

Standard Guide for Selection of a Clinical Laboratory Information Management System



This document covers the selection, purchase, use, enhancement, and updating of computer technology supplied by a vendor as a complete system in the clinical laboratory.



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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 E792-02 but has been redesignated and is now maintained by NCCLS. This document has been approved as an American National Standard (ANSI/ASTM E792-02).

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Suggested Citation

(NCCLS. *Standard Guide for Selection of a Clinical Laboratory Information Management System*. NCCLS document LIS3-A [ISBN 1-56238-491-0]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.)

Published

April 2003

ISBN 1-56238-491-0
ISSN 0273-3099

Standard Guide for Selection of a Clinical Laboratory Information Management System

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.*

2. Referenced Documents

2.1 ASTM Standards:

- E 622 Guide for Developing Computerized Systems¹
- E 623 Guide for Developing Functional Requirements for Computerized Systems²
- E 624 Guide for Developing Implementation Designs for Computerized Systems²
- E 625 Guide for Training Users of Computerized Systems¹
- E 626 Guide for Evaluating Computerized Systems²
- E 627 Guide for Documenting Computerized Systems¹
- E 730 Guide for Developing Functional Designs for Computerized Systems²
- E 731 Guide for Selection and Acquisition of Commercially Available Computerized Systems¹
- E 919 Specification for Software Documentation for a Computerized System¹
- E 1013 Terminology Relating to Computerized Systems¹
- E 1113 Guide for Project Definition for Computerized Systems²
- E 1239 Guide for Description for Reservation/Registration—Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems³
- E 1340 Guide for Rapid Prototyping of Computerized Systems³
- E 1384 Guide for Description for Content and Structure of an Automated Primary Record of Care³
- E 1633 Specification for Coded Values Used in the Computer-Based Patient Record³
- E 1712 Specification for Representing Clinical Laboratory Procedure and Analyte Names³
- E 1714 Guide for Properties of a Universal Healthcare Identifier UHID³
- E 1715 Practice for an Object-Oriented Model for Registration, Admitting, discharge and Transfer (RADT) Functions in Computer-based Patient record Systems³

2.2 IEEE Standards:⁴

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:⁵

- ISO 6592 Information Processing—Guidelines for the Documentation of Computer-Based Application Systems

¹Discontinued. See 2000 *Annual Book of ASTM Standards*, Vol 14.01.

²Discontinued. See 1994 *Annual Book of ASTM Standards*, Vol 14.01.

³*Annual Book of ASTM Standards*, Vol 14.01.

⁴Available from The Institute of Electrical and Electronics Engineers, Inc., 345 E. 47th St., New York, NY 10017.

⁵Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

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 2.4⁶

2.5 *ANSI Standards:*⁵

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

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:*⁷

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:*⁸

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,

⁶Available from Health Level Seven, 900 Victors Way, Suite 122, Ann Arbor, MI 48108.

⁷Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

⁸Available from NIST, Gaithersburg, MD 20899.

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 NCCLS document [LIS9](#).

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.

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 specialities, 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 installation of an information architecture is indeed a rational plan. As noted in NCCLS document LIS9, 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 is to force all 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 ANS/IEEE 1058 plus ANS/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 affect 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 affects 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 mailroom. 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 if reports are 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 NCCLS document LIS9.

5.6.1 Workstation Function Sequence—For each workstation 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 workstations, 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 in-house 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 NCCLS document LIS8 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 LIS5 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 of results. In 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. This is usually 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 these test requests and how they are handled. It is necessary to enter information about each test requested in order for the system to be of assistance in tracking samples, keeping records, and handling requests for status of samples. Test requests should include the appropriate elements from Guide E 1384, adding those elements specifically required by the laboratory.

6.3.1 *Methods of Test Request Entry*—The technique used to enter the test request depends on the sophistication and expense of the system.

6.3.1.1 In systems of limited scope, test requests may be submitted on special forms from various sites in the enterprise and entered into the computer system at a terminal in the laboratory. Semiautomatic procedures may be used, such as optical character readers or mark sense card readers.

6.3.1.2 A more comprehensive system may incorporate communication links connected to the laboratory system and have access from key locations in the enterprise. In some cases, terminals in patient care units will link through the enterprise information architecture to the laboratory system. No direct link need exist, although in networked systems such a link may exist. With remote workstations, messaging may occur using the convention in LIS5 and HL-7. In either of these schemes, test requests are made directly to the laboratory system. In some settings, advantages may be realized by eliminating a transcription step and a physical movement of a piece of paper from one place to another. Further advantages may be realized through the use of the terminals for reporting status, results, and other communications. Such systems tend to be more complicated and expensive and require a higher level of expertise to maintain and operate.

6.3.1.3 The laboratory system should be able to accept orders from and deliver reports to a central enterprise repository. In some systems, test orders and other requests may originate at a patient care area, doctor office, or other site and pass through network nodes to get to the laboratory system. Status reports and other information may be returned to terminals in the patient care area or other places by the reverse process. In other systems, terminals at user sites can communicate directly to the laboratory computer and other institutional computers through a general-purpose local area network.

6.3.1.4 Other technologies may be developed in the future for entering test requests.

6.3.2 *Identification and Specification of a Test*—Each test that may be requested should be given one or more simple names or a unique identifier, or both. Consult Specification E 1712.

6.3.2.1 Determine the maximum number of test names and codes for the system. Verify that ample reserve for future activities is provided.

6.3.2.2 Determine how the test names and code numbers may be added, changed, or deleted. It is preferable that the laboratory management be able to make such changes without vendor assistance.

6.3.2.3 Determine how changes in tests will affect data in active patient files and information already stored in archival files. Establish plans or procedures that will allow this older information to be retrieved from archival files. When a test procedure is changed but retains the same name, determine how the system matches the applicable reference range with the actual procedure used. Ensure that retrieval by test name will recover the old and new tests.

6.3.2.4 Determine how variations in a test are to be specified. In some cases, a new test name and number can be used to specify a difference, such as the same test run on a different type of sample. In other cases, an option field may be used to specify such differences.

6.3.2.5 Determine which tests may be ordered as scheduled tests. Determine if the time to be specified in the schedule indicates when the sample is to be collected or when the physician expects the results to be ready. Determine how far in advance a test may be scheduled.

6.3.2.6 Determine which tests may be ordered as timed tests. Determine the permissible limits that exist on sample collection intervals and total number of sample collections to be made. Determine if a timed test series may also be scheduled.

6.3.3 *Content of a Test Request*—The following information is needed when a test request is entered:

6.3.3.1 Patient name or unique patient identifier (see Specification E 1714). It is desirable if the system recognizes variations in spelling. When either the name or patient number is entered, the system should display the other entry to help with verification. If duplicate names exist in the system, the computer should issue a warning and request verification (see 6.2.2.1).

6.3.3.2 *Test Requested*—It is desirable if the test can be ordered by one or more common names or by code number. The computer may then produce all the identifying information (name and code number) to help reduce errors.

6.3.3.3 *Test Priority*—This entry might include routine, stat, scheduled, or timed.

6.3.3.4 If a scheduled test is requested, the scheduled time value must be entered.

6.3.3.5 If a timed test is requested, and if the time interval or the duration of the test is a variable, this information must be entered. Needed information may include the time when the test is to start, the interval between and numbers of samples to be collected, or other specifications depending on the test. It is better to list standard timed tests, such as glucose tolerance, with their own name and code number. Tests requiring special collection may need correlation to avoid overloading the system. It may be impossible to meet all requirements if too many special requests are received for the same time period. The existence of such a scheduling problem may be recognized by the computer and reported to the laboratory director or the individual making the test request, or both, for resolution of the problem. Alternatively, the system may require all tests requiring special collection be entered by laboratory personnel (in response to verbal or written requests) who can then take steps to keep the demands on the collection mechanism within bounds.

6.3.3.6 Determine if a battery of tests can be ordered with a single name or code number.

6.3.3.7 An indication of the specimen type(s) may be required for some tests if this option is not provided by different test names.

6.3.3.8 Various times are important during a test. They include: the time of physician order, the time of receipt of order at the laboratory, the time the request is entered into the computer system, the time of specimen collection, the time of receipt of sample at the laboratory, and the time the result is reported. The time of entry into the system may be recorded from a system clock.

6.3.3.9 The name of the physician making the request. The system should verify and correct the spelling.

6.3.3.10 Identity of the person entering the test request should be recorded in case there is some need for the laboratory to obtain additional information or correct some problem. This information may be available from the sign-on procedure used by the individual operating the terminal (see 6.3.4.8). Otherwise it must be entered as a part of the test request.

6.3.3.11 Free text. A place should be provided to note special circumstances. This field should not be used as the only communication channel of important information from the test requester to the laboratory. It is too easily missed or misinterpreted by laboratory personnel. Important special directions should be communicated verbally to the appropriate individual by telephone or personal contact and then the appropriate free text message may be entered by the laboratory.

6.3.4 *Order Procedure*— The following considerations are important when specifying the procedures by which tests are ordered:

6.3.4.1 Determine from where tests may be ordered. If there are no remote terminals, test orders can probably only be entered at laboratory reception or the stat laboratory. If there is decentralized receiving, it may be decided to permit test request entry at each individual laboratory section. Otherwise, it may be desirable to place terminals at the wards, in the emergency room, at any clinic operation, or in physician offices.

6.3.4.2 Determine how improper requests are handled. These might include requests for stat, scheduled, or timed tests that cannot be run with that option, requests for unavailable tests, or an improper combination of test and sample type. The computer response is most likely an error or explanatory message followed by a request for new

information. For systems without remote terminals, specify how improper request information returns to the originator and how corrections are made.

6.3.4.3 Determine the procedures that will be followed if a test request is begun but not satisfactorily completed. Entry mistakes may be followed by system prompts to help the terminal operator to complete a request. A terminal hung on an improper entry should reset itself automatically after a certain time. It should not be possible for a remote terminal to start or stop programs or otherwise affect the operating status of the system. Some hospitals choose to specify that uncompleted test requests be reported to laboratory personnel for special follow-up rather than to just ignore the partial or erroneous requests.

6.3.4.4 Determine if the system will prevent duplicate test ordering and what the response will be if such is attempted. A decision on what constitutes a duplicate test depends on the test. Some tests may be ordered minutes apart and be legitimate new tests. The time interval between identical requests that must elapse before the computer no longer questions the uniqueness of the request should be set by the laboratory for each test. When a duplicate test is detected, the system should inform the terminal operator of the existence of the old request and ask for confirmation that the new one is different.

6.3.4.5 Determine if the system should recognize when a redundant test request combination is ordered, notify the requester, and ask for verification. Such redundancy might occur if an individual test is ordered along with a battery of tests that includes the individual one.

6.3.4.6 Determine which parameters are to be used for checking test requests and whether they can be modified by the user. Such parameters are those required to perform the tests described in 6.3.4.2–6.3.4.5. It is preferable that the laboratory personnel be able to modify both the checks to be made and the computer responses without vendor assistance.

6.3.4.7 Determine how the test request may be verified. Some mechanism is important to allow physicians to determine if tests were ordered correctly. In a traditional forms ordering procedure, a carbon copy can be retained at the point of origin as verification that the test was ordered. An order in process can be verified by a telephone call, but frequent calls interrupt the work. In a networked architecture, verification may be performed by direct inquiry to the computer. A display of previous test orders along with an indication of their status (awaiting samples, test in progress, result ready, test delayed, etc.) may be presented for each patient on demand.

6.3.4.8 Determine the security requirements on test ordering. Decide who shall be authorized to make test requests and how the information system will prevent unauthorized input. The usual procedure is the use of a password, but other schemes such as key-operated terminals may also be effective. A password has the added advantage of identifying the operator. The password characters should not be echoed on the terminal printer or CRT. Unused terminals in sensitive locations should automatically erase the screen and close any active sessions that may have been left by the last user.

6.3.5 *Test Cancellation*—The following is important with regard to cancelling a test request:

6.3.5.1 Determine who shall have the authority to cancel a test. This may depend on when the cancellation is attempted. A test may be canceled by the initial requester if the terminal session has not yet ended. After that, it may require a physician to cancel the test. If the sample has been collected, the physician might have to contact the head of the laboratory to cancel the test. Only laboratory supervisors should be able to cancel tests in the laboratory.

6.3.5.2 Decide if it will be possible to cancel a test after it has been started. If there is a deadline for cancellation, decide if this is after the sample is collected, after it is dispatched to the workstation, after it is loaded into the instrument or sample changer, or after the results are reported to the patient file.

6.3.5.3 If a test cancellation is made during or after the test is run, determine if the results are to remain in the patient's file or appear on the reports generated, or both. If results are to be ignored, determine what should happen if the results are abnormal, possibly showing a previously undetected problem.

6.3.5.4 Determine when a bill should be canceled or issued. Also determine the protection needed to prevent double billings.

6.3.6 *General:*

6.3.6.1 For networked architectures, determine the maximum acceptable delay between a request for action and a response. Acceptable response time may vary depending on the nature and complexity of the request. This should be specified both as a typical response time (which may be defined as the response time that will be seen 95 % of the time) and a worst-case response time. Determine if the system permits type-ahead where characters are received properly but not necessarily echoed immediately in times of high activity and where new commands may be entered before the last operation is finished. If there are times when the data management portion of the system requires all the computer time, during which the computer cannot respond to terminals, then intermediate buffering may be required or degraded response tolerated. If buffering, determine its capacity and any differences in protocol if communications to the main computer are temporarily delayed. Verify that the buffer is adequate to meet required response time for even worst-case communication delays. If degraded response is accepted, determine which functions can be carried out while terminals are in use and which must be delayed to night or run offline to achieve satisfactory performance.

6.3.6.2 Determine how the system handles stats and other expedited orders. If these are to be mixed with regular orders, determine how stats are to be identified at the laboratory for special handling. Determine any restrictions that are to be placed on stat orders. Stats may require separate collection lists and different billing procedures. Turnaround time estimates may be needed at the time the order is placed.

6.3.6.3 If stats are ordered by a separate procedure to avoid having them overlooked, determine how and when the request eventually enters the computer for sample tracking and for patient records.

6.4 *Specimen Pickup*— In addition to ordering the test, a specimen must be collected, properly labeled, and delivered to the laboratory. There are four interrelated factors that must be considered: (1) whether the test order is entered at the laboratory or from remote terminals, (2) whether the sample is collected by laboratory or ward level personnel, (3) whether samples enter the laboratory at a central receiving station or go directly to an appropriate workstation, and (4) how the computer is informed about the arrival of sample (check in). The flow chart in Fig. 2 shows some of the possible combinations. The use of bar-coded specimen identifiers, as specified in either LIS7 or AUTO2-A, allows use of specimen-handling automation in the laboratory; determine all of the factors relating to this mode of operation when stating requirements for a laboratory computer.

6.4.1 One major branch is where samples are delivered to the laboratory with attached paper forms giving the test requested. Remote terminals are not used for test ordering and collection of samples is performed by ward level personnel. Samples are labeled at the ward either manually or by use of some noncomputer mechanism such as impression copies of the patient identity or charge card. Responsibility to ensure that test requests and samples are not missed resides with the manual delivery mechanism.

6.4.1.1 At the laboratory, samples may enter through a central receiving station where they are checked in. With this plan, the test request is not entered into the computer and the specimen number is not assigned until the sample is in-hand. A time stamp may be placed on the request form when it is received.

6.4.1.2 Alternatively, samples may be delivered directly to a workstation. If more than one test is requested, an aliquot is withdrawn and the sample is passed to the next workstation. The test request may be entered into the computer before the test is performed or when the result is ready. Laboratory numbers are usually assigned when the computer first learns about the existence of the sample, and some mechanism must prohibit assignment of a new number when the next workstation processes the sample.

6.4.1.3 With ward level collection, problems with unsuitable, insufficient, or undelivered samples must be resolved. There should be a way to notify the physician and the individual who drew the sample, obtain new material or instructions, and enter appropriate information into the computer to properly record the transaction. In some cases, a new sample taken at a later time will not be useful. Special collection problems may exist, such as with synovial or cerebral spinal fluids. In general, these cases require manual action.

6.4.2 The other main branch in Fig. 2 covers all procedures where a test request arrives at the laboratory without a sample. These requests may consist of a paper form or some machine—readable media like mark sense cards. Information would then be entered into the computer by clerical staff at the laboratory. Alternatively, the request could be entered directly by the ward personnel through remote terminals.

6.4.2.1 The remote terminal request may be coupled with ward level collection of sample. The specimen may be delivered to a central receiving station or directly to a workstation. As in 6.4.1.2, the system may be told of the presence of the sample before or after the test is run. In this case, however, the system has already received the test request and can assist by printing expected sample lists, and tentative work lists. Instrument load lists are only possible if samples are checked in before tests are run. Note that in this case, the computer can help identify errors in the manual delivery mechanism by alerting the staff when test requests have been entered but no samples have been delivered in a reasonable time. Procedures should also be prepared to handle specimens that arrive without test request information.

6.4.2.2 In an alternative procedure, the laboratory staff collects the specimens when test requests are made by either paper or remote terminals. There are two mechanisms commonly used.

6.4.2.3 The system can use the test request information to print a collection list for the medical technologist who goes on rounds to collect samples. After a second attempt to collect any missing samples, the medical technologist returns to the laboratory, where either the collected samples, the uncollected samples, or both, are reported. A place on the collection list can allow this information to be recorded during the rounds. In a manual procedure, only the missed samples are reported to a supervisor for follow-up. If the system is used, minimum clerical effort is required to report only uncollected samples, whereas maximum error checking by the system is possible if both collected and uncollected samples are logged in. The value of the latter is frequently judged to be not worth the extra clerical expense. Uncollected samples should appear on a special follow-up list for supervisor action. Depending on laboratory policy and physician directions, missed or unsuitable samples should or should not appear automatically on future collection lists.

6.4.2.4 Alternatively, the system can print sample container labels at designated sites. The medical technologist uses these labels as a guide to determine the samples required. Missed samples may be identified by labels that have not been used. To detect inadvertent loss or destruction of labels, a check-in procedure similar to the collection list is

required. Specimen numbers may be assigned by the system and printed on labels. Abbreviations of tests requested on the labels permits immediate analysis without referring to a requisition or worklist. It is desirable to have a machine-readable code on the label. Bar code, optical character reader, or other schemes are possible. Machine reading of labels helps reduce clerical time and lessens the chance for mix-up.

6.4.2.5 A combination of collection lists (6.4.2.3) and sample container labels (6.4.2.4) can be used.

6.4.3 *Check-In and Acceptance Procedures*—A number of the preceding procedures involve an explicit check-in step at a central receiving station. These schemes have the advantage of allowing the computer to give more assistance in operating the laboratory. One use is to permit samples to be tracked through the laboratory procedures and provide the information necessary for generation of status reports, work lists, and instrument load lists. If test requests are entered prior to sample arrival, this check-in step also permits missing samples to be identified sooner. During check-in, it is important that a record of the time the specimen was collected be recorded. In some institutions, it may be acceptable to enter a single average time for all samples collected during routine rounds. In other enterprises, policy requires the exact time of each collection to be recorded. The collection time should always be noted and entered for any samples drawn for time-critical tests or for any nonroutine collections. Besides indicating arrival, the check-in step should also provide the option of identifying unsuitable samples. In some cases, a sample may prove unsuitable only after some initial treatment, and a mechanism to change the status at a later time must be provided. This change in status may affect the billing information.

6.4.3.1 The check-in procedure may be manual at a central receiving station. A sample requirement checklist is printed by the computer from the entered test requests and entries are checked off on this list as the samples arrive. No system entry is made. After a reasonable time, someone uses the marked checklist to initiate action to collect the missing samples. Sample numbers may be assigned sequentially as samples arrive. Since the system does not know a sample is at the laboratory until one of the test results is reported to it, this method cannot be used to confirm the presence of sample in the laboratory or tests in progress. It also is not able to generate load lists and work lists or some of the other laboratory management aids.

6.4.3.2 The check-in process can involve the system, which then records the presence of the sample and time of entry into the system. Uncollected sample reports are printed periodically for follow-up. Specimen numbers can be assigned sequentially as samples are logged in or samples can be matched to specimen numbers that were assigned when the test request was entered. It may be desirable for the system to permit laboratory staff to assign specimen numbers of their own choice in some cases, subject to system rejection of duplicates. Any inquiry about the status of a test can be answered quickly by the computer which knows if the test has been ordered, if the sample has been received, or if the results have been reported. Computer check-in procedures may involve one of the following devices:

6.4.3.3 A terminal operator enters an identifying number of a missed sample or block of samples taken from the label or collection list. The system responds with more complete identifying information which the operator checks against the label or list. After all missed samples are entered, the operator makes an entry that tells the computer that all others on the list have arrived.

6.4.3.4 A video terminal may present a list of samples expected, perhaps arranged according to ward as they might be expected to arrive. The operator uses cursor and keyboard controls or a light pen to mark either the arrival or nonarrival of each sample. Such a terminal should be convenient to use. It should be human engineered so mistakes are difficult to make, easy to spot, and easy to correct.

6.4.3.5 Each sample label can have a machine-readable segment such as a bar code, hole code, magnetic code, mark sense code, or optical character code. This option most likely requires computer-generated labels. The label of each sample vial is read by appropriate hardware at the receiving section of the laboratory to log the sample in. In the case of bar codes, for example, the receiving clerk passes the optical sensing wand over the bar code of each label. A beep or other feedback indicates acceptance.

6.4.3.6 Other automatic sample check-in procedures may be developed.

6.4.4 *Required Specimen Pickup Information*—When the laboratory collects the samples, the collection list or sample labels will require certain information. If sample collection is performed by the ward level personnel, collection lists or labels can be printed at the laboratory and sent to the wards or, if appropriate remote equipment exists, lists or labels may be printed directly at the wards. The following information may be needed:

6.4.4.1 Patient identification. This should consist of a name and identifying number. Some way of helping establish the identity of a patient with a name similar to another should be included.

6.4.4.2 Room and bed number.

6.4.4.3 Type of sample required.

6.4.4.4 Volume of sample required. This may be satisfied by giving the number and size of the containers needed. Container size and preservatives may be indicated by the color of the top. In the case of labels, multiple containers would be indicated by the existence of multiple labels. Minimum volume may also be indicated in case of collection by syringe.

6.4.4.5 If a timed or scheduled test is needed, the label should specify when the sample is to be collected. Timed tests may be better collected without a computer label. They typically depend on the injection of a drug and are easier to collect on the spot rather than running them through the computer.

6.4.4.6 Stat tests should be indicated to identify the need for immediate collection.

6.4.4.7 Indication should be given if a test is related to drug administration in a way that affects collection time or procedure. The free text field may be used, preferably with some control mechanism through the laboratory supervisor.

6.4.4.8 The collection list or label should indicate directly or by reference to other instructions any special preservatives required or any special handling, such as the need to maintain sterile conditions, special temperatures, or special storage or timing conditions.

6.4.4.9 If there is a special hazard, like hepatitis, AIDS, or tuberculosis, a warning should be given to help protect the individual collecting the sample and all individuals subsequently processing the sample. This should be prominent, and if hardware permits, should even be printed in a different color.

6.4.4.10 There are always special circumstances. A short free text field on the list or label is desirable.

6.4.4.11 If automatic check-in is used, an identification number in machine-readable form is needed on the label.

6.5 *Allocation*—In some enterprises, all samples arrive at a central receiving station. They may come in various containers suitable for immediate dispatch to the workstations for analysis. Sometimes a sample must be divided into aliquots and sent to different workstations and in other schemes the central station performs some initial treatment steps on the samples. In other hospitals, samples are delivered to individual receiving points close to the various workstations. The way that labeled specimens are allocated to workstations and their associated lists shall be determined; use of bar codes (see LIS7) and instrument/computer interfaces (see LIS1, LIS2) allows specimens and associated data to be routed directly and automatically to workstations while bar code labels on reagent containers convey reaction conditions. The ways that these capabilities are to be used to maintain laboratory quality objectives shall be stated in the laboratory information system requirements.

6.5.1 The number and type of different tests required determines the amount of specimen that must be collected and the number of containers in which it must eventually be placed. The computer can anticipate this during the specimen pickup stage by specifying on the collection list the number and size of containers to be used or by printing sufficient labels for each container. To do this, the system must have information on sample requirements for each test. In the most convenient case, enough different containers are used so that no aliquot steps are required at the allocation station. This cannot always be the case. Sometimes patient convenience or the need to conserve sample (as with infants) must take priority over laboratory convenience.

6.5.2 The test requests determine how the samples are to be distributed to the workstations. The system can provide the receiving clerk with information to assist this job.

6.5.3 There should be a method to allow the receiving clerk to record observations about the sample. This could include comments such as unusual color, short draw, and inappropriate sample handling or container.

6.5.4 The special problem of stat tests must be considered. These samples must be identified in some way for special handling. Some hospitals elect to never collect stat specimens in the normal manner. They go to a separate receiving station or even possibly to a separate laboratory to expedite processing. Consider how to report these samples to the laboratory system for inclusion on records and billing.

6.6 *Test Performance*— After the samples have been dispatched, the tests must be performed and the results entered into the computer. Here the nature of the process depends on the kind of test and instrument used. Communication with the physician may be required and the physician's name should be available to the technologist. The system may be configured to allow a message to be transmitted to the doctor along with the test results in special cases.

6.6.1 *Individual Tests*— For tests run individually at a workstation, a work list may be created by the system to go with the samples supplied by the allocation center. The tests are performed by a technician and the results are entered by several means associated with the terminal/workstation, these include either a direct instrument interface or a variety of manual means. Terminals may be placed in the laboratory for each to serve several workstations.

6.6.1.1 It is important to correctly establish the identity of the sample and put the result into the correct patient file. If the sample is identified by number, the system may return the patient name so the technician can check this against the label. Verification procedure should discourage automatic non-thoughtful operator response. Alternatively, the sample label may have a machine-readable portion. In this case, a terminal and label reader is probably required at each workstation.

6.6.1.2 The test result itself may be entered by the operator. If the instrument is interfaced, the test result may be acquired by the system automatically. In this case, the system should display the result for the operator to verify. In either case, provision for manual override of errors is required. This should allow the technician to correct a typing mistake before the end of a terminal session or repeat a test and discard the old value.

6.6.2 *Multiple Sample Instruments*—In the case of multiple-sample analyzers, the system may generate a load list that tells the technician how to place samples in the instrument. Alternatively, the technician may enter the load

list manually. Results from these instruments usually go directly to the system through an interface, but could be entered manually after a run in some configurations. When directly coupled, most do not provide for positive sample identification. They depend on the operator loading the sample tray to agree with the load list. It would be of advantage if a computer-readable label were attached directly to the specimen container in the instrument.

6.6.2.1 The system should be capable of manual alteration of the load sequence. This is important if a stat sample must be inserted ahead of others or a sample must be rerun. If a sample is removed from the load list, it should appear on a subsequent list.

6.6.2.2 The results of a run should be displayed for verification.

6.6.2.3 In addition to sequence changes, the system should be capable of accepting a rerun sample, a diluted sample, or an otherwise altered sample. These become necessary in some cases depending on the results found during the first trial. The new result should replace the old one. The additional test may count in the management statistics concerning workload, but it should not be a part of the number of tests performed or a part of the patient bill.

6.6.2.4 Some automated multiple sample analyzers use internal microcomputers or other control circuitry based on their own protocol and numbering scheme. The compatibility of these instruments with the laboratory information system being planned should be determined. One problem in this area is that upgrades or alterations in the instrument, the interface, or the internal software may affect its compatibility with the laboratory system. Verification of performance may be included as a contractual requirement in the acceptance criteria.

6.6.3 *On-Line Instruments*—When instruments are interfaced directly to the system, additional considerations are important:

6.6.3.1 The electrical compatibility of the instrument and the computer must be examined. Many newer instruments are designed with so-called standard interfaces, but in fact, they will not always properly connect to other devices using the same standard. Part of the problem is that the standards (1) allow incompatible options to be added and (2) do not always define all the required communication protocols.

6.6.3.2 Also determine that the system software will properly interact with the online instrument. The computer must be able to interpret the data being received, exercise any required control functions, and respond in a timely way to the instrument when it needs service.

6.6.3.3 It may be desirable to separate into two or more computers the data management duties from the instrument control and data acquisition activities (see, for example, NCCLS AUTO3-A). These computers may be linked and each used to best advantage for its respective task. It also allows one function to continue if a problem develops with one of the other computers. For example, instruments are still serviced properly if the larger data management computer is in the middle of a verification routine or a dump.

6.6.3.4 Determine the procedure to be used in the event of possible failures. Determine how data will be collected and transmitted to the patient files if an interface fails.

6.6.4 *Verification*—An important part of the test performance segment is data verification. This may be performed at various levels.

6.6.4.1 The technician may see a table of results for the latest work session and examine this to determine if all values are reasonable and there are no extra or missing entries. Provision should be made for deleting errors or repeating tests. The terminal procedures should be designed to facilitate use and reduce operator errors.

6.6.4.2 The system may examine the results, flag values outside of linearity or calibration, outside of normal, and possibly take more extreme action for improbable results. Some hospitals have chosen to require the supervisor to intervene in the latter case before additional activity can proceed at that workstation. This is to prevent defective instruments or techniques from continuing. Sometimes widely deviant samples are consistent with diagnosis or drug treatment and the value must be allowed to stand. It requires a trained individual to determine the difference. To obtain the information required for this review, the diagnosis or drug administration history of the patient may be needed. If this information is in other computers in the enterprise, appropriate interfaces may be desirable. If not, it may be helpful to explain anomalies in free text.

6.6.4.3 The system should have the capability of performing a delta check (7, 8). This should be done before verification of results. Its significance depends on the test and the magnitude of the values. Delta checks may be computed as an absolute difference or as a percent difference from the previous result.

6.6.4.4 The information system can be valuable in supporting quality control (9). Quality control material may consist of a manufacturer assayed or unassayed pool. Patient samples may also be used for verification of an instrument system. These may take the form of individual samples, pooled material, or material that has been altered by addition of certain constituents.

6.6.4.5 Evaluation of a test system should occur both immediately and retrospectively. Numerous quality control evaluation methods exist for analysis of individual patients or pooled material. They should be presented in a form that gives graphic or tabular information, or both, to the user.

6.6.4.6 Presentation of information may be in the form of Shewhart Charts, Youden plots, individual data points, or reduced information (mean, standard deviation, number of points) with selection by date of analysis, control or a

subset of data points (for example, only those that were unacceptable). Reduction and interpretation of quality control material could be through the use of algorithms such as CUSUM (10), Westgard Multirules (11), Trigg's Trend Analysis (12), or Brian Bull's Patient Mean (13). The above are not inclusive and serve only as examples.

6.6.4.7 The quality control display and evaluation should precede the certification/verification and release of patient results. The system should report prior to release of patient results any quality control result out of range.

6.6.5 *Data Integrity*—Quality control also includes verification of the data in the computer system. Such problems as writing over old records, software bugs under peculiar circumstances, and computer operator mistakes should be guarded against.

6.6.5.1 A program that verifies the content of files can be run periodically to detect some of these errors. The program might check the data in each field of each file to ensure that it is reasonable. Numerical fields should not have alphabetical characters, result values should be reasonable, identification numbers should have the right number of digits and the right check character, and patient identification fields should be alphanumeric without unusual character codes. Other checks might be designed into the plan, such as check codes that verify major parts of the record (6). Test programs that consume significant computer time should be scheduled for slack times. Some checking should be done with every file access.

6.6.5.2 If errors are detected, their cause should be determined and corrected. If they are the result of laboratory personnel errors, operating procedure changes may be required or the software may be changed to make the error less likely. If a software bug is the cause, it should be corrected, most likely by the vendor.

6.6.5.3 One way to track down errors in the computer is to maintain an activity file or audit trail. This is a record of all transactions and activities recorded as they take place during some defined time period, usually since the last verification or the last dump to backup storage. This activity file can be used to track down errors by showing the circumstances just prior to and right after the failure. It is also an important tool for restarting a system after a failure because it has information about all activities not saved since the last dump. A rudimentary audit trail is provided if all entry is through hard-copy devices.

6.6.5.4 The verification program may require extensive machine resources for a certain time. If so, the system should be designed so normal operation is not disrupted to the extent that test requests or test results are lost.

6.6.6 *Operations*—The system should be convenient to use in the normal working environment. This means it must be able to handle the usual irregularities that occur.

6.6.6.1 The information system must be able to deal with the test requests that for one reason or another have not been performed yet. It may be necessary for the system to respond to inquiries by giving the time when the test is scheduled or the time remaining until the test is done. At the very least, the computer should inform the inquirer about the status of the test. This status might include (1) no knowledge of test, (2) no sample at laboratory, (3) sample at allocation center, (4) sample at workstation, (5) sample sent out for analysis, (6) sample now in the instrument, and (7) results if ready.

6.6.6.2 The system should produce overdue test lists and incomplete test lists on demand to alert the laboratory personnel of work still to be performed. The time limits used by the system to define overdue should be capable of modification to adjust to special conditions such as slow workdays due to sick personnel. These limits are also test dependent and may vary from 1 h for some stat tests to over 2 weeks for tests that are sent out.

6.6.6.3 In the event a test must be repeated, the system must be able to include appropriate information on a new collection list or sample label list if a new specimen is to be collected. It should be possible to specify that the same specimen be used if sufficient quantity remains. The repeat must also be rescheduled in the work lists or load lists. It must be possible to enter a repeat either with or without an additional charge to the patient.

6.6.6.4 The cancellation of a test is an important decision that should be possible only by the highest-level personnel. It is appropriate that the test request remain in the file along with the reason for cancellation. Normally, cancellation of a test will also cancel the bill, but in some cases, this may be a separate issue.

6.6.6.5 Determine the procedure to be used if a physician cancels a test already in process. If such a test is already run, determine if it should remain in the file and if it should be printed in the report. Decide how the canceled test should be counted in the various management reports that will be prepared. In general, such cases should count as test events but not be charged to the patient. Also, determine if the results should be included in the quality control routines. Any deleted result should be filed to an exception log or in some other way recorded so that the original datum is not lost completely. If a result has already been reported, it should continue to appear on subsequent cumulative reports but may be accompanied by a comment indicating the result is old or bad or deleted.

6.7 *Reports*—The external reports issued by a laboratory are primarily to communicate results to physicians and other users of patient data. While reporting may continue to use printed formats, posting to computer-based patient records will become increasingly prevalent; the printed format may occur directly from that electronic patient record or it may also be printed on a remote printer directly from the laboratory computer. The format of the report is important because it projects the image of the laboratory. It is the report that users see as the end product of the laboratory. Reports may be presented in temporary form on CRT devices or in more permanent printed form.

Archival reports may be in microform. Internal reports are for laboratory staff and convey other information needed to help run the laboratory.

6.7.1 *External Report Types*—Communication of laboratory results to others in the hospital may be of the following types:

6.7.1.1 Ward reports are supplied to each organizational unit of the hospital giving the results of the tests ordered in the most recent time period, usually one day. These reports may be printed in alphabetical order by patient name or in order by patient room for each ward.

6.7.1.2 Physicians reports. These would be similar to ward reports except that all the patients of each doctor would be grouped together.

6.7.1.3 Cumulative printed reports for medical records may be supplied to wards, doctor offices, and hospital records. This report gives a summary of test results over a longer period and becomes a part of the permanent paper medical record. The format of this report is most conveniently a table with results in one direction and time intervals in the other. There may or may not be separate formats for reports intended for physicians and pathologists, interns and residents, and nurses. If different, each would be designed to maximize the usefulness to the intended recipient. There may or may not be differences between reports generated for outpatients, inpatients, emergency room patients, or other types.

6.7.1.4 A discharge summary, or final cumulative report, may or may not be put onto a format different from the regular cumulative reports. Also at discharge, a complete paper record on the patient may be generated for the physician's files. The electronic report of these results needs to be posted to the designated addressees only once.

6.7.1.5 Individual patient reports should be possible. These would normally result from an inquiry about a single test or all tests of a particular patient before the routine reports are printed or if a duplicate copy is requested. If the inquiry is for a specific test, the result should be displayed irrespective of how the test was ordered. The best format for this report would put the most recent results first. With electronic posting, these may be designed as electronic views only.

6.7.1.6 STAT reports are given as soon as the result is verified, without waiting for other work on the specimen to be completed or for a scheduled print time. STAT reports may be sent directly to an output device at the point of test order origin, often the emergency room, and it may be part of an electronic alerting message. It is desirable to have these reports either printed or displayed automatically, perhaps with an alert, without requiring the remote user to make an inquiry.

6.7.1.7 Intensive care reports may be required. Because of the large volume of data resulting from frequent tests, a special format may be needed.

6.7.1.8 A provision should be made for promptly reporting stat results. These reports should be generated as soon as the results are verified and transmitted immediately to the requester. One approach is a telephone call plus inclusion of the result on routine reports. Other methods include either a special remote printer for stat results or a facsimile or wireless device transmission.

6.7.1.9 Interim reports for nurses and others at the ward level would provide information on the test status. It would report partial results if available, and indicate where the remaining requested tests are in the system.

6.7.1.10 An outside user's report may have a different format. This report would go to outside physicians or other medical institutions to report results of work requested by them of this laboratory. It too may be transmitted by wireless technology.

6.7.1.11 Billing reports may be issued in hard copy and used by the business office to help compute the patient's bill. Alternatively, they may be produced in machine-readable form or transferred by direct link to the enterprise billing system.

6.7.2 Internal reports are those that are available for use by the laboratory staff and management.

6.7.2.1 Abnormal reports. Results that are not within the normal limits are usually the most significant. These results alert the laboratory to possible procedural errors or the need to give special notification to the physician. It is desirable if the system allows retrieval of abnormal reports by various criteria such as range, combination of specimens, technologist, time, or physician. Some enterprises desire two levels of out-of-bound reports. The lesser set of limits takes the form of a printed message whereas exceeding the wider limits, suggesting absurd values, causes an audible alarm or a refusal of the system to take any more data until review by a supervisor.

6.7.2.2 Overdue test reports are printed when test results are not reported to the system within a prescribed time after the sample for the test passes through the allocation center. Supervisor attention may be needed to determine why the tests are late.

6.7.2.3 Outstanding test request reports would tell the laboratory about test requests that were made but for which no sample has yet arrived. Appropriate action must be initiated to obtain the sample.

6.7.2.4 Quality control reports are issued periodically and may include tabular and graphical displays giving such information as comparison of means and standard deviations with other laboratories using the same method, comparison of means with previous values (to determine drift in the mean), comparison of standard deviations with previous values (to determine drift in precision), merged reports of results on periodic surveys plus results on daily

specimens, absolute values and trends of differences on blind duplicates, exception reports based on absolute as well as statistical criteria, and free-text descriptions of problems and corrective actions taken.

6.7.2.5 Management reports may be requested periodically. These reports help the laboratory management operate effectively and provide data for the various records and reports that must be filed for various agencies. Typical management reports include (1) weighted work load reports, (2) test count reports, (3) turnaround reports, (4) activity logs, (5) department or workstation summaries, (6) peak work load period reports, (7) staffing reports, (8) terminal time usage reports, (9) patient census, (10) room census, (11) special reports (example: duplicate names), (12) space utilization reports, (13) computer operation schedules, and (14) computer resource utilization reports.

6.7.2.6 Preventive maintenance reports may be printed to remind the laboratory of the need for routine maintenance on the system or other laboratory equipment.

6.7.2.7 Verification reports give the results of an internal test program that verifies the integrity of data in the files.

6.7.2.8 Personnel schedule reports might be used to help laboratory management keep track of personnel assignments. It would identify who is available for the different shifts, individual preferences, and other criteria that the director needs to manage effectively. The program helps avoid misunderstandings that may leave the laboratory understaffed.

6.7.2.9 Attendance reports can be used to help management. If the check-in procedure has sufficient security, the computer can be used as a time clock and attendance recorder. Since laboratory personnel are reporting results to the computer throughout their shift, the computer can also keep track of personnel activity. This may identify individuals who are not sufficiently productive and who may need additional training.

6.7.3 *Video Display Reports*— Video display reports provide a limited amount of information in response to an immediate need. They are suitable for individual test results, stat reports, interim or status reports, and some of the internal or management reports. They are also useful if one wishes to step through a large amount of data, such as a review of quality control reports. It should be noted that some video displays allow a hard copy reproduction of the screen image on command.

6.7.3.1 The video display report may be used by laboratory personnel to help them answer telephone inquiries. The system should allow them to get the information they need quickly.

6.7.3.2 If remote terminals are provided, they may be used by physicians and other authorized ward personnel. Video display terminals may be located in the doctor's lounge, doctor offices, the emergency room, at the wards, or wherever they may be needed.

6.7.3.3 Retrieval of reports at the video display terminal should be restricted to authorized personnel. In many situations, the same security that governs test requesting may be appropriate for report inquiries. Remote terminals used exclusively for input, such as those at the admissions desk, should not be capable of producing reports on patient tests. In some locations, terminals may be equipped with hoods to shield sensitive information from view.

6.7.3.4 Remote terminals used for test requesting and temporary report generation should not be able to affect the system in other ways. It should not be possible to enter test results or change any of the system parameters from remote terminals.

6.7.3.5 Test results should be verified prior to reporting. The result from a reporting station or online instrument is not to be considered ready for output until this verification step is complete. Verification may be carried out in some cases by the technician scrolling through the results with a video display. Other hospitals may elect to have a supervisor review all results.

6.7.3.6 Remote video displays are used by hospital staff to answer questions that occur during their day wherever they might be in the building. The system should therefore allow retrieval of results from patient name or number, physician name or number, test name or code, date of test, or other combinations of parameters.

6.7.3.7 The remote video display is also useful as a tool to provide information on patient preparation, specimen collection requirements, and result interpretation.

6.7.3.8 The video display report format may be different from printed reports because of the limited space for characters. This limitation may result in significant operational problems. It may be better to devise a system where any report may be displayed on a video display or printer. Information displayed may include patient identification, the date and time of collection, the test name, the test result, a delta check, a high—low designation, the standard deviation from the mean, the percentile, and the normal range. Except for laboratory management reports, it should not have unnecessary information such as the laboratory accession number, any other internal identification numbers, or the name of the medical technologist who did the test.

6.7.4 *Remote Printers*— Printers or terminals may be used at the wards to provide hard copy test results. Such units may be used alone or with video displays. They are useful for reporting stat test results to emergency rooms or intensive care units.

6.7.5 *Line Printers*— High-speed line printers will most likely be employed to produce the bulk of the hard printed copy reports, but such reports are becoming less common. Ward reports, cumulative reports, individual physician reports, and discharge summaries will make up the majority of this activity.

6.7.5.1 The printer selected places limitations on the number of pages in the forms. Some printing mechanisms, such as thermal or electrostatic, permit only single copies. Impact printers can often be used with multiple-part forms, but the number of parts may be limited. The total time required for production of reports is the important specification. A printer with faster cycle time may actually be slower if multiple runs are required to get the accessory number of copies. The number of copies required depends, in turn, on the total system configuration and the workflow of the hospital.

6.7.5.2 These reports are usually printed on a regular basis. Decide when during the day this activity should occur. This decision depends on when most data will be ready and when the physicians need or expect the results. Consider this aspect in view of possible irregularity in physician rounds. In some systems, the printing of reports consumes much of the system resources, and is often scheduled at night. Plan enough system capability if daytime printing is a requirement.

6.7.5.3 Determine the method of distribution of the reports. There may be legal requirements concerning security and special provisions may be needed for disposal of unneeded paper.

6.7.5.4 Determine the time required to print a report and the number of reports that may be needed. Evaluate the adequacy of the number of line printers. The worst-case evaluation is more significant than an average degradation.

6.7.5.5 If the computer has reduced capacity to perform other functions while printing reports, determine the effect on operations. Make sure no test requests or test results can be lost. If a spooling or another buffering technique is incorporated to relieve the problem, determine its capability and evaluate its adequacy. Determine if the spooling system includes the most recent results in the output.

6.7.5.6 If the system stops when reports are being output, determine if the system is able to take up where it left off or whether the report generation must restart from the beginning. Also determine if a restart of some or all of the report printing can be performed in the event of a paper jam or other problem.

6.7.5.7 Determine if it is possible to generate additional copies of single pages of ward and cumulative reports. Determine if there are time constraints on when this can be done.

6.7.5.8 Determine if reports can be generated on the basis of other criteria. It may be desirable to produce a set of reports for all patients of a given doctor, all patients in a given ward, all patients using a particular service, or all patients of a given type.

6.7.6 *Forms and Displays*—The design of the report format should be given attention. Each type of form should be considered individually, as should each type of visual display that may be subsequently printed. The construction of a form will determine whether it will run successfully on a given printing device. The form construction depends on whether the form is printed on demand or in batch mode, whether decollating and bursting equipment or manual detachment is to be used for multipart paper forms, and how the form is used once it either leaves the laboratory or is printed at a care site. It may be necessary, for example, to limit the page size and provide holes or margin space for attachment to a clipboard or other binder. Any forms committee, operations committee, or other group that has responsibility to maintain or alter the way forms are to be stored or used in the hospital should be consulted when these forms are designed.

6.7.6.1 A good format reduces errors by making the information clear, easy to read, and easy to handle. Information of a similar nature should be grouped and clearly labeled. Decide whether the latest information should be presented first or last on the form. Too much material tends to obscure the important entries. Insufficient material may leave the reader confused about the meaning of the report.

6.7.6.2 The printing or display hardware selected determines the limitations of the forms. Consider the character width of the device, the availability or absence of lower case and special characters, and the presence or absence of graphic capability that might be used to add borders, column boundaries, or other special effects. It may be desirable to design a form that can be printed or displayed on a variety of equipment. Although it may not use the full capabilities of the most powerful device, it eases the problems if other units must be used for backup. In the future, the use of graphical output is likely to become more popular. Also consider the quality of printing for the major and or permanent reports. Some of the newer ink-jet and laser printers are capable of excellent definition and contrast, even when printing at 15 characters per in.

6.7.6.3 Consider the option of using preprinted forms. Key results can be highlighted by color or background. Borders, column boundaries, and fixed information may be printed on the form, and a more attractive report can be achieved. The use of background color may provide additional information, such as identifying the type of form or as an aid to filing. Color is an effective charting aid for differentiating permanent and temporary reports. On the negative side, a change in output format requires a change in the form. The printer mechanism and forms must be coordinated, reducing the ability to use a different printer mechanism in a backup mode. Alignment becomes critical with preprinted forms so that printed information is placed in the designated areas properly. Some forms vendors may supply overlay versions of forms with print positions marked to be used for checking alignment prior to

production of the form. Any preprinted form should be tested on all printers that it might be used in before large quantities are ordered.

6.7.6.4 All forms have some mandatory fixed information. This includes (1) name and address of the institution, (2) name of the laboratory director, (3) any fixed labels or directions, and (4) other information that helps when reading the final result.

6.7.6.5 Individual pages of ward, physician, and cumulative reports for each patient should be numbered to identify sequence and detect missing pages. In addition, a page identification scheme may assist sorting and distribution.

6.7.6.6 Desire to change the format of the output at a later time is common. A system configuration that permits easy format changes without vendor assistance is desirable. The placement of identifying information, the order of test results, the ability to report a result in more than one place, the listing of normals, the values of reference range, the column widths, and the content of the report are things that may change.

6.7.6.7 A number of decisions must be made concerning report format. For example, if a single result from a battery of tests was requested, determine if the form headings for the other tests are also printed.

6.7.6.8 On some forms, the ability to add free text in special circumstances is useful. Determine where free text messages concerning a particular test are to be placed. On preprinted forms, free text messages require advanced planning. The location and maximum size of the message must be determined. Special messages about a particular test should be placed near the results of that test.

6.7.6.9 There are special problems in the use of computer-printed labels. Labels should pass through the printer easily without separation from the backing, receive lettering properly without smearing when they are applied to a sample container, separate easily from the backing paper when needed, and adhere well to the curved specimen vials. Labels should be tested for adhesion under all possible environmental, storage, and operating conditions (such as in the refrigerator) before ordering in large quantities.

6.7.7 *General*—The following points relate to reports:

6.7.7.1 Some tests can be run by different methods. These often have different normals because of different sensitivities and different interferences. The test naming convention facilitates unique identification of such tests. Consult Specification E 1712. Determine the conventions to be used to report such results.

6.7.7.2 Determine which units to use in reporting results. In some cases, it may be necessary to report a single result two or more times in different units.

6.7.7.3 Determine how corrections in billing reports can be made. It should be possible for an error to be corrected even after the information has been passed on to another computer. Determine if there are any time limits on this ability.

6.7.7.4 Determine if stat reports are to be printed at appropriate remote terminals and how receipt of results is verified. Partial results for stat tests should be reported immediately, even if the entire test request order is not yet completed.

6.7.7.5 Make sure all file information remains available for the necessary final reports, even if the patient has been discharged.

6.7.7.6 Forms construction and format must be planned. Lead time for form development and interactions with a forms vendor may require several months.

6.8 *Archival Storage*—Legal requirements and good judgment demand that test results be saved for some defined length of time. In some enterprises, no records have even been discarded. The information system must be designed to allow periodic creation of permanent records for offline storage.

6.8.1 *Offline Media*—There are a number of considerations that affect the choice of offline media:

6.8.1.1 Machine-readable media consists of magnetic tapes and disks, laser disks, and other media for saving information in a way for the computer to use it afterwards. Such media facilitate future use of the data for long-term patient care, research, and other purposes. They may also allow storage of more information in a given volume than paper. They are, however, not usable without a computer. Also, the inevitable changes that take place in file content and data organization over the years may make the media unreadable by the current system. It is therefore necessary to save old versions of the operating system to read old files, or to otherwise take precautions to avoid this difficulty. Laser disks might become an especially attractive medium for archive files. Once a given portion of the disk surface is written, the information cannot be changed. The disk itself is removable for storage and it can save very large amounts of data.

6.8.1.2 Microform records can be created directly by computer. They can be read by humans without a computer and therefore do not become obsolete if programs are changed. It is difficult to use the information in microform records for any systematic studies.

6.8.1.3 Paper is relatively bulky for permanent records. Alternative storage should be considered if space is limited. Possibilities include microfiche, magnetic tape, and disk. These systems should be carefully planned. An index in machine-readable form or online is useful to locate a given record quickly and easily.

6.8.2 *General*—Additional considerations about archival storage are:

6.8.2.1 Determine how often records are transferred to archival storage. Generally it is important to clear data from the active system as soon as it is not needed. This is necessary to avoid overloads.

6.8.2.2 Determine if the information system is able to function properly on its other duties while it is moving information into archival storage. Make sure no test requests or test results can be lost during this period.

6.8.2.3 When designing archival storage, consideration should be given to making the output compatible with other computers or equipment. This will widen the potential for future uses of the information.

6.8.2.4 Flexibility is important for this aspect of the system. The number of patients, the number and kind of tests reported, the number of days in active storage, and other items are things that will change as the laboratory grows. Plan an archival system that can accommodate these changes. Be especially aware of the problem of interpreting old data when test procedures and reference values have subsequently been revised.

6.9 In almost all healthcare applications there is now, or shortly will be a requirement for laboratory information systems to exchange information with the other enterprise computers, other computers in networked architectures, or with remote computers over extended networks. This communication should be conducted in accordance with HL-7, or other protocol.

6.9.1 A common data protocol is essential. There are several different standards that apply at each of several different levels of the communication process. An enterprise may choose to adopt a particular standard at each level for all hospital electronic data communications (14). These levels include:

6.9.1.1 The format of each item (for example, line, record, and packet) of information to be transferred.

6.9.1.2 The character encoding scheme:

6.9.1.3 The electronic representation of the data in the interface, including transmission speed.

6.9.1.4 Any hardware or software handshaking requirements, including error checking and flow control.

6.9.2 The information contained in the communication depends on the application. The programs in both the transmitting and receiving systems must agree on the format and organization of this data.

6.9.3 If communication with the laboratory system is possible from computers outside of the enterprise through networks, security against unauthorized access is essential.

6.9.3.1 Nearly all systems will require one or more levels of password to prevent improper use. Passwords must be changed from time to time.

6.9.3.2 As an added precaution, a system may only allow certain activities to be performed at designated sites. Even authorized users are restricted to these functions if they access the system through the network. This limitation restricts the convenience allowed to authorized users, but it reduces considerably the possibility of serious damage by vandalism by outsiders.

6.9.3.3 A very good protection scheme requires all potential outside users to call the system, make a sign-on request, and hang up. The system then calls back, but only to previously authorized locations.

6.9.4 Allocation of functions is of special concern when a laboratory information system is connected to an enterprise information system. The following are examples of functions normally present in a stand-alone laboratory system that may be done differently if interfaced to another system.

6.9.4.1 Patient registration, inpatient admittance, including all admission-discharge-transfer information, including inpatient admittance, outpatient registration, changes in patient data (including transfers to different services, bed swaps, outpatient to inpatient status), and discharge.

6.9.4.2 Billing for patient services and other business transactions should be conducted electronically according to HL-7.

6.9.4.3 Medical records and archive preparation and maintenance.

6.9.4.4 Test order entry, relayed from remote terminals throughout the enterprise to the laboratory information system.

6.9.4.5 Status, stat, and other result reporting relayed to remote terminals and printers by the enterprise system. It is important to confirm that reports sent to a remote site through the enterprise system or directly by the laboratory system are actually delivered. Some kind of verification scheme is needed to insure that a remote printer is turned on, ready, and actually working.

6.9.5 When the enterprise system to laboratory system connection is designed, the type, purpose, and format of every message that crosses the interface must be specified. These will include the messages needed to transmit the information, verify its successful and correct reception, make changes in previous data sent, and manage the communication link itself. The latter would include messages like suspend or resume communications, reset the link, and report errors. Both systems must be programmed to properly process these various message types.

6.9.6 It is important that the laboratory be able to function even if the connection to the enterprise system is not operative. This may happen regularly if the two systems have different schedules for preventive maintenance or unexpectedly in the event of a failure. To be able to function, the laboratory system needs redundant functions.

6.9.6.1 The laboratory system must maintain a recent copy of patient demographic data with the ability to enter changes in patient bed location or other data, and to add new patients. Provision must be made to keep this information up to date in normal use as changes are made in the enterprise system. The laboratory system may also

have to maintain information for real or pseudo patients that will never be in the enterprise system. These include reference samples and work done for outside submitters.

6.9.6.2 The laboratory system must be able to accept test orders even if they normally come through the hospital system. Often such orders will be transmitted on paper requisitions and entered at terminals in the laboratory when the normal mechanism is not available. It is important that wards still be able to verify that test orders were received, specimen collections are scheduled, or samples were actually received by the laboratory. If such verification is normally provided by the enterprise system, a back up method should be available in case of interruption of this service.

6.9.6.3 The laboratory must be able to produce stat reports immediately on its own printers for hand delivery if the mechanism that allows them to be printed directly in the emergency room or other remote site is not operating.

6.9.6.4 Regular reporting must also be possible if extended out-of-service condition exists. In addition to delivering reports printed by the laboratory system to doctors and patient care areas, it may be necessary to transfer test results to the enterprise system by another mechanism. Such data may be needed for medical records or to support other departments like dietary and pharmacy. Often this level of backup will be accomplished by exchange of tapes or disk cartridges.

6.9.6.5 When proper operation of the interface between the enterprise and laboratory systems is restored, both systems must be brought up-to-date and verified. Special attention must be given to making sure both systems have correct and consistent data after any interruption in communications has occurred.

6.10 *Redundancy, Backup, and Recovery after Failure*—Plans must be made to allow the laboratory to operate in the event of a failure in part or all of the system.

6.10.1 Consider the redundancy required:

6.10.1.1 There should be redundancy on peripheral items such as terminals and printers. In case of failure, operations can be switched to another device until repairs are made.

6.10.1.2 Consider designs that include redundancy of disk drives. This might involve duplicate copies of the data on separate drives that are either continuously updated or where one drive is periodically copied to the backup.

6.10.1.3 There should be an adequate supply of spare parts to allow rapid repair of all failures. If this supply is maintained at the vendor instead of within the enterprise, verify the adequacy of the inventory and the response time for acquisition of the parts.

6.10.1.4 It may be worthwhile to consider a spare central processor, or a design involving multiple CPUs that can operate at reduced capability without one member, if necessary.

6.10.1.5 Reliability plans should include software backup as well as hardware. Maintain reserve copies of all software in case the resident system is damaged.

6.10.1.6 Consider redundancy that may be required at the site. Determine if backup air conditioning or power supplies are required. The use of an uninterruptible power supply should be examined. Some systems are more sensitive to the environment. This should be considered when evaluating different systems.

6.10.2 Determine how redundancy features might be invoked:

6.10.2.1 The computer system should be designed to fail soft on a power failure. Power loss detection is available in most computers, and appropriate software stores the complete machine status in a safe place at the first sign of failure, before all power is lost. Resumption of operation from the point of interruption is then easier when the power is restored.

6.10.2.2 Devise a plan to restart the computer after it is repaired following an abrupt failure. Determine how much information will be reloaded, and how and from where this information will be obtained. This information usually comes from the last dump and the audit trail file since that last dump.

6.10.3 A backup system must be available in case a computer system failure cannot be repaired within an acceptable time. Usually this is a manual procedure using paper forms, but often different from the one in use before the computer was installed. Return to the old manual system may be impossible because of changes in workflow. Even use of a revised manual system is difficult after everyone becomes accustomed to the information system, and it should be attempted only as a last resort.

6.10.3.1 The backup plan should allow for (1) acceptance of samples, (2) analysis of samples, and (3) report generation to physicians. It is usually not necessary to back up cumulative and management reports. The backup system may be designed for partial implementation. For example, an automatic instrument normally giving results directly to the computer may be equipped with a printer or tape unit to provide an alternative method of transferring data when the automatic link is inoperative.

6.10.3.2 The quality and extent of the backup needed depends on the quality of warranty and maintenance support. In situations where rapid and reliable service is not available, the probability a backup system will be needed from time-to-time is higher, and it should be prepared with more care. Document all failures, maintenance, and repair in accordance with LIS6.

6.10.3.3 It may be wise to hold practice exercises using the manual backup system every so often, such as every 6 months.

6.11 *Constraints*—Near the end of the preparation of ideal functional requirements, when the desired system is more clearly understood, review the constraints identified in project definition (see 5.6.5). Include all appropriate constraints in the ideal functional requirements.

7. Vendor Survey

7.1 A vendor survey should be performed. It helps assure that no better system is inadvertently overlooked. Various lists of vendors are published from time-to-time and can be used. Some professional societies maintain vendor lists. Additional vendors may be identified through conventions, conferences, expositions, trade journals, colleagues, and other users. Contact each vendor identified to determine which ones are really possible vendors of the required system.

8. Refinement of Functional Requirements

8.1 *General*—This section describes how to transform the desires determined in Section 6 to the realities found in the marketplace. The end result of this step should be a refined and realistic description of the functional requirements.

8.2 *Priorities*—Take each of the provisions of the specifications developed in Section 6, in accordance with ANSI/IEEE 1362 and place them in one of the three categories (1) required, (2) desirable, or (3) provision for future addition. This procedure will give a basis for evaluating proposals. Vendors that fail to meet one or more of the required items can be eliminated. It may happen that all are eliminated if the “required” category is too rigid. Revisions in the plans are needed in this case.

8.3 Preliminary Vendor Contact:

8.3.1 Discussions with one or two likely vendors can help define a more reasonable project.

8.3.2 Sometimes it is helpful to submit a preliminary proposal to determine how the specifications developed are received by the vendors. The responses can be used to better define the goals and identify what requirements to include or exclude. Evaluate the response in terms of priorities at the hospital.

8.3.3 Identify features present in the proposed systems that you did not request. Some may be useful to include in the final specifications.

8.3.4 Identify the features you require but are not present and determine how and at what expense they may be added.

8.4 *Site Visit*—An important mechanism for better defining the project is to conduct a site visit to other institutions running comparable systems (15).

8.4.1 A site visit can help identify aspects that need to be modified, excluded, or added to the specifications. Other users can provide information on the vendor's reputation and helpfulness, ease or difficulty of system installation, ease or difficulty of everyday use, system reliability, vendor ability and willingness to fix problems, and whether the system actually fulfills stated functional requirements. It is best to visit an institution similar to your own. A system that works well in a commercial lab may be unsatisfactory in a university teaching hospital, for example.

8.4.2 Before any site visit, review the functional requirements and prepare a list of items to be checked or questions to be answered. This is important to help get the most from the visit. Other users selected a system based on their own functional requirements. Try to determine how closely they match the current project. Remember that a site visit may inconvenience the host. Restrict the list of questions to the essential items. A preliminary phone conversation may be helpful.

8.4.3 The following points and concerns relate to site visits:

8.4.3.1 Do not let the personality of the host influence your judgment. A disagreeable and pessimistic host can make a good system look bad and a cheerful, enthusiastic individual can describe a mediocre system in glowing terms. Try to seek objective information and be quantitative where possible (for example, ask about the number of down times per month, rather than accept the statement “It works pretty well”).

8.4.3.2 Institution management and personnel climate can affect the system performance. A poorly organized staff with high tension levels, jealousy, and in-fighting will be more likely to experience operational problems with any system, computer or manual. A happy, well-run laboratory, on the other hand, is more likely to be successful.

8.4.3.3 The chief information officer, the director of the laboratory, and the individual actually operating the system should be consulted. It is also helpful to get the opinions of people of lower echelon who are more familiar with the details of day-to-day operation.

8.4.3.4 Since night is often a time when reports are generated and other system functions different from daytime are carried out, the night staff may have a different view of the system performance.

8.4.3.5 The nurses and physicians who use the input and output features of the system may have additional information. If these opinions are to be sought, it is wise to make such plans ahead of the visit and secure the cooperation of the head of staff.

8.4.3.6 The person who planned and chose the system may have a biased opinion. His comments are important, but should be evaluated within this context, particularly if there is a difference between his observations and the system users.

8.4.3.7 It is better if representatives of the vendor are not present during the site visit. Friendships and the inclination to be courteous may prevent a thorough discussion of any annoyances or real problems.

8.4.3.8 Potential hosts can be identified by personal knowledge, colleagues, other users, and the vendor proposing the system.

9. Approvals

9.1 *General*—Narrowing the specifications to a workable project is only part of the process. It is also necessary to pass several legal and administrative hurdles before requesting proposals.

9.2 Write the application for the certificate of need. The public law to contain spiraling health care costs is administered locally. Consequently, the extent of material required to satisfy it differs in various parts of the country. In general, computer systems do not meet the limitations that allow a nonsubstantive waiver, so the application for a certificate of need is usually required. Most institutions are able to show that computerization of the laboratory is cost effective, so the certificate is usually made available. Many of the points discussed in the cost/benefit section (all of 5.5.4 and 5.5.5) can be used to justify the system for the certificate of need.

9.3 There are also administrative and budget approvals required. These steps depend on the institution and must be followed. Often there is a local computer committee that must give approval.

9.3.1 Determine the required organizational and statutory requirements. Identify the various points where approval may be required.

9.3.2 Determine the route the budget request must follow through the organization.

9.3.3 Determine the documentation required for each level of approval and any necessary lead time at each level.

9.3.4 In some places the director of the existing data processing facility is a part of the chain, not in others. In either case, his cooperation is desirable (or essential if connection is being made to the existing system).

10. Request for Proposals

10.1 *General*—When institutional approval has been obtained and all vendors identified, submit a request for proposals. The process may be carried out in two stages. An initial request may be in the form of a questionnaire. Vendors may be asked which of the desired features are presently provided by their system and the estimated cost for adding those that are not. The initial request may be used to determine which vendors are to be selected for serious negotiations. The following points of concern are for the second, more formal request for proposals.

10.2 Portions of the official request for proposals involve agreements that the institution and vendor will later include in the contract. Some of the points of concern are described in [Section 11](#). The request for proposals should anticipate these factors. Legal assistance is recommended.

10.3 Each acceptable vendor is given a copy of the functional requirements and constraints of the system. Vendors are requested to make proposals and price estimates, and to supply lists of users of systems similar to the ones they propose.

10.4 If it is not clear how a proposal meets the functional requirements, obtain clarification. If a written proposal has less capability than a verbal understanding, have the additional promises placed in writing. Do not assume any unclear or unstated aspect will work satisfactorily.

10.5 Vendors may not quote to meet specific user performance requirements, but instead offer their existing hardware and software as components of a system. The request for proposals should clearly state that vendors are to quote systems that most closely meet the functional requirements and any deviations must be stated in the quotation.

10.6 The vendor quotation must include itemized hardware and software prices, installation prices, delivery date, and detailed specifications. Options and alternatives to the system should be itemized separately. Maintenance agreements, service contracts, and warranty provisions must be quoted. Adequate site requirement specifications, such as any special physical, environmental, or electrical requirements must be indicated (see [14.1](#)). Vendors must state their enhancement and update policy and how they keep customers informed about future enhancements and updates. The expiration date for the quotation should be stated.

10.7 Insist that specifications be supplied for system performance. Component performance and system performance may be quite different. The laboratory may indicate certain conditions and ask the vendor to specify such things as guaranteed terminal response time or maximum report printing time.

11. Evaluation of Vendor Proposals

11.1 *General*—Each vendor proposal should be evaluated against the refined functional requirements derived from Sections 6 and 8. Translate the vendor specifications into the same terms used in the functional requirements. Review each item.

11.2 *Evaluation of Cost*—It is the total cost of buying and operating the system that is important. Comparison of different vendors should be based on purchase price, maintenance, site preparation, installation, transportation, personnel, training, and supplies over a defined period of time. Many of the costs were described in the cost/benefit section (see 5.5.4). See also the following sections on maintenance (11.4), backup systems (11.7), training (11.9), site preparation (14.1), and use (Section 17). Finally, additional cost considerations are outlined in this section.

11.2.1 *Package Cost*— This may involve separate charges for hardware and software. It may also involve a lease cost that could be a fixed rate per year or so much per test.

11.2.2 *Shipping Costs*— Determine whether shipping includes delivery to the desired room or just to the grounds of the institution. Determine who shall move the unit indoors and solve such problems as doors not being wide enough or elevators strong enough. Find out, for example, if the institution must provide a lift truck. Estimate these costs if they are the customer's responsibility.

11.2.3 *Installation Costs*—In particular, determine who is responsible for stringing signal or power cables and meeting local building and fire codes. Determine who shall correct the installation to eliminate troublesome interference or noise should it exist.

11.2.4 *Cost of Operation*—Determine if there are fees for software and hardware maintenance, cost for new software releases, costs of supplies, etc.

11.2.5 If old equipment is being replaced, determine any trade-in allowance.

11.2.6 Consider the cost and possible penalty for late delivery.

11.2.7 Some institutions choose to compute the cost of the computer per test to better compare it with other options.

11.2.8 Determine the terms of payment. Payment may be due on delivery or on acceptance. If the latter, determine what constitutes acceptance (see 11.10).

11.3 *Warranty*:

11.3.1 Determine what the warranty includes. A single warranty that includes overall system performance as well as both hardware and software is best. Sometimes, however, only software and hardware are warranted, in some cases by different companies. In this situation, determine who has the final responsibility if the two companies do not agree where a particular problem exists. Determine if there are any exclusions in the warranties.

11.3.2 Determine when the warranty starts and how long it lasts. Some warranties begin at delivery and some on the date of acceptance.

11.3.3 Determine the conditions of repair under the warranty. It should be specified who will make the repairs and within what time period. Repairs should be made promptly. These conditions should be comparable with service contract provisions and can be evaluated on the same basis. Any steps taken to determine the source of a failure which resulted in damage to components of another manufacturer should not delay repairs.

11.3.4 In some respects, warranty and acceptance are related. Determine the consequences if the system cannot meet performance specifications during the warranty. This may involve a penalty or recourse clause in the contract and may involve consequential or liquidated damages, or both. Be sure these terms are properly defined. Conditions for rejecting the system and not making payments should be specified. Any arrangements for arbitration in either the warranty or acceptance should be defined. Determine any legal requirements that bear on this aspect of the warranty. Determine what happens if the nonperformance judgment is reached after the warranty expires.

11.3.5 If there are provisions for enhancements and updates, determine the conditions, including notification of availability and effect on maintenance and continued vendor support.

11.4 *Maintenance*— Maintenance is a key consideration. A system is only as good as it can be maintained in the field. Hardware and software maintenance might better be considered as separate items because they are quite different and are probably the responsibility of different individuals, even if they are warranted by the same vendor. In some cases, remote peripherals may be maintained under separate responsibility.

11.4.1 Some maintenance is best performed by laboratory or in-house personnel and some by manufacturer servicemen. Determine what limits exist on this activity to ensure the warranty or service contract is not voided.

11.4.2 The question of in-house or outside maintenance depends on the local staff. Determine the staff required to run the system and the type of maintenance for which they will be responsible. Sometimes this may only include clearing paper jams, restarts, etc. Other times it may include board or component replacement. The individuals performing service may include (1) operators, (2) the system manager, (3) a maintenance specialist, and (4) the vendor.

11.4.3 If in-house maintenance is planned, determine if backup or consulting assistance is available. The experience of other users with 24-h hotline services should be investigated.

11.4.4 Determine what spare parts inventory is required.

11.4.5 Determine if the maintenance contract includes parts and labor, only parts, or only labor. Find out if the contract is limited in the number of hours before additional charges and if it includes travel.

11.4.6 Determine the location of the serviceman and the expected or required response time. It may be appropriate to ask about the number of people trained for service and the number of systems for which they are responsible.

11.4.7 The service response time may be specified in terms of the maximum down time that can be accepted. Define when the response time period shall begin and end. Also determine whether it includes nights, weekends, and holidays. It may be appropriate for a service contract to specify any penalties for failure to meet response time. These might be designed to help compensate the hospital enterprise for overtime wages needed to operate the laboratory without the computer. A realistic response time for maintenance based on local experience may be determined from other user laboratories.

11.4.8 It is reasonable to expect that the service vendor maintain a sufficient stock of spare parts to repair any difficulty. If not, the cost of maintaining a spare parts inventory at the hospital should be included in the evaluation. Some critical items, such as a backup printer or disk may be advantageous to stock.

11.4.9 Determine the preventive maintenance required and who shall perform it. Elapsed-time meters may be included on units that require regular periodic maintenance. Determine how preventive maintenance is to be scheduled to reduce the impact on normal operations.

11.4.10 In some cases, a sequence of tests or a series of diagnostic programs can be run by laboratory personnel prior to calling the serviceman. The results can be reported to the serviceman when he is called to permit him to bring the right tools and parts.

11.4.11 Acquire and evaluate the adequacy of service manuals, diagnostic programs, diagnostic interpretation manuals, and other service requirements and aids. It is desirable that a complete wiring schematic that identifies every discrete component be supplied at the time of delivery.

11.4.12 Troubleshooting by remote telephone link is likely to increase in popularity. Determine if such a service is in existence or planned for the system.

11.4.13 In some cases, maintenance of older equipment is frustrated by obsolete parts. Determine if there are guarantees that such parts will be available. Require that engineering drawings be made available for any parts that become obsolete so that they at least may be fabricated if the need arises. Vendor spare parts policy should be given significant weight during evaluation and selection.

11.4.14 In any maintenance contract, there should be some guarantee of availability with penalty provision for failure to comply.

11.4.15 If service provisions are suspect or unacceptable, consider system designs that include better redundancy and backup sections.

11.4.16 Determine which provisions will be maintained in service contracts if they are subcontracted. It is suggested that the language specify all services will be maintained in this event.

11.4.17 The original purchase contract should include a provision that service contracts shall be available for a determined number of years. Provide a contingency plan in case a vendor sells or drops a product line, is merged with another corporation, or goes out of business. To guard against the latter, a requirement to post a performance bond may be included. Determine how both hardware and software will be maintained, as well as availability of spare parts. At the very least, the contract should provide that full documentation and schematics be made available in the event vendor or subcontracted maintenance cannot be continued. Determine any financial liability of the vendor for failure to honor a service contract.

11.4.18 Sometimes there is controversy between vendors concerning rights to software or hardware. The service contract should provide for continuation of support even in the event of litigation involving the vendor.

11.4.19 A good feature of some service contracts is a hierarchical scheme. If the initial serviceman fails to correct the problem within a specified time, a supervisor is automatically called. If the problem is not resolved within an additional specified time, higher qualified individuals are brought in, and so on until the system designers themselves are working on a particularly difficult problem. In this way, increasingly knowledgeable individuals become involved in a timely and automatic way depending on the difficulty of the problem.

11.4.20 A serious problem with maintenance is that documentation goes out of date because of changes made over a period of time. Determine how such documentation will be kept up-to-date. Also, determine what changes can be made at the hospital without interfering with this aspect. Planned changes should be negotiated with the vendor. Some systems are promoted as "easily changeable." Make sure that any such changes will be supported by the maintenance contract. It is important that the system control programs written by the users so they cannot interfere with the main system and so program crashes will not spread throughout the system.

11.4.21 Another problem encountered with maintenance contracts is that the quality of service deteriorates. Employee turnover and expanding workloads at the vendor means that individuals with limited experience are

sometimes used. Maintenance contracts might include a provision specifying the qualifications of the serviceman to be sent. It might, for example, specify that service requests will not be answered by a trainee.

11.4.22 To evaluate the service program proposed by the vendor, consider the following: (1) Is the program satisfactory compared to those of other vendors in the field? (2) Is the vendor well established and reputable? (3) Is an adequate supply of spare parts maintained? (4) Are sufficient personnel available? (5) Is documentation in existence, available, and adequate for software and hardware?

11.5 *Hardware*—Do not be overwhelmed by the electronic specifications of the hardware. The evaluation process must fix on the effectiveness of the system at the user interface, not how the system accomplishes its functions. Hardware and detailed software specifications are of interest only to assure the purchaser that the operational specifications can be met by the user programs. In evaluating the hardware component of a vendor proposal, the following points are among those that should be considered. It is helpful in this and the next section if the system details are specified in a way that allows these evaluations to be made.

11.5.1 *Storage Capacity*—This is best evaluated in terms of enterprise performance and is an area where many systems are found to be deficient. Determine the maximum number of both inpatients and outpatients likely to be in the system at one time, the maximum number of tests likely to be stored for each patient, and the number of ways this information should reside in active storage. Determine the disk space required to store each piece of information. From this, compute the disk space used. Allow for inefficiency in packing data into records. Add to this the space needed for the operating system, other overhead, and other records that may be required. If the other records include blood bank, determine the number of transactions and the space required for each. A good plan is to double the space calculated so far to allow for contingencies, future expansion, and higher workloads. An alternative is a disk storage system that is expandable at a later date.

11.5.2 *Input Devices:*

11.5.2.1 *Terminals*—Determine the maximum number of terminals the system will support and the distance they can be from the computer. Determine terminal characteristics such as speed and capacity. Evaluate the degradation in system performance by running the maximum number of terminals.

11.5.2.2 *Bar Codes*—Bar codes may be used on wrist bands for patient identification, on original patient sample containers and any subsequent aliquots, for reagent and other inventory control, for employee identification, and for blood bank inventory. They can be used to order tests from a menu, and to inform the system how an instrument sample tray is loaded by reading the label, either manually or by the instrument, as each sample is inserted into the tray. Be aware that there are many bar code formats and the laboratory may have to deal with several different kinds. Some bar code readers can understand different formats. Avoid using a bar code format that does not have check characters for positive verification. Avoid producing any document or label identified only with a bar code. Always include human readable identification as well.

11.5.2.3 *Other Inputs*—Some systems are capable of voice input.

11.5.2.4 *Strategy*—When planning input protocols, avoid procedures that include frequent switching between different input mechanisms. Many users find it inconvenient to have to constantly switch between bar codes and keystrokes or light pen and keystrokes, etc. There may be unacceptable error rates if users are expected to select choices and options by reading a bar code or using a light pen with a menu that has a large number of closely spaced options.

11.5.3 *Other Peripherals*—Determine the expandability of the system. Consider additional line printers, other devices, disks, memory, and if the design permits, CPUs.

11.5.4 *Redundancy*—Check the redundancy features and evaluate against the specifications.

11.5.5 Review and evaluate the use of any nonstandard media, such as special magnetic tape (unusual cassette, cartridge, or reel sizes), nonstandard paper tape or cards, or nonstandard disk packs. Determine if such nonstandard media may eventually lead to availability or pricing problems.

11.5.6 *Documentation*—Require adequate documentation. The system design manual, as specified in the life cycle, should include this documentation. For example, obtain connection drawings, schematics, board drawings, diagnostic aids, operating instructions, and training manuals.

11.5.7 *Diagnostic Aids*—To evaluate the quality of diagnostic aids, either printed or software, consult with other users.

11.5.8 Evaluate the systems tolerance of electromagnetic interference, pulses on the power line, humidity, and other environment disturbances. Determine if isolated power supplies or other special apparatus is needed.

11.5.9 Specify the standard types of connectors, cables, and shielding that will be used. Refer to Federal specifications that limit the radio frequency emissions of video displays to be used in the cardiac intensive care unit. Allow for sufficient redundancy in cabling to permit expansion or to allow for continued system functions in case of damage to some of the conductors, shields, or sockets.

11.5.10 Evaluate enhancements in the vendor proposal that were not part of the specifications with regard to value added versus added cost.

11.5.11 Determine the existence and value of any standardization. Determine if there are other identical systems over which the hardware design costs can be distributed.

11.6 *Software:*

11.6.1 Evaluate the operating system in terms of ease of usage, flexibility, expandability, reliability, and system degradation due to overhead. Operating systems may also be evaluated in terms of the number of installations and the firms supporting the system. Nonstandard operating systems may not be supported as well and may be more vulnerable if the original vendor goes out of business. The existence of database management features and the nature of the file structure may also be evaluated.

11.6.2 Evaluate operating system utilities. These include loader programs, disk control and file management routines, general utility libraries, and other miscellaneous features such as PROM programmer routines.

11.6.3 Evaluate the language used to write the programs. Examine the ease of modification, quality of documentation, and the ease of learning how to use the language. Higher-level languages, particularly those that self-document well (such as structured languages), are preferable from the standpoint of making alterations and ease of learning. It is extremely difficult to incorporate even minor alterations in assembly language or hard-wired systems. Availability of database management and string manipulation features may be considered. Some languages tend to run slower or take more memory. There may be advantages in choosing a language known existing personnel.

11.6.4 Determine if single- or double-precision arithmetic is used for statistical computational processes. Evaluate the adequacy of computational precision.

11.6.5 Determine that necessary support software is present if changes are considered a possibility. Editors assist making source modifications and compilers are required to produce new object programs from modified source programs. Linking programs are required to join different object modules together to form a complete operational software system.

11.6.6 Determine the flexibility of the existing software. Many support operational changes without generating a new operating system. Evaluate the ease with which (1) tests can be changed, added, or dropped; (2) output format can be changed; (3) table organization can be altered; and (4) limit values and internal checks and restrictions can be changed without vendor support. A brief description of what parameters may be controlled from user-defined tables is helpful. Determine if unused functions can be deleted from the operating system or application programs by the user. If the vendor provides the user with the ability to make these changes through a special system language, evaluate it against the same criteria in 11.6.3. This is also a suitable topic for discussion during a site visit. It is helpful to actually observe user changes being made in order to visualize how easily and quickly these occur with a total system still in operation. This may also be seen at the vendor site.

11.6.7 Making changes not originally provided for in the software requires adequate documentation at the programmer as well as user level be available. This includes a well-commented listing, flow charts or other printed material explaining the algorithm, and other aids such as lists of the meanings of variable names, diagrams of table or data organization, or memory maps. All software should be documented in accordance with ANS/IEEE 610.2-1290, 729-83, 730-89, 828-83, 829-83, 830-93, 983-85, 1002-92, 1008-93, 1012-92, 1016-93, 1058-93, 1063-93, and 1074-95 and ISO 6592, 9127, and 9294. In some systems, this information is available as a part of a licensing agreement. Because of proprietary considerations, complete documentation is usually available only if the enterprise signs a nondisclosure agreement. It is a serious limitation if this information is not available at all, and such cases should be considered adversely in the evaluation. In some cases, refusal to disclose software is a screen to hide deficiencies in the programs or the documentation itself. If good documentation does not even exist, the system should be rejected. In addition to possible modifications, this documentation is needed if the vendor goes out of business and maintenance must be assumed by someone else.

11.6.8 It may be possible to use the computer as a word processing machine in some systems that have sufficient excess time and appropriate software. This is useful for report or document generation for such things as anatomical, surgery, SNOP, and autopsy reports. Many of these are standard and require only entry of names, sizes, and other descriptors, after which the entire report can be typed. Word processing can also be used to generate up-to-date procedure manuals.

11.6.9 The computer may also be used for record keeping in a form that allows better retrieval and consequently better health care. This may include tumor registration, number and types of surgery by patient, and diagnosis by patient. Retrieval could be by name of individual, diagnosis type, tumor type, surgery type, etc.

11.6.10 Determine how often dumps to backup storage are required and if the system will be available for other activities during this time.

11.6.11 Find out if file cleanup routines have to be run periodically. If so, determine how long each run will take and if the system performance is degraded during this time.

11.6.12 Determine if system performance is degraded when billing or cumulative reports are being output. A spooling type of print out often reduces the effect of these reports on the rest of the system.

11.6.13 In evaluating output performance, actual lines per minute printed under typical and worst case conditions is more significant than a quoted lines per minute value that may have been obtained with no other system activity.

11.6.14 Evaluate the adequacy of the audit trail. Determine if it is sufficient to protect the data without being overly consumptive of resources. Evaluate the procedure needed to recover from a crash using the audit trail.

11.6.15 Determine the existence and value of any standardization. Compare with the standards matrix in the section on identification of the network domain in LIS9. Determine if there are additional systems over which the software costs can be distributed.

11.7 *Backup System*— Evaluate the backup system required for each vendor. Consider the ease of usage, the expense of maintaining it, the amount of practice needed to keep it operational, the ability to use part of it if only a portion of the computer system is inoperative, and degradation of laboratory services it would cause if it had to be used for an extended time.

11.8 *Interfaces*—There are several interfaces to the laboratory computer.

11.8.1 Evaluate interfaces to laboratory equipment. Determine how the software supports these interfaces. Evaluate the ease of adding additional interfaces for equipment not yet purchased. Determine the maximum number of such interfaces and evaluate the adequacy of that number. Determine how much system degradation will occur if additional interfaces are added. Determine the feasibility of nonstandard interfaces as well as standard types.

11.8.2 For laboratory computers interfaced to main enterprise information systems, determine if an interface failure will cause either the laboratory or the enterprise system to be inoperative. If the patient data were stored on the main computer disks, for example, a failure of the link severely limits the capability of the laboratory system.

11.8.3 Interface specifications should specify LIS1 for the hardware interface and either LIS2 or AUTO3-A for the message structure whenever possible and include electrical characteristics, baud rates (for serial), character code conventions, transaction protocol, and linkage to the operating system, if needed. Thus, it can be seen to involve both hardware and software aspects.

11.8.4 Interfaces are often components that are not specified properly in sufficient detail in the original plans. Minor variances, misselection of options, improper protocols, and other small details often thwart proper operation. It is recommended that interferences be evaluated on-site if at all possible. One test of the interfaces is to run programs with the highest time, memory, and priority demands and see if all interfaces still work satisfactorily. Determine how instrument interfaces will support laboratory automation. Determine the message structures for both directions in the link.

11.9 *Training*:

11.9.1 Evaluate the level of training needed for the various individuals impacted by the system. These include:

11.9.1.1 Physicians.

11.9.1.2 Nursing staff.

11.9.1.3 Pathologists.

11.9.1.4 Computer management.

11.9.1.5 Laboratory supervisors.

11.9.1.6 Computer operators.

11.9.1.7 Hardware maintainers.

11.9.1.8 Software maintainers.

11.9.1.9 Laboratory technicians.

11.9.1.10 Ward clerks.

11.9.1.11 Laboratory secretaries.

11.9.1.12 Admission personnel.

11.9.1.13 Billing personnel.

11.9.1.14 Site maintenance personnel.

11.9.1.15 Records department.

11.9.2 The different subjects on which training is required include:

11.9.2.1 Physical operation of terminals.

11.9.2.2 Terminal protocol, which includes procedures for ordering tests, getting status and results for patients, and admitting patients into the system.

11.9.2.3 Definition of terms that appear in reports and the organization of those reports.

11.9.2.4 Operation of online instruments.

11.9.2.5 Manual data entry methods.

11.9.2.6 First level of troubleshooting (to decide if a simple fix or serviceman needed).

11.9.2.7 Preventive maintenance.

11.9.2.8 Detailed maintenance and repair.

11.9.2.9 Housekeeping in computer room.

11.9.2.10 Operation of the computer.

11.9.2.11 Selection of options and functions (file content, report format, limit values, test code selection, internal cross checking, etc.).

11.9.2.12 Operation of archival system.

11.9.2.13 Training the teachers.

11.9.3 The vendor may train a few individuals, often selected members of the original project team. They, in turn, may become part of an installation cadre, which, among other duties, would have responsibility for training programs for the rest of the enterprise.

11.9.4 In general, systems that are used in a conventional and natural way require less training and are easier to use. Some systems are self-instructive to a large extent and may reduce the need for separate training requirements.

11.9.5 If a vendor offers training, determine how many individuals, what level, and for how long a time period the offer covers. Determine the total cost of this training, including travel and living expenses, tuition, and lost productivity of that individual away on training.

11.9.6 After initial training of some key enterprise personnel, many institutions create a continually self-perpetuating program of training in-house. In some cases, this may be largely informal and in others, a formal training program is used for each newly recruited technologist. Determine what training materials are available from the vendor and what needs to be written by the enterprise.

11.9.7 Security becomes a consideration during training. Individuals should not become knowledgeable enough to perform unauthorized alterations, get into sensitive files, or otherwise disrupt the operation. Special supervision of night shift personnel may be required.

11.10 *Acceptance*—Make sure the acceptance procedures offered by the vendor are realistic. The decision on when to accept a system is difficult because one is never sure if all the bugs have been found and all the possible failure modes have been tested. Most laboratories cannot afford the manpower to operate the old and new systems in parallel. Others feel that it is valuable to run parallel for a day or so with the vendor on-site. Another tactic is a phased implementation.

11.10.1 During the specification phase, a list of things to be checked during acceptance should be developed. This list should be augmented from the vendor proposal and specifications. Each test in the acceptance procedure should be signed off by an authorized person from the vendor and the enterprise as it is completed.

11.10.2 There are a number of steps that can be taken to help confirm satisfactory operation:

11.10.2.1 Test each feature with close observation of its operation. Many difficulties can be located just by watching each aspect of a system as it operates.

11.10.2.2 For each online instrument, verify each result by offline alternative methods.

11.10.2.3 Exercise the system under simulated full load before stopping the manual system. Use dummy data to load the system and run all stations. This may be done using the regular staff with an hour or two of overtime.

11.10.2.4 Another possibility is to phase in the operation of that new system a little at a time, with careful verification after each step. Not only should the newest step be tested, but its effect on the older operations should be determined. This plan may place less pressure on the installation cadre. A phase-in acceptance plan can be related to a phased payment plan.

11.10.2.5 The new system can be verified in many of its modes by running the diagnostic tapes.

11.10.2.6 Another acceptance test is to operate the system during a trial period. The initial contract, for example, may state that acceptance will occur after the system has run for x hours with full load with no more than y errors as shown by file verification programs. Completion of this step may end the acceptance phase, to be followed by full payment.

11.10.3 Acceptance procedures should be determined and be made part of the contract. It is advisable that the enterprise lawyers play a role in this portion of the contract.

11.10.4 It is unwise to write acceptance procedures that demand too much of the manufacturer. It is recommended that optional language be used for acceptance procedures in the request for proposals and that vendor responses for this be evaluated along with the other factors.

11.11 *Evaluation of Vendors*—The vendor organization itself should be evaluated.

11.11.1 *Vendor Stability*—Yearly audited financial reports may be requested for the past few years in order to obtain information on the viability of the vendor. Other indications of stability include the number and type of employees, independence or subsidiary status to a larger corporation, recent growth, and other commitment to health care products and services. The concerns about documentation and maintainability become even more important if the possibility the vendor may go out of business is significant.

11.11.2 *Customer Relations*—Evaluate the cooperation of vendors to help solve problems and the satisfaction of other users with vendor service. This information might be obtained by attending meetings of the user's group if it exists, and during site visits.

11.11.3 *User Groups*—The existence of user's group for the system is valuable and should be given some weight during evaluation. Common problems can be addressed, and help from other users sought to promote better use of the system. User's groups are often a catalyst for enhancements and upgrades.

12. Selection of Vendor

12.1 *General*—After all available information has been collected, a decision must be made. Because of the complexity and scope of most projects, and the fact that no vendor may meet all the desires, this step is not necessarily straightforward. The process might, in fact, be iterative. One might select a system and yet during negotiations be unable to arrive at a mutually acceptable contract. One might then have to repeat the process with the second best system. In the meantime, new developments in this rapidly growing field may sometimes make it desirable to change the specifications and prepare a new request for proposals. There are different management techniques that can assist in complex decision-making. The one recommended here is a scoring system. It should be emphasized that this is to be used only as an aid in reaching a decision. It is not necessarily the final word.

12.2 Compare each quotation with the list of essential requirements developed in 8.2. Eliminate from further consideration any system that does not meet all essential requirements. If no proposals are received that meet the requirements or the budget, it is necessary to (1) postpone or cancel the project, (2) change the functional requirements, or (3) change the budget.

12.3 Assign a numerical weight to each of the functional requirements listed as desirable or useful for future additions in 8.2. Weight assignment is a subjective procedure and depends on prior perception of the importance of each feature. In the absence of experience, it is very difficult to judge the worth of many features. Help may be desirable from outside experts and other users. As a general guide, use weights between 7 and 10 for items that are very important, but not essential, 4 to 7 for items that are important, for convenience, and 1 to 4 for features that are nice, but not really important. Reserve the weight of 0 for things that are really useless for system operation.

12.4 Compare and score each functional requirement for each vendor. Assign a score of 0 if the system does not meet the functional requirement, 1 if the system is satisfactory, and 2 if the system substantially exceeds the requirement. This step is also subjective.

12.5 Multiply the score of each system by the assigned weight for the requirement. The result is a rating of that system for that result.

12.6 Tabulate the results so that all systems can be compared on a feature-by-feature basis. Use this table to help make a final decision.

12.7 Summarize the scores by subcategory to get a comparison of the major components of the various systems. Use these numbers to help form a decision.

12.8 Compute a total score. Use this number only as one aid in reaching a decision. It is risky to attempt to reduce a complex system to a single number and then use it without further thought. Remember the subjective nature of the weighting factors.

12.9 Many people find that their views change on the importance of various system requirements. In this event, the weighting and scoring factors may be changed. Do not, however, arbitrarily change factors to make the results agree with a preconceived outcome.

12.10 When nearing a decision to accept a system, it is helpful for the laboratory director and some of the technologists to “walk through” the entire system. Review the sequence of operations as seen by the hospital users and the laboratory. Include the test requesting, sample collection, check-in, result reporting, inquiry handling, and report generation and distribution steps. This may be done as a paper exercise or with a similar or simulated system at the vendor. This exercise helps identify unnoticed problems and may also improve morale and acceptance by laboratory personnel. After this, it may be decided to reweigh the scores, respecify the system, or proceed with negotiations.

13. Purchase

13.1 When a decision has been made on the system that best meets the functional requirements, the purchase phase is entered. A well-written purchase order is important to reduce unexpected deficiencies when the system is delivered. This document is usually arrived at through negotiations with the vendor. The vendor's terms and conditions of sale or lease should be examined carefully by both the system users and the institution legal staff. Clarification or changes in wording may be needed to make the conditions acceptable to both parties.

13.2 The purchase order must contain all the conditions and provisions relating to the project. These will have been developed and reviewed in the previous steps and should include itemized lists of all components, acceptance criteria, warranties, software update policy, maintenance agreements, and training arrangements. Delivery date, site preparation requirements, and responsibility for installation should also be specified. The final version of the terms and conditions of sale should be stated and signed by representatives of both user and vendor.

14. Installation

14.1 *Site preparation:*

14.1.1 Usually the enterprise must assume responsibility for site preparation. Determine who at the institution will take leadership of this task.

14.1.2 Begin site preparation as soon as a purchase contract has been completed. All necessary modifications to the site should be prepared before any equipment is delivered.

14.1.3 Review the site preparation requirements that are accepted in the purchase order. Obtain installation, startup, and operation documents.

14.1.4 Computer systems often require new clean air ventilation or air conditioning units, noise filters on electrical equipment, special clean power supplies, cable conduit, shielded cables for communication terminals, raised flooring, and special fire suppression equipment.

14.1.5 There will also be a need for floor space for the system as well as offices for additional personnel and storage of supplies and materials. Order forms, paper, ribbons, magnetic storage media, and other supplies that will be needed to operate the system. Also order file and storage cabinets, racks and binders, and other miscellaneous office hardware for documentation, printout, magnetic tape reels, disk packs, and other such items.

14.1.6 Many of these items require a long lead-time to implement, and must be planned well in advance of delivery. The site preparation schedule should allow for unexpected site problems, labor difficulties, or budget deficiencies.

14.1.7 Determine if and how the site facilities may be tested. Vendor statements like “clean room required” should be better defined so the adequacy of site preparation is measurable. Specifications for power supply quality should include tolerable limits for conducted and induced electromagnetic disturbances, voltage and current requirements, and required regulation. Specifications should also include limits for temperature, humidity, static electricity, airborne particulate matter, and heat removal requirements.

14.2 *Delivery*—Include plans for delivery. Designate the individual responsible for delivery. Alert the Receiving Department prior to the expected delivery date. If applicable, arrange for off-hour delivery. Arrange for unloading, delivery to the desired room, and unpacking as specified in the sales agreement. If appropriate, a representative of the vendor may be present during this step. If temporary storage is required, arrange for it. When the equipment arrives, inspect for damage and compare with the packing list. Document any discrepancies.

14.3 *Installation*— After the equipment arrives, the vendor usually installs the system. If the system interfaces to existing systems, arrange for the necessary local assistance required for the vendor to complete this aspect. Be prepared to carry out other installation requirements as provided in the contract.

14.4 *Startup*—System checkout and startup should be carried out in accordance with the provisions decided upon in the purchase agreement.

15. Training

15.1 Training should begin early and run parallel to site preparation. Follow the plans prepared in 11.9.

15.2 Obtain and circulate training and operator documents to selected individuals.

15.3 If off-site training is provided, send operators and others as required to the training site. If training involves remote simulation, prepare suitable data for the exercise.

15.4 If on-site training is planned, make suitable arrangements for classes, instructional materials, and appropriate attendance.

16. Acceptance

16.1 Carry out the acceptance procedures as specified in the contract.

17. Records and Evaluations

17.1 *General*—Records should be kept documenting the use of the system throughout its lifetime. These will be important for evaluation and error diagnosis. They will also be useful when a decision to replace the system is being considered.

17.2 *Documentation of Normal Operations*—Keep records to document normal operations, which include:

17.2.1 Use of the system. This may be a record of extent of activity as determined by the audit trail. This documents the growth in the use of the system with time.

17.2.2 Comments from users on problems, and the disposition of these problems. They may arise because of inadequate system design, inadequate operator training, and normal failures.

17.3 *Documentation of Maintenance*—Keep maintenance records as follows:

17.3.1 Record each scheduled maintenance and note any special maintenance performed at the same time.

17.3.2 Record all unscheduled maintenance required. Note the repair needed, the response time of the serviceman, and the adequacy of the repair. All records should be filed at a single location in chronological order.

17.3.3 Record all use of any hotline service, including the names of the individuals on both ends, the nature of the problem, and any follow-up action to be taken. The hospital should designate only a few individuals authorized to use the hotline to avoid excessive use and also to make proper recordkeeping more feasible.

17.4 *Evaluation of System Performance:*

17.4.1 Carry out periodic evaluations. These may be scheduled after a specified time and be used to determine if the system is performing as expected.

17.4.2 An evaluation is appropriate whenever a substantive modification is planned in the system. It is also appropriate to evaluate the system at the time of its retirement.

17.4.3 An evaluation should include consideration of the following:

17.4.3.1 Actual use of the system compared with its expected use. Determine if all the features originally planned were used with the frequency expected. Record any applications of the system that were not originally planned.

17.4.3.2 Observed performance compared to the vendor specifications. Note any aspects that, after long-term experience, were below specifications. Also record features that worked better than expected.

17.4.3.3 Observed performance compared to actual needs. As experience is gained, it frequently becomes possible to identify areas where a better scheme could have been implemented.

17.4.3.4 Any features that turn out to be exceptionally valuable. Sometimes aspects originally thought to have been of limited value are later seen as very useful. Record these unexpected benefits.

17.4.3.5 Any aspects that are unsatisfactory. Also record unexpected problems and their resolution. These points may assist in planning modifications for the existing system or when the next system is being developed.

17.4.3.6 Down time, maintenance needs, and response time.

17.4.3.7 Technologist satisfaction with respect to ease of operation, reliability, and utility.

17.4.3.8 The satisfaction of the users of the laboratory services with the system. This should include report clarity and format, timeliness of reports, ease of usage, response to errors, resolution of problems, and overall satisfaction.

17.4.3.9 The satisfaction of the laboratory and hospital management with the system.

17.4.3.10 Desired enhancements in the existing system or to be included in the next one.

17.4.3.11 Evaluate the cost of the system and compare it with expected costs.

17.4.4 The evaluation should consist of a written report. The information may be gathered through (1) formal surveys, (2) separate discussion meetings with users, the laboratory staff, and management, and (3) the personal opinions of the laboratory manager and computer system staff.

18. Enhancements and Updating

18.1 For at least the following three reasons, the selection and implementation of enhancements and updates will be appropriate during the life of a clinical laboratory information management system.

18.1.1 To keep pace with changes and improvements in computer science,

18.1.2 To adapt to changing laboratory needs, financial status, regulatory policy, or current activities, and

18.1.3 To improve performance, lower costs, or delay obsolescence.

18.2 Enhancement is the addition of different equipment or software to improve performance or add new features to the system.

18.3 Update is replacement of original equipment or software by newer items to correct errors or deficiencies, but generally not intended to add new features or substantially improve performance beyond that which was specified in the original system or a previous enhancement.

18.4 Enhancements and updates may be available from the original vendor, other commercial sources, other users, or user support groups. Enhancements and updates are sometimes undertaken as in-house projects, but they often have an adverse effect on warranty, maintenance contracts, vendor support, and compatibility with future vendor enhancements.

18.5 During the life of the system, the system management should originate or implement updates and enhancements as needs or opportunities arise. These changes shall be part of a software life cycle developed from the principles in ANS/IEEE 610.12-90, 729-83, 730-89, 828-83, 829-83, 830-93, 983-85, 1002-92, 1008-93, 1012-92, 1016-93, 1058-93, 1063-93, and 1074-95. They might decide upon an enhancement or update in the same manner as during decisions leading to the purchase of the original system. The existence of enhancement or updates may become known to the system managers from:

18.5.1 Information from the original vendor,

18.5.2 Advertisements from other vendors offering add-on features,

18.5.3 Trade literature, journals, and expositions,

18.5.4 User groups for the system, and

18.5.5 Professional meetings and contacts.

18.6 Enhancements and updates may be installed by the original vendor, other commercial sources, or the system management.

18.7 Before an enhancement or update is installed, the system management should understand the criteria under which the original vendor maintenance contractor, or both, will continue to support the system. Support includes documentation, revision, maintenance, repair, and warranty.

18.8 Performance tests are needed to verify that specified performance is obtained at installation of the enhancement or update, and afterwards as a part of normal performance assurance procedures.

18.9 When an enhancement or update is made, the system documentation must be revised to reflect the changes. This may be the responsibility of the system management or the vendor offering the enhancement.

19. Keywords

19.1 clinical laboratory; functional requirements; laboratory test ordering; laboratory work management; software acquisitions; software life cycle; software project; software requirements

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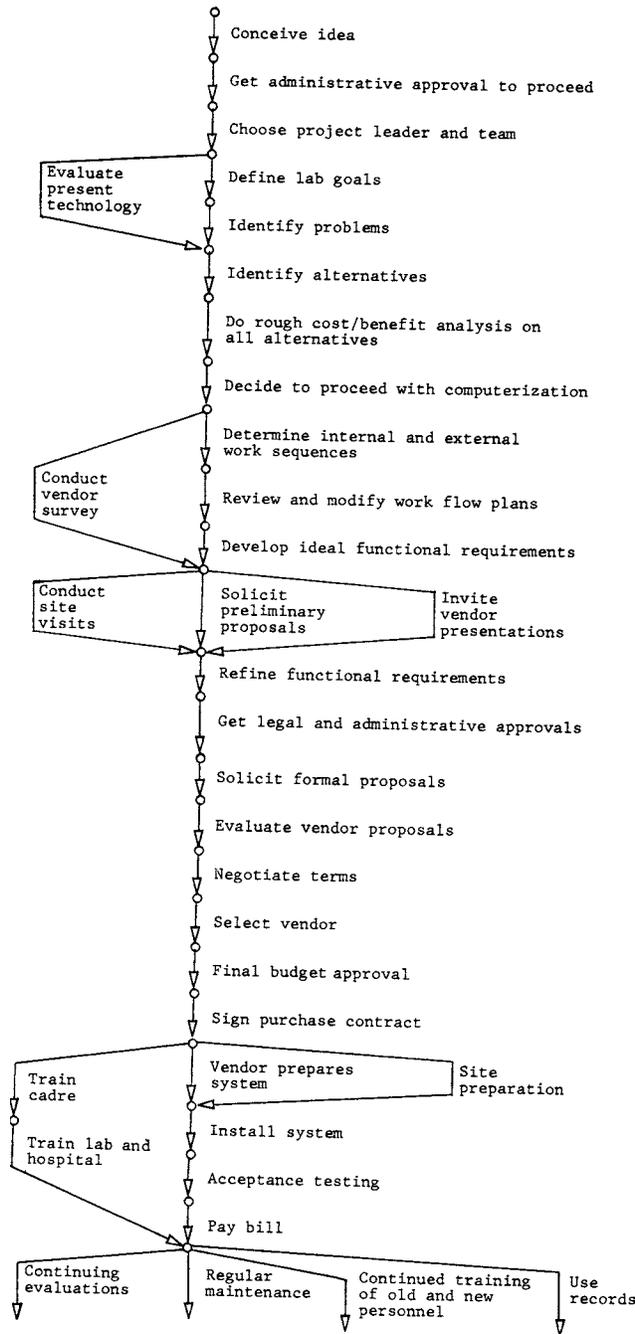


FIG. 1 Sequence of Steps in a Laboratory Automation Project

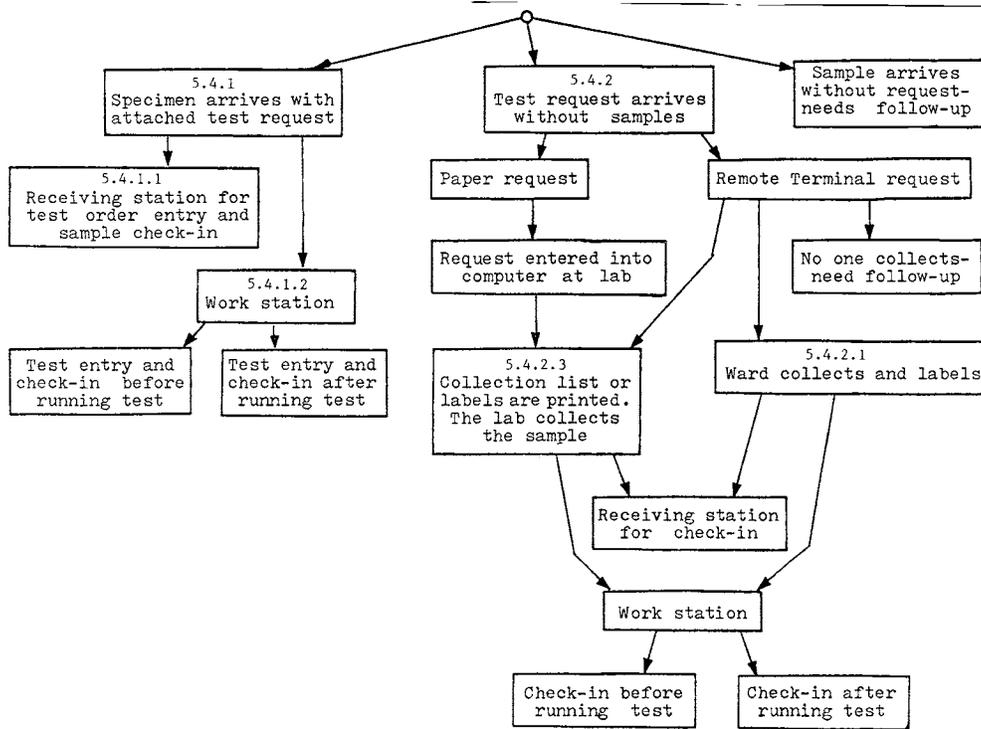


FIG. 2 Various Schemes for Sample Collection Check-In

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