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An American National Standard

Standard Guide for Selection of a Clinical Laboratory Information Management System¹

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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:

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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.*

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2. Referenced Documents

2.1 ASTM Standards:

- E 622 Guide for Developing Computerized Systems²
- E 623 Guide for Developing Functional Requirements for Computerized Systems³
- E 624 Guide for Developing Implementation Designs for Computerized Systems³
- E 625 Guide for Training Users of Computerized Systems²
- E 626 Guide for Evaluating Computerized Systems³
- E 627 Guide for Documenting Computerized Systems²
- E 730 Guide for Developing Functional Designs for Computerized Systems³
- E 731 Guide for Selection and Acquisition of Commercially Available Computerized Systems²
- E 919 Specification for Software Documentation for a Computerized System²
- E 1013 Terminology Relating to Computerized Systems²
- E 1029 Guide for Documentation of Clinical Laboratory Computer Systems⁴
- E 1113 Guide for Project Definition for Computerized Systems³
- E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems⁴
- E 1239 Guide for Description for Reservation/Registration—Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems⁴
- E 1246 Practice for Reporting Reliability of Clinical Laboratory Computer Systems⁴
- E 1340 Guide for Rapid Prototyping of Computerized Systems⁴
- E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems⁴
- E 1384 Guide for Description for Content and Structure of an Automated Primary Record of Care⁴
- E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems⁴
- E 1466 Specification for the Use of Bar Codes on Specimen Tubes in the Clinical Laboratory⁴
- E 1633 Specification for Coded Values Used in the Computer-Based Patient Record⁴
- E 1639 Guide for Functional Requirements of Clinical Laboratory Information Management Systems⁴
- E 1712 Specification for Representing Clinical Laboratory Procedure and Analyte Names⁴
- E 1714 Guide for Properties of a Universal Healthcare Identifier UHID⁴
- E 1715 Practice for an Object-Oriented Model for Registration, Admitting, discharge and Transfer (RADT) Functions in Computer-based Patient record Systems⁴
- E 2118 Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures⁴

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 2.4⁷

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

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.

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.



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.

4.4 If a person is recruited from outside the enterprise, it should be on a permanent and not temporary basis. The position in the organization and responsibility to the enterprise should be clearly established. If an existing member of the enterprise's staff is selected, adequate allowance for the time demands of the project must be made. In either case, the project leader should report to an individual supportive of the project and high enough in the power structure to ensure cooperation and support from impacted units. A chain of command with an excessive number of links between the project leader and the higher management levels is unsatisfactory.

4.5 The project leader should have sufficient authority to call meetings, make operational and procedural decisions concerning the project, and commit planning funds.

4.6 If the individual chosen is not well-versed in information systems, he or she must acquire some of that knowledge. It is important that the project leader, while not necessarily an expert in all the areas of specialization needed for the project, be able to communicate with individuals in both the information technology field and the medical field.

4.7 It is also important that a proper team be selected to carry out the information system project. This team should be configured to give representation to all concerned parties. These include the users of the laboratory services (test requestors, readers of reports, etc.); the laboratory personnel that perform the services; the hospital admission-discharge-transfer (ADT) and billing personnel; the enterprise computer center, and the enterprise management. The project leader may elect to include assistance from individuals with specific proven expertise from the institution.

4.8 It is possible for a project team to become so large and unwieldy that little can be accomplished. A core team may be selected to carry out most of the work turning to the entire body for major policy decisions. It is recommended that the core team consist mostly of individuals based in the laboratory, but should often include a member of the enterprise information services staff.

4.9 The project team should also include individuals to provide the necessary skills and expertise. These include knowledge of enterprise operations, knowledge of laboratory operations, computer systems design, knowledge of data and file management systems, hardware and software specialties, information systems life cycle processes, management skills, forms design, and micrographics (if planned for archives). A cooperative skeptic is also useful on the project team to help the others face the limitations and realities of their plans.

4.10 Information systems projects are usually complex. Such projects require careful initial planning and, as the project proceeds, require periodic revision of actions and goals (1).³ (See also ANS/IEEE 1074-8x, ISO 12207, ISO CD 15288.) The use of PERT charts, GANT charts, and other project management tools (2) is recommended to assist management planning, updating, and strategy. Fig. 1 is a chart that shows the sequence of steps as described by this guide.

5. Project Definition

5.1 *General*—When a clinical information architecture is first conceived as a possible alternative to current practice, the first step should be a thorough self-examination to determine if

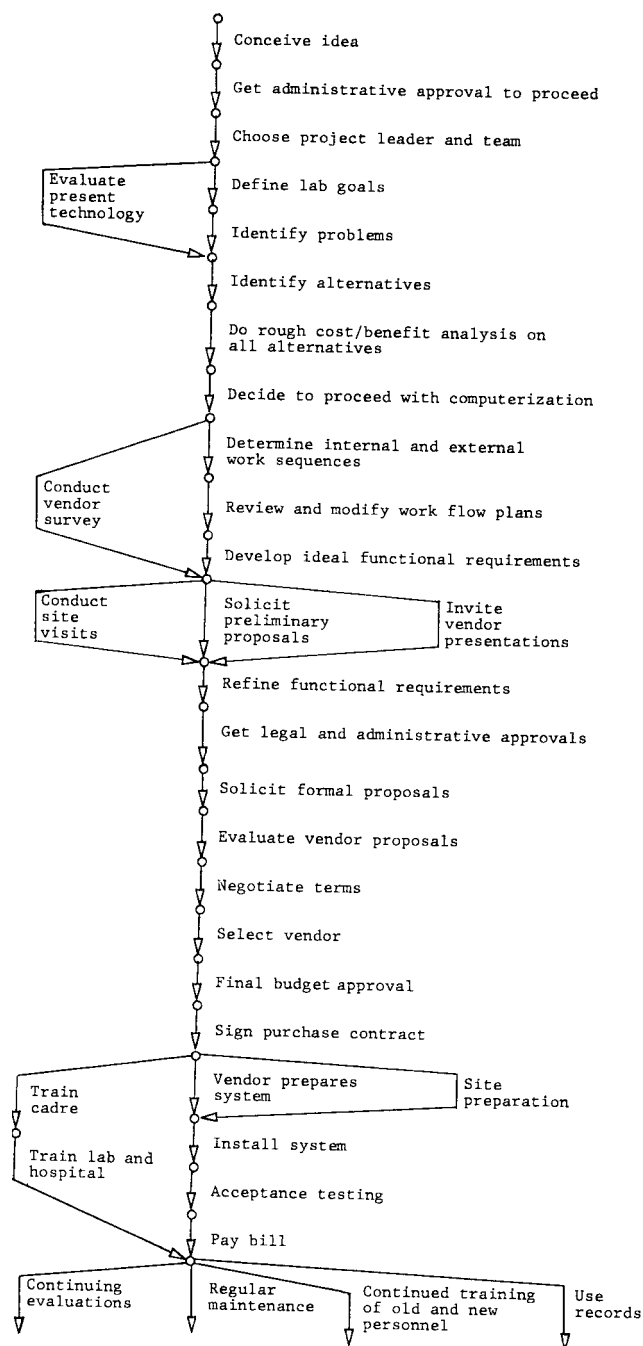


FIG. 1 Sequence of Steps in a Laboratory Automation Project

installation of an information architecture is indeed a rational plan. As noted in Guide E 2118, the ANSI/IEEE 1362 Concept of Operations document is a good way to approach this examination. The self-examination is also valuable because it may reveal both positive and negative situations and characteristics about the clinical laboratory that heretofore had gone unnoticed. If reasonable grounds exist to proceed, a project definition should be developed. An ANS/IEEE 1058 Software Project Management Plan is recommended for this definition. This should be a general statement of all objectives and constraints, and it should be based on inputs from institution administration, laboratory management, laboratory personnel, and end-users of the laboratory. A major purpose of the



interested parties to formulate a mutually agreeable definition of the project. As the project is carried out, it is likely that some of the goals and objectives will be altered. The project leader should be given authority by top management to make these changes.

5.2 Self-Examination—It is important that written documents (such as ANSI/IEEE 1058 plus ANSI/IEEE 830 Requirements Specification) be the result of this self-examination. This not only encourages more careful thought, but it also provides the starting point for justifications that must be prepared later. The purpose of this step is to acquire an understanding of the relationship and communication links of all concerned parties rather than to lay the framework for an attempt to exactly duplicate the existing manual system.

5.2.1 The logical place to begin the self-examination (see ANSI/IEEE 1362) is to define the functions of the laboratory. These might include:

- 5.2.1.1 Generation and communication of test results.
- 5.2.1.2 Research and development.
- 5.2.1.3 Education (interns, residents, physicians, technology trainees, etc.).
- 5.2.1.4 Generation of revenue.
- 5.2.1.5 Consultation.
- 5.2.1.6 Job satisfaction. One laboratory function is to provide stimulating and meaningful employment. The availability of educational opportunities, convenient arrangement of the workspace, and a cordial atmosphere of significance and accomplishment are all important.

5.2.2 Identification of Laboratory Users—The self-examination should continue with identification of the users of the laboratory operation (see ANSI/IEEE 1362). It may be helpful in discussions with users to restrict the topic to output formats and protocol. Some possible users are:

- 5.2.2.1 Physicians.
- 5.2.2.2 Physician offices.
- 5.2.2.3 Nurses.
- 5.2.2.4 Clinical pharmacologists.
- 5.2.2.5 Patients.
- 5.2.2.6 Administration.
- 5.2.2.7 Pathologists and laboratory staff.
- 5.2.2.8 Research staff.
- 5.2.2.9 Other laboratories.
- 5.2.2.10 Third-party payers.
- 5.2.2.11 Health agencies.
- 5.2.2.12 Professional service review organizations.
- 5.2.2.13 Intermediaries. In some hospitals there are intermediary personnel, such as ward clerks, who are recipients of the laboratory results. These personnel, if any, should be identified.

5.2.3 Features of Importance to Users—It should be determined what aspects of the laboratory operation are considered important by the different users (see ANSI/IEEE 1362). The following factors may be considered:

- 5.2.3.1 Accuracy, reliability, precision, specificity, sensitivity.
- 5.2.3.2 Speed or response time.
- 5.2.3.3 Costs.
- 5.2.3.4 Ease of use of laboratory services.

- 5.2.3.5 Interpretation assistance.
- 5.2.3.6 Decision-making assistance.
- 5.2.3.7 Patient convenience.
- 5.2.3.8 Test availability.
- 5.2.3.9 Archival accessibility.
- 5.2.3.10 Data security.
- 5.2.3.11 Report content and format.

5.2.4 Priorities—An identification of the importance or priority of each of the above functions, users, or needs should be made.

5.3 Unfulfilled Goals—Once the nature of the laboratory has been defined by the previous steps, it should be possible to concisely state the unfulfilled goals under the current system. In most cases, this will be a statement of the reasons, with perhaps new insight, why an information system was suggested in the first place. The importance of each unfulfilled goal should be evaluated (see ANSI/IEEE 1362). These unfulfilled goals may include:

- 5.3.1 Laboratory functions that are not being adequately performed.
- 5.3.2 Users that are not being adequately served.
- 5.3.3 User needs that are not being adequately met.
- 5.3.4 Reduction of costs in existing system.

5.4 Alternatives—Before automatically selecting computerization as the one cure for these unfulfilled goals, alternatives should be identified (see ANSI/IEEE 1362). For one or more of the goals, one of the following alternatives may be a better choice:

5.4.1 Improved management and coordination of existing manual systems. The existing mechanisms may be adequate, but simply not functioning properly. For example, new personnel may not have received proper orientation and training or there may be insufficient personal contact between laboratory, nursing, and the clinical staff to promptly identify and work out minor day-to-day problems, which accumulate and become large problems. Poor communications with physicians or the wards (Note 2), slow reporting of results, overloads during certain time periods, difficulties handling stats, or problems with just one section of the laboratory might be better solved by reorganization or alteration of operating procedure.

NOTE 2—The word “ward” will denote any patient care area.

5.4.2 Improved manual system (3). Improvements may involve new policies and procedures, new work schedules, new workflow, new or additional laboratory equipment, improved forms design for requests and reports, and reorganization (such as separation of stat work into a separate area).

5.4.3 Additional Personnel—The addition of an information system will most likely also require additional personnel. This is often a complex question which involves estimating improved productivity through information technology against the added cost of acquiring and maintaining a more complicated system. A wide variety of immediate and long-term factors are usually important. Often, the merit of the added personnel alternative cannot be fully assessed until the information system project is more carefully explored. If consideration of this option is delayed, it is important to raise it again later in the project before final commitment to proceed with computerization.



5.4.4 Limited computer systems based small computers. These systems might only be applied to a limited portion of the laboratory operation. The evaluation and selection of such systems frequently need not involve all of the items discussed in this guide.

5.4.5 For this guide to be appropriate, all or a significant number of the problems identified above can presumably be alleviated by an information system. It is important to identify at this point which portions of the unfulfilled goals the information system is intended to fulfill.

5.5 Selection of Option:

5.5.1 This is perhaps the most important step during the entire project. The previous activities, in addition to providing a basis for planning described later, are intended to help provide the best data to the project and enterprise management to make this decision. Select an information system only if it appears better than or is needed in addition to other alternatives. If a computer is proposed, specifically define and limit the goals that are expected to be achieved. Examine with considerable skepticism any plan to computer-automate portions of the operation that are currently satisfactory.

5.5.2 Ultimately, a complete cost/benefit analysis will be required before final budget approval is granted. A preliminary analysis should be performed at this point in the project for each of the possible options. Use these results to select the best solution. Many of the costs and benefits can only be roughly estimated at this time, but the cost/benefit analysis prepared now can be refined as the project is developed, and will be used for the final budget approval.

5.5.3 To perform a cost/benefit analysis (4), identify the costs associated with the project and with running the laboratory with the information system installed. Also identify the benefits of the new system and quantify these in terms of monetary savings. A comparison of these numbers gives an indication of the economic viability of the project.

5.5.4 Some of the costs that should be considered are:

5.5.4.1 *Cost of the System*—Approximate estimates from vendors can be obtained even in these early stages of the project.

5.5.4.2 *Personnel*—If information system staff, clerks, or additional service people will be needed.

5.5.4.3 *Site Preparation*— This may be expensive if it includes special air conditioning, backup power generators, raised flooring, fire suppression, or extensive remodeling. The square footage, arrangement, and location of the site affects other parameters, such as the number of personnel needed to operate the system, (see 14.1).

5.5.4.4 *Installation*.

5.5.4.5 *Maintenance*— The cost of long-term hardware and software maintenance should be determined.

5.5.4.6 *Backup System*— As explained later, a set of backup systems (manual or otherwise) is required (see 6.10 for examples). The cost of establishing and maintaining this should be determined.

5.5.4.7 *Cost of Failures*— The costs of actually using the backup system should be determined. For example, operating the backup system may require considerable overtime wages be paid.

5.5.4.8 *Paper and Other Supplies*—Slow delivery may make it necessary to stockpile supplies and the cost to provide space for such storage outside of the laboratory should be estimated.

5.5.4.9 *Training*—This involves both the initial training of the laboratory personnel and the continual training needed for new personnel. Also include the cost of initial and continuing education for the rest of the enterprise staff to properly use the system.

5.5.4.10 *Travel*—The planning and execution of this project will probably require the project leader and members of the team to travel for site visits, training, and other purposes.

5.5.4.11 *Amortization Over Lifetime*—Depending on accounting procedures used, the depreciation of the system over its lifetime may be listed as a cost instead of or in addition to the initial purchase cost.

5.5.4.12 The time required to adjust to the new system should be determined and evaluated as a cost. During initial startup, the system will be used inefficiently until people become accustomed to it. Plan on needing overtime for the first week or two, perhaps 2 h per day for each person during the first week. Include the cost of running simulations if that is chosen for training or performance tests, or both.

5.5.4.13 Determine the cost of implementing the new system if it requires new forms, new formats, or other changes in procedure.

5.5.4.14 Estimate the indirect effects caused by reorganization and changes within the laboratory and the rest of the enterprise.

5.5.4.15 Estimate the cost of indirect effects caused by the way the information system effects personnel. Determine in advance if key individuals may have trouble accepting or adapting to information systems and estimate the cost of corrective action.

5.5.4.16 Include an estimate of the cost of planning and executing the project.

5.5.4.17 Estimate the cost of making new additions at a later time.

5.5.4.18 Estimate the cost of archival storage of results.

5.5.5 Some of the benefits that may result are:

5.5.5.1 The new system may reduce clerical effort because the system performs more of the bookkeeping. Benefits may be realized in the laboratory and other departments, such as the billing department, nursing stations where results are charted, medical records, and the mail room. Frequently no personnel savings are realized.

5.5.5.2 The automated system may reduce the number of bills that get lost in the manual system. The retrieval of these charges may reduce lost income.

5.5.5.3 Automation may permit bills to be issued more promptly; this usually results in better collection and may reduce the interest cost on accounts receivable.

5.5.5.4 There may be reduced clerical work for those tests that are sent to other laboratories for analysis. These must be reported separately on bills to patients, and the computer can perform this chore.

5.5.5.5 There may be a savings in time for the physicians and a substantive improvement to medical care.



complete and easier to read.

5.5.5.6 Improved efficiency in interpretation of reports may result in a decrease in the patients length of stay.

5.5.5.7 Automatic generation of cumulative reports may reduce the number and cost of specialized forms.

5.5.5.8 There may be reduced drudgery for personnel if the computer converts raw data into more meaningful numbers. This might be found in radioimmunoassay, quality control, etc.

5.5.5.9 If the system has programs to help interpretation of results, time can be saved and mistakes reduced.

5.5.5.10 When remote terminals are used, there should be less need to telephone the laboratory for status. This reduces interruptions and wasted time.

5.5.5.11 When telephone calls are made, the laboratory is able to give better and faster response. The pathologist, for example, can use a terminal to view the patient results and render an opinion more quickly, perhaps during the same telephone call.

5.5.5.12 There may be reduced duplicate test ordering and reduction of inappropriate orders because of internal computer checks.

5.5.5.13 The information system can be used to alert personnel if inappropriate test orders are being placed for a patient based on the presumed DRG of that patient.

5.5.5.14 Phlebotomy time may be reduced if blood already ordered for another test has been collected and is available.

5.5.5.15 The use of critical values can quickly detect out-of-bound readings caused by deviant samples or procedure errors. Several boundary levels may be defined to find results that fall outside the linear or calibrated range of an instrument, indicate that the physician should be contacted by phone, or reveal deteriorating quality control or outright instrument failure. Early identification of problems can reduce the need to repeat work and fewer errors will leave the laboratory and have to be corrected.

5.5.5.16 There will be reduced transcription errors on reports, due to checking of input and automatic printing of results.

5.5.5.17 There will be a reduction of sample mix-up errors if automatic label-making is included in the system. This will also yield benefits through reduced time required for specimen collection.

5.5.5.18 There will be less transcription errors if online data acquisition is planned.

5.5.5.19 Real-time control of instruments usually increases productivity.

5.5.5.20 There will be reduced volume paper in circulation and in the patient's folder if the system prints combined results in one report.

5.5.5.21 If the computer can be used for education, it may contribute to the program of a teaching hospital. In most settings, this must take secondary consideration to providing better laboratory service.

5.5.5.22 The data that are collected become a useful pool on which to draw for future research projects. If it is in computer-readable form, projects become feasible that would not be attempted if only manual files were kept.

5.5.5.23 If the computer can function as a word or text

processor, it may be easier to maintain current procedure manuals. These can be prepared to give laboratory procedures or teach ward personnel how to use the terminals and interpret the results. Alternatively, it may be better to use separate equipment for word processing.

5.5.5.24 The data needed for management reports are easier to acquire. Such things as weighted work loads, personnel allocation, turnaround time records, and personnel productivity estimates, quality control, reagent inventory, preventive maintenance schedules, and infectious disease monitoring can be obtained from the computer.

5.6 *Laboratory Definition*—If it is decided to continue with a project to install an information system, planning should now proceed with a detailed characterization of the laboratory operation. The purpose is to give the project team responsible for selection or system design a means of understanding the setting for the information system, to aid in selection of appropriate computer technology, to assist in development of system protocols that minimize disturbance of existing procedures, and to allow determination of how the laboratory may be positively or adversely impacted by the new system. This characterization should include a system study resulting in a flow chart of operations (5). See the section on identification of the network domain in Guide E 2118.

5.6.1 *Work Station Function Sequence*—For each work station impacted by the proposed project, provide a sequential description of what is done, by whom, how often, and with what equipment. A process flow chart is an appropriate device to use. Include information regarding how orders and specimens are received, how specimens are identified, and how they are stored if the test is not done immediately. State how tests are named (see Specification E 1712), performed, and how data are to be collected, analyzed, and verified. Indicate how results are reported, how results are compared with previous data or normals, and how other quality control operations are performed. A detailed description of this type should be prepared for all laboratory operations. Function sequences should be prepared for those who do not work at classical work stations, such as phlebotomy, reception, supervisors, etc.

5.6.2 *External Function Sequence*—Prepare a description of what is done outside the laboratory that affects laboratory operations. Such things as doctor rounds, ward clerk ordering and charting patterns, billing department routines, and emergency room practices should be included. It may be appropriate to supplement such descriptions with appropriate flow charts.

5.6.3 *Overview Summary*—The information in 5.6.1 and 5.6.2 consists of a series of individual task descriptions and flow charts. (See ANSI/IEEE 1362.) Prepare written descriptions and flow charts as needed to show how these tasks interrelate with each other and with external interfaces to the laboratory.

5.6.4 *Modifications*—Often at this point it becomes possible to see how individual work functions or the flow diagram could be altered to better accommodate the computer system or streamline the laboratory operation. If so, note these possibilities for future consideration during the design stages.

5.6.5 *Constraints*—Identify all constraints on the project.



and the desired system. (See ANSI/IEEE 1362.) These may include:

- 5.6.5.1 Upper cost limits,
- 5.6.5.2 Time deadlines for completion of design, purchase, installation, or both,
- 5.6.5.3 Requirements that the system be expandable for an anticipated future project or activity,
- 5.6.5.4 Requirements that the system be capable of integrating into and/or sharing data with existing systems, and
- 5.6.5.5 Compatibility with existing institutional policies. An institution may have decided that a particular hardware vendor, language, or operating system will be used as an inhouse standard.

5.6.6 *Laboratory Personnel Participation*—For better morale and easier acceptance of the new system, it is important that existing personnel be involved in the preparation of this laboratory definition. Individuals should be encouraged to participate in preparation of their own work function descriptions and be involved, at least in some way, in any plans to change existing procedures.

6. Functional Requirements

6.1 *General*—These guidelines are written assuming the enterprise will acquire a complete system from a vendor. Many of the characteristics of each vendor's system are fixed, and the hospital only has the choice of accepting the restrictions or rejecting the entire package. In other cases, system performance can be tailored to the needs of each institution.

6.1.1 Some users may wish to purchase components of a laboratory information system from different vendors. This may become more prevalent as the use of networked architectures increase in the laboratory. These guidelines can be used where appropriate for each separate functional portion of the system. In addition, however, there will be important concerns related to compatibility of the different components, and integration to produce a viable and properly functioning total system. The problem of proper integration of separately purchased subsystems is not fully discussed in this guide.

6.1.2 It is recommended that functional requirements first be developed independent of the system of any particular vendor. In the next section, these requirements will be refined to be consistent with the market place realities. Several iterations of this process may be required to reach an acceptable and realistic set of functional requirements.

6.1.3 The remainder of Section 6 gives a set of criteria to help develop the functional requirements, but Guide E 1639 should be consulted. They are grouped according to various distinguishable activities with which the computer system must deal.

6.2 *Admission-Discharge-Transfer Section*—The problem of excessive paper work and less-than-satisfactory hospital communication is a common reason for consideration of the laboratory computer. With the advent of computer-based patient record systems, communication of patient data to the laboratory system concerning patient demographics, test ordering, and other clinical data can now be done by common communication protocols specified by Specification E 1238 and using registration data specified in Guides E 1239 and E 1384. To be of help, the computer must have a file (defined

as any appropriate computer structure for saving related information) for each patient that includes (1) identifying information (2) tests requested, (3) test results, and (4) other selected information. In this context, the term "patient record" refers to the complete unit of information on a single patient in computer-readable form. It may be in the computer memory, stored within an online tape or disk drive, or kept offline in a tape or disk pack stored in a cabinet. Information is eventually moved to archival storage and is often kept in the latter form. This section deals with how that computer file is first created, how it is updated, and how it is finally cleared from the active computer system.

NOTE 3—The information regarding the patient record content is addressed in Guide E 1239 or Practice E 1715.

6.2.1 *Creation of a Patient Record*—In some enterprises, an electronic information system is used in the admissions department, and all appropriate information is collected there to start a new patient record. In this case, it may be appropriate to install a direct link to the laboratory system so that a laboratory file is created whenever the admissions computer accepts a new patient. Almost all patients use some laboratory services, so this plan is logical. If the hospital does not have an admissions system, it is conceivable that the laboratory system may become one. An additional set of criteria must be considered for an admissions system that is beyond the scope of this guide. The following points need to be examined with regard to creation of a patient file:

6.2.1.1 Maximum number of patient records the system is to be capable of holding must be determined.

6.2.1.2 System should check to see if a record already exists for the patient being entered. This may occur from erroneous duplicate procedure or from a recent discharge followed by readmission.

6.2.1.3 Determine how the system is to be used for pre-admittance tests. Determine the limits on how far in advance of admittance these tests can be processed. Devise a procedure that will handle billing and maintenance of records for situations that exceed the designed limits.

6.2.1.4 Determine how and when newborn infants become separate records with new identifying numbers. Determine how twins and larger multiple births are handled or if names have not yet been selected.

6.2.1.5 Determine how anonymous patients will be entered into the system.

6.2.1.6 Determine if the system should allow a patient to be entered without generating a bill. Determine conditions, limitations, and security that cover this courtesy category.

6.2.1.7 Certain programs affect response time. Determine how long a delay may be tolerated during terminal sessions used to create new records. Determine what restrictions this places on the time available for creation of new files.

6.2.1.8 If the system will not allow a record to be created without a patient unique identifier, determine how test requests will be entered if they are needed in an emergency when such a number is not available.

6.2.1.9 Determine if any restrictions may or should exist on when a new record can be created and how long afterwards it can be used for test ordering or reporting results.



particular, find out if both creating and test ordering should be allowed in the same terminal session.

6.2.1.10 Determine how entries are to be verified and corrected. It is typical to allow corrections and additions to be made during the same terminal session used to create files. Determine if there are any restraints on when and from where corrections can be made after that session. This mechanism may be used to enter information on newborns as it becomes available.

6.2.1.11 In cases where another computer is creating the record, determine the error checking to be performed on the transferred data. Consider the problem that occurs if the laboratory computer is busy when another computer wishes to transfer a new record. Determine how long the process can be delayed at the sending computer, or how large a buffer is needed to temporarily hold the information. Compare with the maximum time the laboratory computer may be unavailable and verify that no information can be lost.

6.2.2 *Content of the Patient File Informational Block*—The following information should be supplied when a patient record is created. The required information may be different for specimens from nonresident patients, such as referrals, outpatients, etc. The data elements used in the laboratory computer should comply with those described in Specification E 1633 and Guides E 1239, E 1384.

6.2.2.1 *Name of Patient*— It should be possible to locate a particular file in the computer from this entry alone. It is desirable that some method be provided to locate names when spelling is uncertain. There are phonetic-match programs that may serve here. It is helpful if the computer distinguishes between first and last names in its output, such as listing the last name all in capitals and the first name in lower case. Determine how prefixes such as “Mc,” hyphenated names, or last names consisting of more than one word are handled. Determine desired flexibility of the input format. For example, determine if the convention of a comma or a comma and a space between last and first name is mandatory or optional. Determine how name changes through marriage or legal action will be handled. The system should make users aware of the existence of different patients with the same or similar last names every time a record is accessed. One approach is for the computer to list all such names and await verification that the operator has the right one. Verification should be structured so it cannot easily be bypassed without thought. It might, for example, require the operator to enter the patient initials or part of the patient number rather than simply typing a “y” which may become automatic for the operator. Some provision must be made for cases where both the first and last names agree, and possibly even the address agree as well. Consider the case where father and son with identical names are both admitted at the same time. Use of date-of-birth or hospital number, or both, may be important for these cases. Also, a free-text field is appropriate to handle other rare but important situations.

6.2.2.2 *Identifying Number*. A hospital number, a medical record number, a social security number, or a laboratory number is usually required for internal- or cross-computer referencing. The number can also provide additional verification that the accessed record belongs to the patient in question,

that the sample is being drawn from the right patient, or that the test result being reported is added to the correct record. It is desirable that the number of different numbers describing a given patient be kept to a minimum, preferably one. It is acceptable for different numbering schemes to be used internally by the computer or any of its subunits (automated instruments, etc.) as long as hospital staff is not required to make correlations or translations. Sometimes space is required in the record for an identifying number supplied by an outside user of the laboratory service. This number is printed on reports sent to that user. Since the validity of these numbers is vitally important to avoid identity mistakes, the number should contain internal check characters and be verified each time it is used (6). It should be determined what limitations exist on the numbering system, such as how long the system can be used before the same number appears again, whether it is possible to have two active identical numbers because of this, and whether numbers in archives can become confused with later numbers. Determine what detection and notification mechanism is required to guard against such occurrences. Determine whether readmitted patients will be assigned their original number or a new one. If the latter, determine if and how any correlation or cross index to the older records will be maintained.

6.2.2.3 A separate incident number may be used in place of a permanent number to define the patient record. This allows records to be handled separately by admittance, episode, or treatment program. When desired, these separate records might be combined into a consolidated clinical record for the patient.

6.2.2.4 *Doctor Name(s)*— This entry may include more than one doctor, and each may be associated with the patient in a different capacity. The computer system should also permit additional doctors to be added later, in case a consultant or specialist is called in on the case. The computer system may be programmed to correct misspelled names and to have the addresses of doctors in its memory. The latter is useful for generating mailing labels for laboratory results that must be sent out. It is also useful to identify the physicians that have surgical privileges to help verify operating room schedules. Doctors may be identified by name, initials, or code number. Determine whether doctor names may be entered that are not included in the defined list. If acceptable, it may be useful to print a list of such names daily. If additional doctor names are not permitted without updating the doctor name and address file, determine how special situations will be handled.

6.2.2.5 *Ombudsman*—Some enterprises will assign each patient to one ombudsman to protect the patient’s rights.

6.2.2.6 *Sex of Patient*.

6.2.2.7 *Race of Patient*.

6.2.2.8 *Age or Date of Birth*—Age can be generated from the date of birth if needed; it is therefore preferred. Some systems use a Julian calendar and a software conversion may be desired.

6.2.2.9 *Patient Type*— One or more codes should be entered to distinguish outpatient, inpatient, emergency, clinic, student (if a university hospital, for example, treats students on a different basis), employee health records, or other special categories that may exist in a particular institution. Specify the number of types of patients that will be defined.



already defined by the enterprise bookkeeping system.

6.2.2.10 *Ward, Room, and Bed*—The location of the patient should be specified. This entry may change if a patient is moved. It should be determined how the computer system will accommodate this case. For example, determine when and where reports will be sent, how the change is made known to the computer, etc. Determine how special situations will be handled. For example, patients might be placed in the halls or temporary wards during a space emergency. Patient location should be updated as new information is received and checked regularly against the master list.

6.2.2.11 *Warnings*—An entry in the file should be made if the patient has hepatitis, AIDS, or some other medical history that may endanger hospital personnel. This entry should cause warning messages to be printed on sample collection lists, sample containers, etc. Determine if the system allows identification of patients in isolation and the type of isolation.

6.2.2.12 *Diagnosis*—If known, the diagnosis may be entered or updated. This will help the laboratory understand anomalous test results. The entry should remain confidential and be retrievable from the system only to authorized personnel.

6.2.2.13 A presumptive DRG assignment, capable of revision, should be entered. It can be used to monitor test orders and results to detect findings that indicate the need to change the DRG.

6.2.2.14 *Security*—There are situations where files must remain more confidential than normal. This might occur in the case of celebrities, police cases, unwed mothers, psychotics, hospital employees, or others. The system should allow this option.

6.2.2.15 *Other*—Some institutions like to retain additional information about a patient to improve security, lower mistakes, improve convenience, or for some other reasons. For example, sometimes the mother's maiden name is requested to help establish identity.

6.2.2.16 *Free Text*—In order to meet special cases, determine the availability and size of free text fields.

6.2.3 *Use of the Informational Block*—The following points should be considered with regard to the use of the files:

6.2.3.1 Determine how the information may be retrieved. It should include ability to locate and display (with due regard to security) a single patient by name or number; all patients in a given ward; all patients with a given doctor; all patients of a given type (inpatient, outpatient, etc.); or all patients using a given service (cardiology, maternity, etc.). In some institutions, additional criteria may be important for file retrieval. It is useful if retrieval is possible through multiple criteria combined with the usual logical operators AND, OR, or NOT.

6.2.3.2 Determine how changes are made in the content of the informational block. These changes might include location in enterprise, doctor names, diagnosis, patient type, etc. Determine what ramifications each change should have on the rest of the system operation. Consider things like destination of reports, retention of old information for permanent records, time constraints on when changes may occur, etc.

6.2.3.3 Determine which information entries are required in order to successfully create a file, which can be temporarily

ignored if the data are to be supplied later, and which are optional. Determine what will happen if all the information is not available when the patient checks in.

6.2.3.4 Determine the procedures required to make changes in the composition of the patient file. It is desirable for the enterprise management to be able to add fields for additional information, delete items, include new laboratory tests, change fixed parameters or stored data (such as doctor names and addresses), and alter the interrelationships between or requirements of the various items. It is less desirable if such changes must be purchased from the vendor. Determine what security should exist to prevent unauthorized changes.

6.2.4 Removal of the file from active storage. The limited capacity of backup storage requires that patient files be transferred to offline storage when they are no longer current. Consider the following:

6.2.4.1 Determine how the discharge of a patient from the hospital is communicated to the laboratory computer. If discharge is handled by another computer, this information may be passed by direct link. Otherwise it is entered manually in response to some other information received at the laboratory.

6.2.4.2 Determine how long a patient file should exist in the laboratory computer after discharge from the hospital. The file should exist until all outstanding test results are either entered or cancelled, all final reports printed, and all billing information transmitted to the business office unless this would result in excessive storage time. Tuberculosis tests, for example, may require a month. On the other hand, if a patient is to be seen regularly as an outpatient, it may be desirable to keep the file active even if all the above criteria for closing it are met. For these reasons, it should be possible to override the usual decision mechanism to move a record to archives.

6.2.4.3 In many cases, the report may not be complete until some time after discharge, and a mechanism to get all the late test results to the physician and the patient's permanent records must exist.

6.2.4.4 Determine the circumstances, if any, that can result in a patient being discharged without a final report ever being printed.

6.2.4.5 Determine the file closing procedure in the event of the death of the patient.

6.2.4.6 Determine how older information is removed from the system for a patient resident for an extended period. Determine after what length of time such information is removed, and how it is to be stored for more permanent records.

6.2.4.7 If the laboratory computer is linked to other computers, determine if any time constraints exist on the above processes. The billing computer, for example, should be able to accept laboratory charges for a patient even after discharge of the patient.

6.2.4.8 Determine how long outpatient data are held in the system. Determine what happens if an outpatient is admitted.

6.2.4.9 Determine the procedure to be used for the more permanent storage of patient file information after the final reports are made (see 6.8).

6.3 *Test Ordering*—The laboratory responds to requests for tests. The subject of this section is the nature of the