. One part would be instructions for writing and using such system supported features. The second part would be the detailed description of the entire system. In some cases, the latter may consist of a basic operating system supplied by the computer manufacturer plus one or more “application programs” written by the system supplier. The typical user, however, cannot change either of these two components without expert programming ability or vendor assistance, or both. Such changes often have serious effects on system maintainability.

12.3 The application software user's guide shall describe the programming or system configuration changes permitted by the system as part of the system life cycle (see IS 12207 and IS 15288).

12.3.1 In some cases, this may include a programming language. In other cases, user programs may be restricted to read-only access of the laboratory database. Any user manipulation of data is only permitted on copies made from the original, which remains undisturbed.

12.3.2 This guide shall describe the limitations that must be observed to prevent either maintenance or evolutionary system development activities from interfering with existing clinical laboratory functions. Any effect on warranty and maintenance contracts shall be described in explicit detail.

12.3.3 Any user-supplied enhancements produced as a result of life cycle maintenance process activities shall meet the same documentation standards as described in this guide. Such documentation shall exist prior to use of the enhancement. See Section 13.

12.4 *Operating System*—For those systems that utilize a computer manufacturers or other commercial operating system as a platform for the Clinical Laboratory Information Management System (CLIMS), documentation for that system shall be available. If the operating system is customized for the CLIMS application, the items in this section are still important, but may not be separately identifiable from the items in 12.5.

12.4.1 An operating system users guide shall provide all the information needed by programmers writing or modifying application programs that run under the operating system. For example:

12.4.1.1 An overview narrative, describing the basic structure and philosophical approach of the operating system, the required command structure, and any other features of a general nature.

12.4.1.2 A list of available utilities, their function, and instructions for using each.

12.4.1.3 A description of the interrupt handling mechanism, particularly with regard to how an application programmer can incorporate additional input/output devices. This is important, for example, if a nonstandard interface to laboratory equipment must be added.

12.4.1.4 A description of how to use each of the I/O device driver programs supported by the operating system, along with their device addresses.

12.4.1.5 A description of the file accessing mechanism, with examples of how files may be created, changed, deleted, or read by application programs.

12.4.1.6 A description of memory management schemes, if any.

12.4.1.7 A description of all system programs that monitor the system, including error logs, transaction logs, accounting logs, and security violation logs.

12.4.1.8 A description of all software patches to correct previously reported or new operating system errors. Also include here all uncorrected errors, giving the circumstances in which they occur, the ramifications of the error, and tactics to avoid encountering the error. The method and form by which new patches or newly discovered errors are reported to the laboratory by the vendor shall also be described in the documentation.

12.4.2 The detailed operating system description is for those responsible for maintaining and improving the operating system itself and is not generally available or useful to laboratories.

12.5 *Application Programs*—The application programs specialize the computer platform for the clinical laboratory as differentiated from other applications, and the documentation of such software shall be available. These programs manipulate the database, track samples, display information, write reports, and perform management assistance, quality assurance, and other such functions.

12.5.1 The application software can almost always be divided into logical segments, which in this guide will be referred to as individual application programs (whether or not they are actually assembled or compiled separately or are part of the same source file in the case of interpretive languages). With modularity of design, these can be referred to as components.

12.5.2 Documentation of components or application programs shall describe the procedures needed to prepare the programs. Many of these procedures include languages, linking programs, utilities, or include other function components of the operating system and may thus overlap with 12.4.

12.5.2.1 Documentation for each programming source language used to write the components or application programs shall be available. It should describe correct data structures, state the purpose and structure of each command (and its syntax as well as its semantics), give liberal examples, show the procedures and style for using the language, and provide a list of all possible error messages, their meaning, and suggestions for correcting the error.

12.5.2.2 The procedures for using any editing program source code shall be described.

12.5.2.3 The procedures for using a linking program to combine application programs into an operational system shall be described.

12.5.2.4 The procedures for using libraries, subroutines, and interfaces shall be described.

12.5.3 When program-linking procedures are utilized to combine application programs into a system, a list of the names of the application programs, their functions, and how they interrelate to one another shall be available.

12.5.4 Each component or application program shall be described, including:

12.5.4.1 A narrative and flow chart or equivalent logical description to explain the algorithm, formulas, and calculation methods used. Citations and references should be included where appropriate.

12.5.4.2 A description of the data structures and their organization, table structures, names and purposes of variables, and other such information.

12.5.4.3 The input and output requirements of each application program, including all user interactions needed to understand the functioning of the program.

12.5.4.4 A list of the files or persistent data structures needed by each application program. This list should also tell if and how the file is altered by the application program.

12.5.4.5 The context of each application program. This part of the documentation should indicate which hardware peripherals are needed and which other software segments are required for the application program to run properly. It should include the names of the programs and files each program accesses or affects, as well as those that access or affect this program.

12.5.4.6 Liberal comments. In the case of an interpretive language where comments consume memory, a separate commentary keyed to program line numbers is satisfactory. Even with a compiled language, comments consume file space for the source programs. If this space is scarce, comments can be kept on paper. In the absence of such constraints, it is better if comments are kept in a way that permits them to be easily included in the source code listings.

12.5.4.7 A method of testing operation. This may include sample test cases used regularly to verify proper operation. It may also include thorough test procedures to check all aspects after a program modification has been made. The latter should verify that functions still work, legal inputs are still accepted, and illegal inputs are still rejected.

12.5.4.8 The documentation shall be reviewed or revised, or both, according to the guidelines of this section if any program portion is altered.

12.5.4.9 All software changes that have been applied in order to correct application program errors shall be provided. All known, but uncorrected errors shall be described, giving the circumstances in which they occur, the ramifications of the error, and tactics to avoid encountering the error. The method and form by which new changes

or newly discovered errors are reported to the laboratory by the vendor as part of the life cycle processes should also be described in the documentation.

12.6 The database management system itself shall be described, including the structure of the data, access methods, and security.

12.6.1 For each file in the database related to the clinical laboratory operation, there shall be a description containing the following items:

12.6.1.1 Name of the file.

12.6.1.2 Purpose of the file.

12.6.1.3 Organization of the content. This should include a description of the structure of the records.

12.6.1.4 An identification of the fields that can be used as access keys.

12.6.1.5 A description of any ordered lists (sorting) of the records. These might be used, for example, to print the file content in a certain sequence.

12.6.1.6 Access privileges, if any.

12.6.1.7 Any limits on the size of fields or records or other features within the file.

12.6.1.8 A list of all programs that use the file, along with an indication of whether they create, modify, delete, or simply access the records of the file.

12.6.1.9 A list of any related files, along with a statement of the relationship. This may include its links, whether it is accessed from or itself accesses other files, how it interacts with the data base software, and any other interactions with other files.

12.6.1.10 Device dependency, if any.

12.6.1.11 Logical limits on file size and address restrictions, if any.

13. Improvements

13.1 Documentation shall describe what can be changed in the system without destroying its integrity. Documentation should also describe the purposes and effects of such changes. This may include new hardware, a new operating system, different hardware configuration, additional files, system configuration changes using existing files, new software components, and the like. A description of other hardware, or other features that the system can support should be provided.

13.1.1 Improvements include correction of errors, expansion of capacity, or adding new features and functions.

13.1.2 Each change to the system, either supplied by the vendor or accomplished internally, shall be documented as described by the other sections of this standard. It is important that documentation be kept current with regard to any alterations made to the system. In addition, this documentation should describe the purposes and effects of such changes.

14. Use Records

14.1 There is an ongoing responsibility throughout its lifetime to maintain accurate usage records for the system. This shall include:

14.1.1 Regular logs, giving regular operating statistics, including all startups and shutdowns, and all performance test results.

14.1.2 Installation, maintenance, and repair records.

14.1.3 Records of system changes and enhancements.

14.1.4 Restart logs.

14.1.5 Actual system downtime (see LIS6).

14.1.6 Site monitoring records. Monitoring may include electrical supply, electrical emission, acoustic level, and heat output.

14.1.7 Evaluation of performance and user satisfaction.

14.2 A record of the changes made in the documentation itself shall be maintained.

14.3 These records shall be maintained for a time period specified by institutional policy, vendor policy, or legal requirements.

NOTES

NOTES

NOTES

NOTES

NOTES

NCCLS ▼ 940 West Valley Road ▼ Suite 1400 ▼ Wayne, PA 19087 ▼ USA ▼ PHONE 610.688.0100
FAX 610.688.0700 ▼ E-MAIL: exoffice@nccls.org ▼ WEBSITE: www.nccls.org ▼ ISBN 1-56238-492-9