Designation: E 792 – 02

An American National Standard

Standard Guide for Selection of a Clinical Laboratory Information Management System[1]

This standard is issued under the fixed designation E 792; 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 the selection, purchase, use, enhancement, and updating of computer technology supplied by a vendor as a complete system in the clinical laboratory. The purpose of the guide is to assist hospitals, clinics, and independent laboratories through the entire automation project in order to minimize the risks and maximize the benefits. It provides a process that may be used by the medical institution to carry out laboratory information projects in a rational and orderly manner. It also includes checklists of items to be considered at each stage of planning to help guard against the unpleasant consequences of oversights. It includes planning and design aids to assist in carrying out the project. In addition, there is information (see Section 18) about enhancement and updates after the system is purchased.

NOTE 1—The term "stat," as used in this guide is the abbreviation for the Latin word *statim*, which means immediately.

1.2 This guide is not concerned with digital or computer electronics used only within instrumentation. Rather, it deals with the application of information systems to a large segment of the laboratory operation, and generally is concerned with how Information and Communications Technology (ICT) can be used to enhance the interaction of the laboratory with the rest of the institution, improve workflow in the laboratory, and help keep records. Such systems will normally include segments for patient biographical information, test ordering, specimen collection, workstations worklists, test result entry, result verification, patient result reporting, management reports, archiving, and other special functions.

1.3 The major topics are found in the following sections:

1.4 *This standard does not purport to address all of the safety concerns, if any, 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.*

[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. This guide was prepared in cooperation with the American Association for Clinical Chemistry.

Current edition approved Jan. 10, 2002. Published March 2002. Originally published as E 792–81. Last previous edition E 792–95ε1.

2. Referenced Documents

2.1 *ASTM Standards:*

E 622 Guide for Developing Computerized Systems[2]
E 623 Guide for Developing Functional Requirements for Computerized Systems[3]
E 624 Guide for Developing Implementation Designs for Computerized Systems[3]
E 625 Guide for Training Users of Computerized Systems[2]
E 626 Guide for Evaluating Computerized Systems[3]
E 627 Guide for Documenting Computerized Systems[2]
E 730 Guide for Developing Functional Designs for Computerized Systems[3]
E 731 Guide for Selection and Acquisition of Commercially Available Computerized Systems[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[4]
E 1113 Guide for Project Definition for Computerized Systems[3]
E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems[4]
E 1239 Guide for Description for Reservation/Registration—Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems[4]
E 1246 Practice for Reporting Reliability of Clinical Laboratory Computer Systems[4]
E 1340 Guide for Rapid Prototyping of Computerized Systems[4]
E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems[4]
E 1384 Guide for Description for Content and Structure of an Automated Primary Record of Care[4]
E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems[4]
E 1466 Specification for the Use of Bar Codes on Specimen Tubes in the Clinical Laboratory[4]
E 1633 Specification for Coded Values Used in the Computer-Based Patient Record[4]
E 1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems[4]
E 1712 Specification for Representing Clinical Laboratory Procedure an d Analyte Names[4]
E 1714 Guide for Properties of a Universal Healthcare Identifier UHID[4]
E 1715 Practice for an Object-Oriented Model for Registration, Admitting, discharge and Transfer (RADT) Functions in Computer-based Patient record Systems[4]
E 2118 Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures[4]

2.2 *IEEE Standards:*[5]

2.2.1 *IEEE Computer Society Standards:*

ANS/IEEE 610.2-87 Computer Application Terminology
ANS/IEEE 610.12 Glossary of Software Engineering Terminology
ANS/IEEE 730-84 Software Quality Assurance Plans
ANS/IEEE 828-83 Software Configuration Management Plans
ANS/IEEE 829-83 Software Test Documentation
ANS/IEEE 830-84 Software Requirements Specification
ANS/IEEE 983-85 Software Quality Assurance Plans Guide
ANS/IEEE 1002-87 Taxonomy for Software Engineering Standards
ANS/IEEE 1008-86 Software Unit Testing
ANS/IEEE 1012-86 Software Verification and Validation Plans
ANS/IEEE 1016-87 Software Design Descriptions
ANS/IEEE 1058–99 Software Project Management Plans
ANS/IEEE 1063-87 Software User Documentation
ANS/IEEE 1074-8x Software Life Cycle Processes
ANSI/IEEE 1362 Concept of Operations
IEEE EMBS Standards

2.3 *ISO Information Systems Engineering Standards:*[6]

ISO 6592 Information Processing—Guidelines for the Documentation of Computer-Based Application Systems
ISO 9127 Information Processing—User Documentation and Cover Information for Consumer Software Packages
ISO 9294 Information Processing—Guidelines for the Management of Software Documentation
ISO 11756 M Programming Language
ISO 12207 Information Technology-Software Life Cycle Process
ISO CD 15288 Information Technology-System Life Cycle Processes

2.4 *Other ISO Information Systems Related Standards:*

HL-7, Health Industry Level Interface Standards, v 2.4[7]

2.5 *ANSI Standards:* [6]

ANS X3.88-1981 Computer Program Abstracts
ANS X3.172-1990 Dictionary for Information Systems
ANS X3-TR-6-82 Guide for Technical Documentation of Computer Projects
ANS X3-TR-89 Documentation of Consumer Software Packages
ANS X11.1 The MUMPS Programming Language
NCCLS AUTO1-A Laboratory Automation: Specimen Container/Specimen Carrier
NCCLS AUTO2-A Laboratory Automation: Bar codes for Specimen Container Identification
NCCLS AUTO3-A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices and Information Systems

[2] Discontinued. See 2000*Annual Book of ASTM Standards*, Vol 14.01.
[3] Discontinued. See 1994 *Annual Book of ASTM Standards*, Vol 14.01.
[4] *Annual Book of ASTM Standards*, Vol 14.01.
[5] Available from The Institute of Electrical and Electronics Engineers, Inc., 345 E. 47th St., New York, NY 10017.
[6] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.
[7] Available from Health Level Seven, 900 Victors Way, Suite 122, Ann Arbor, MI 48108.

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

NCCLS AUTO5-A Laboratory Automation: Electromechanical Interfaces

ANSI/NCCLS ASTP2 Point of Care In-vitro Diagnostic Testing

ANSI/NCCLS GP19 Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and Software Systems Validation, Operations and Maintenance

2.6 *Federal and DoD Standards:*[8]

FIPSPUB 38-76 Documentation of Computer Programs and Automated Data Systems

FIPSPUB 120-87 The MUMPS Programming Language

FIPSPUB 64-79 Documentation of Computer Programs and Automated Data Systems for the Initiation Phase

DoD Stand 7935 Documentation of Computer Programs and Automated Data Systems

DoD Std 2167A Defense System Software Development

DoD Std 2168 Software Quality Assurance Requirements

2.7 *NIST Standard:*[9]

NBS Handbook 118 The MUMPS Programming Language

3. Significance and Use

3.1 The decision to define and implement an information architecture for a clinical laboratory is an extremely critical one, and needs to be approached with utmost care. There are numerous examples where such attempts have met with financial and operational failure, as well as many successful projects that have improved laboratory and hospital operation. A key factor in most of the failures is poor planning or bad administrative design decisions at some point in the project. There are many far-reaching manifestations of a system Life Cycle that are not always fully appreciated at the early stages of the project when key decisions are required.

3.2 This is not a purchase guide. It is a description of the best recommended practices and procedures a hospital laboratory should follow over the system Life Cycle to most likely result in a productive and viable information architecture that meets the needs of the laboratory. It contains sections that may not be appropriate in all settings, and users of this guide must decide what is important and what is not.

3.3 In any such project, there is obviously a technology component. Appropriate hardware and software must be installed to provide necessary communications, database storage, processing activities, and user interaction functions. There is usually also a need for a strong “human orientation” that includes meaningful input protocols and easily understood output displays. Besides the system’s technical considerations, there is an organizational component to be examined. Those changes in the enterprise view that will be necessary in the traditional procedures within the laboratory, or in the rest of the institution, should be considered during the planning of the project.

3.4 The importance of getting input into the planning from all concerned parties is stressed in this guide. These include the institution administrators, laboratory management, laboratory staff, physicians, nurses, other laboratory customers, and information system vendors. Also stressed is the importance of thorough program review, consideration of alternatives, and careful definition of expectations before a decision to develop information architecture is made. Information systems should be installed in response to defined operational need, not for other reasons like institutional prestige or the necessity to use up available funds. Finally, this guide will prescribe very thorough planning and documentation of criteria prior to commitment to a particular system. All too often, the decision to use the product of a particular vendor is made before the requirements of the project are fully understood. A key first step in the Life Cycle is the completion of a Concept of Operations Document (ANSI/IEEE 1362) as noted in Guide E 2118.

4. Project Leader and Project Team

4.1 The project leader should be chosen early in the project with care since success of the project depends in large part on this individual. It is best if the project leader is based in the laboratory as opposed to other enterprise units. The leader must be well-motivated and respected by the staff. This usually means the individual should be a member of the senior medical staff of the clinical laboratory, or at least someone with good rapport with that staff. If not a physician, the individual must have sufficient knowledge of medicine and enterprise procedures to converse with the medical staff.

4.2 A good candidate for the project leader is the director of clinical laboratories, provided that individual has sufficient knowledge of informatics and a commitment to the project. People above the laboratory director, such as hospital administrators, are usually not close enough to the detailed laboratory operation to appreciate the significance of seemingly minor differences between systems. Also, the laboratory director is in a position to make changes in laboratory operations which may be required. A second choice for project leader is head of clinical chemistry if the information system is to be limited to chemistry. A third choice is chairman of pathology if this individual has a strong interest in the project.

4.3 The individual should be of sufficient status within the institution to allow effective communication with management, physicians, and others concerned with the project. The project leader needs the cooperation of key individuals and must be capable of working effectively with them. They include the administrative board, the chief executive officer, the budget officer, the head of the laboratory, the chief information officer, the head of the planning office, and the main users, the head of the medical staff and the head of nursing. Since the clinical laboratory information system project usually affects a wide segment of the enterprise, and is sometimes disruptive of established routines, the project leader must have the strong support of (*1*) someone high in the overall enterprise management; and (*2*) the laboratory director. Without this support, the project is likely to be unsuccessful for the simple reason that necessary cooperation from the various segments of the enterprise will not be forthcoming.

[8] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

[9] Available from NIST, Gaithersburg, MD 20899.