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## Standard Guide for Selection and Acquisition of Commercially Available Computerized Systems<sup>1</sup>

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### 1. Scope

1.1 This guide covers a procedure for selecting and acquiring an existing commercially available system, through a single vendor, that includes all necessary hardware and software to perform a specified job. This guide describes a systematic procedure for selecting a computerized system, and for specifying the requirements that the system must fulfill. Installation and use of the system are discussed. Several important items of system documentation are described.

1.2 This guide addresses only those project phases necessary for the selection and acquisition of off-the-shelf computer systems. If a customized system is required, or if any portion of the system needs to be designed, refer to Guide E 622 for a more detailed procedure. For a clinical laboratory system, refer to Guides E 792 and E 1029. For computerization of existing equipment, refer to Guide E 1206.

1.3 In following this guide, users should comply with all local requirements such as labor contracts, organization policies, applicable laws and regulations, etc.

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 Systems<sup>2</sup>
- E 625 Guide for Training Users of Computerized Systems<sup>2</sup>
- E 627 Guide for Documenting Computerized Systems<sup>2</sup>
- E 792 Guide for Selection of a Clinical Laboratory Information Management System<sup>2</sup>
- E 919 Specification for Software Documentation for a Computerized System<sup>2</sup>
- E 1013 Terminology Relating to Computerized Systems<sup>2</sup>
- E 1029 Guide for Documentation of Clinical Laboratory Computer Systems<sup>2</sup>
- E 1206 Guide for Computerization of Existing Equipment<sup>2</sup>

#### 2.2 ANSI Standard:

### ANSI/IEEE 1063 User Documentation for Computer Software<sup>3</sup>

### 3. Project Phases

3.1 Not all of the project phases described in Guide E 622 are appropriate in selecting and acquiring a commercially available system, but it is appropriate to review them here. See Terminology E 1013 for terminology specific to this and referenced ASTM standards.

3.1.1 *Project definition*, which develops a brief statement of what is to be accomplished and why (Guide E 622, Section 6).

3.1.2 *Functional requirements*, in which all inputs to and outputs from the system, and transfer functions that produce the outputs from the inputs, are identified and described in detail (Guide E 622, Section 7).

3.1.3 *Functional design*, which produces an exact, concise description of the system that is independent of particular hardware and software. This includes all flows of information, timing diagrams, and state transition diagrams. The functional design often takes a graphical form. This step is not required under the scope of this guide (see 1.2).

3.1.4 *Implementation design*, in which hardware and software components are selected, and implementation, operation and maintenance procedures are developed. This step is not required under the scope of this guide (see 1.2).

3.1.5 *System assembly, installation, and testing*, in which components are acquired, built, programmed, assembled, installed, and placed in operation (Guides E 622, Section 10 and E 625).

3.1.6 *System evaluation*, in which the system is compared with its requirements to determine how well the requirements are met, to determine possibilities for growth and improvement, and to preserve the lessons of this project in preparation for the next one (Guide E 622, Section 11).

3.1.7 *System documentation*, which is prepared as the project proceeds. It is not a separate phase. An important product of each of the above six phases is documentation which is used in the following phases. (Guide E 627, Specification E 919, and Guide E 1029).

### 4. Significance and Use

4.1 This guide should be used by a purchaser to define the computerization project, establish functional requirements and proceed through the formal acquisition process. It is

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intended primarily for use in the selection and acquisition of off-the-shelf systems. This may include those systems described as turn-key systems provided that no specially designed components are used. It is not intended for use in the selection and acquisition of any systems where portions of the system are required to be designed or specially modified. Some customized systems will be excluded because they have been specially modified and are no longer off-the-shelf systems. The terms *off-the-shelf*, *customized*, and *turn-key* are defined in Terminology E 1013.

## 5. System Definition

5.1 System definition begins with project definition, that is, a description of the problem. From the project definition document, a detailed list of functional requirements and descriptions is generated. This list describes the ideal system for solving the problem described in the project definition, and is used as a basis for comparison of available systems. The next step is a market survey of potential system vendors. Vendor proposals are evaluated using the list of functional requirements and descriptions. A survey of users of similar systems can provide valuable information on the reliability and performance of both systems and vendors. If an organization is not experienced in the acquisition of similar systems, it may be prudent to retain an experienced outside consultant.

5.2 *Project Definition*—The primary purpose of this first step is to ensure that all concerned parties formulate a mutually agreeable definition of the project. In essence, the definition becomes a brief statement of the overall goals. Therefore, the project definition should include a general statement of all objectives and constraints. The basic information contained in the definition should come from several sources, including management and the eventual users of the system and its output. See Guide E 622, Section 8 for a detailed approach to the development of a project definition. The project definition includes: (1) present or anticipated problems that indicate that a computerized system would be advantageous, (2) present capabilities of the organization's equipment and personnel, (3) expected results or improvements from installing the computerized system, (4) how the system will fit into future plans for the organization, and (5) budgetary considerations. Consider the following in the order presented:

5.2.1 Define the nature of the problem, the reasons for considering a computerized system, and the need that the system will meet.

5.2.2 Describe the present situation. An important part of project definition is a realistic assessment of the current capabilities of the organization and of existing equipment, if any. Even with today's steady decline in the cost of computing power, the installation of a computerized system may represent a substantial investment of time and capital, and a future commitment to use of the system. The project definition must show that the current personnel, equipment, and other resources do not meet the stated needs. Consider the following points:

- 5.2.2.1 Present work load,
- 5.2.2.2 Human resources (number, experience, abilities),
- 5.2.2.3 Present cost of operation,
- 5.2.2.4 Space available,

5.2.2.5 Present experience with computer services, if any,  
5.2.2.6 Equipment now available, age, and degree of amortization, and

5.2.2.7 Applicable consensus standards and internal company standards.

5.2.3 Describe the results and improvements expected from installing the system. This section should include a list of *realistic* goals for the system. These may include increased capabilities, savings in time and money, or expected increases in manpower capability. Where possible, quantitative estimates of the goals should be supplied. The word *realistic* should be stressed here. A project that is justified on the basis of unrealistic goals can jeopardize chances for an unbiased appraisal of future proposals.

5.2.4 Describe the expansion and facility improvement plans for the organization and how this system relates to those plans. Few organizations are static in nature. This section should point out system capabilities that may be needed to allow expansion and modification to meet future needs. A system initially dedicated to one specific purpose may need to be flexible enough to accommodate improvements. Long-range plans may help reduce the onset of obsolescence by considering potential new system requirements and uses, system replacement, possible leasing effects, and advances in the state of the art.

5.2.5 Projects have been delayed and, in some cases, have failed because the need for a budget, data processing, or other review-committee approval was not considered. Determine what procedures must be followed to obtain necessary financial and technical approvals:

5.2.5.1 Relevant organization and statutory requirements,

5.2.5.2 The route that the budget request must follow through the organization,

5.2.5.3 Approvals required,

5.2.5.4 Documentation needed for each level of approval, and

5.2.5.5 Necessary lead time at each level.

5.3 *Functional Requirements*—This section assists users in writing descriptions of their needs which the system is to fill. Additional information is found in Guide E 622, Section 7.

5.3.1 *Present Operations*—Describe how the operations falling under the scope of this project are currently handled. The subsequent subtopics do not exhaust all possibilities, but suggest items that may need to be addressed. Treat them as a checklist. Appendix XI contains an example of a more detailed checklist for describing laboratory operations that are to be computerized.

5.3.1.1 Information on each item of equipment used.

5.3.1.2 Schedule of operation or use for the equipment.

5.3.1.3 Required inputs for each item of equipment.

5.3.1.4 Data collection procedures.

5.3.1.5 Calculations performed.

5.3.1.6 Reports generated.

5.3.1.7 Graphic displays, if any (for example, video monitors, printers, plotters).

5.3.2 *Desired Functions in the Computerized System*—The subsequent subtopics do not exhaust all possibilities, but suggest items that may need to be addressed. Treat them as a checklist. Appendix X2 contains an example of a more detailed checklist.



- 5.3.2.1 Equipment control requirements.
- 5.3.2.2 Data collecting methods.
- 5.3.2.3 Calculations required.
- 5.3.2.4 Data output and reports, including graphic displays if any.

5.3.2.5 Communications capabilities, including data interchange method and format.

5.3.2.6 Security, reliability, and safety.

5.3.3 *Potential for User Modification*—Computerized systems are sometimes selected because of the potential for future modifications. Such modifications may take the form of adding more operations or functions, or diversion to a completely different use. The plans described in the project definition (5.2.4) determine the nature and extent of likely future modifications. The software and documentation available for a computerized system are keys to the flexibility for modifications. The situation wherein one must depend on the vendor for modification may not be desirable, but may become the fact, if one does not include in the functional requirements adequate potential for user modification. Open systems and data import/export features meeting consensus standards should be considered if modifications are likely to include additional software packages and communications capabilities. The importance of the following items should be considered:

5.3.3.1 Completeness of documentation for hardware and software.

5.3.3.2 Availability and cost of hardware and software improvements.

5.3.3.3 Ease of user modification of hardware and software.

5.3.3.4 Source code availability.

5.3.3.5 Programming language availability.

5.3.3.6 Utility routine functionality.

5.3.3.7 File editor availability.

5.3.3.8 Operating system capabilities and restrictions.

5.3.3.9 File structure restrictions.

5.3.3.10 Terminal response time.

5.3.3.11 Software and hardware reliability.

5.3.3.12 Software changes concurrent with system operation.

5.3.3.13 Possible effects of future hardware or software modifications on warranties and maintenance agreements.

5.3.4 *Documentation*—Users may become frustrated when poorly documented or undocumented systems are purchased. Undocumented systems sometimes must be scrapped if the vendor discontinues support. Some software products are so difficult, inconsistent, awkward, restrictive, or generally complex that they cannot be used without substantial documentation and training. See Specification E 919 and Guide E 1029 for more details on documentation. It is recommended that conformance to Specification E 919, Guide E 1029, IEEE 1063, or other consensus standards be required for software documentation where possible and applicable. If an organization is not experienced with computerized systems and software, it may be prudent to retain an outside consultant.

5.4 *Obtain Market Information*—After developing the functional requirements of the desired system, the purchaser enters the market to obtain information. The market contains, among others, system vendors and system users.

5.4.1 *Vendor Survey*—Identify possible vendors for the required system. Develop a list of possible vendors from several sources, including conventions, conferences, expositions, libraries, trade journals, colleagues, users, published market surveys, and the classified section of the telephone directory. Contact each vendor identified to determine which ones are possible vendors for the required system.

5.4.1.1 Give each possible vendor a copy of the functional requirements of the system. Personal and telephone contacts are important at this point. One can obtain information in such contacts that cannot be obtained in writing.

5.4.1.2 Request that potential vendors suggest systems and give estimated prices. Vendors should be required to give user contacts for systems similar to the ones they propose. Vendors should also demonstrate systems identical to the ones proposed, and perform the functions or operations required by the user.

5.4.1.3 Compare the vendors' suggested systems and price estimates with the functional requirements and budget for the system. Ask for clarification if it is not clear how a proposal meets the functional requirements. If a written proposal guarantees less capability than verbally promised, have the verbal promises expressed in writing. Do not be hasty to select a system or a vendor.

5.4.2 *User Survey*—Identify users through personal knowledge, by colleagues, by the vendor proposing the system, and by other users. Try to make contact with people in the user organizations who work with the system, as well as those who specified it.

5.4.2.1 Request user information on the vendor's reputation and helpfulness, ease or difficulty of system installation, ease or difficulty of use, system reliability, vendor's ability and willingness to fix the system when it fails, and whether the system can fulfill the functional requirements. Before contacting any user, develop a list of questions for the user to answer. Remember that other users selected a system based on their own functional requirements; try to determine how closely the functional requirements are matched.

5.4.2.2 Information obtained from the users supplements the information obtained from the vendors. It helps to decide which vendor proposals really meet or exceed the functional requirements and budget, and to select the best proposal and price.

5.4.3 *Other Choices*—If the surveys fail to locate a system that meets the functional requirements and budget, or if the potential vendors cannot demonstrate a system, then it is necessary to consider one of the following choices:

5.4.3.1 Postpone or cancel the project,

5.4.3.2 Revise the functional requirements,

5.4.3.3 Revise the budget, or

5.4.3.4 Develop a custom system.

5.4.4 If the functional requirements are to be revised, be careful not to compromise the original objectives. If a custom system is contemplated, review the more detailed procedure of Guide E 622 and consider the potential for development of the system in-house versus external development.

## 6. System Procurement

6.1 System procurement deals with the selection of a system. Selection is comprised of three steps: (1) request for