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Standard Guide for Computerization of Existing Equipment¹

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1. Scope

1.1 This guide provides a procedure for the computerization of existing equipment. This guide describes a systematic process for the specification, selection, and acquisition of a computer system that is to be added to, or made a part of, some item of existing equipment. The phases of the process are discussed and the documentation that may be required at each stage is described.

1.2 This guide follows the outline of Guide E 622. It addresses only those things necessary for the computerization of existing equipment. If it is found that any portion of the system needs to be designed, use the more detailed procedure described in Guide E 622. In some cases Guide E 731 or Guide E 792 may be found more appropriate.

1.3 When 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 Systems²

E 625 Guide for Training Users of Computerized Systems²

E 627 Guide for Documenting Computerized Systems²

E 731 Guide for Selection and Acquisition of Commercially Available Computerized Systems²

E 792 Guide for Selection of a Clinical Laboratory Information Management System²

E 919 Specification for Software Documentation for a Computerized System²

E 1013 Terminology Relating to Computerized Systems²

E 1029 Guide for Documentation of Clinical Laboratory Computer Systems²

3. Terminology

3.1 *Definitions of Terms Specific to This Standard*—The following project phases are described in Guide E 622. Not all of these terms are appropriate in computerizing existing

equipment, but they are reviewed here as follows:

3.1.1 *functional design*—a design that 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. Functional design often takes a graphical form. This phase is not required under the scope of this guide, (see 4.1).

3.1.2 *functional requirements*—a requirement 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, (see Section 7 of Guide E 622).

3.1.3 *implementation design*—a design in which hardware and software components are selected, and implementation, operation, and maintenance procedures are developed. This phase is not required under the scope of this guide, (see 4.1).

3.1.4 *project definition*—a brief statement of what is to be accomplished and why, (see Section 6 of Guide E 622).

3.1.5 *system assembly, installation, and testing*, components that are acquired, built, programmed, assembled, installed, and placed in operation, (see Section 10 of Guide E 622, Guide E 625).

3.1.6 *system documentation*—documentation that is prepared as the project proceeds. It is not a separate phase. An important product of each of the phases in this section is documentation that is used in the phases described in this guide, (see Guide E 627, Specification E 919, and Guide E 1029).

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

4. Significance and Use

4.1 This guide is applicable to the acquisition of a computer that may be connected to existing equipment by the user, and may include the selection and acquisition of options to be supplied with the computer. If any special designs are necessary in this process, the use of Guide E 622 is recommended.

4.2 One possible application of this guide is the addition of a complete microcomputer system to the existing equipment. Many such systems are available with components or accessories that may be used to adapt the systems for various applications. Included in this general class of computers are the so-called “personal computers” or PC’s. In planning a project, the possibilities of using PC’s should not be overlooked.

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² *Annual Book of ASTM Standards*, Vol 14.01.

 E 1206

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 characterizes systems that solve the problem described in the project definition, and is used as a basis for comparison of available systems.

5.2 Project Definition:

5.2.1 The primary purpose of this first step is to formulate a mutually agreeable definition of the project among all interested parties. In essence, the definition becomes a general statement of the overall goals, objectives, and constraints. The basic information contained in the definition should come from all pertinent sources, including management and the users of the system and its output, (see Section 6 of Guide E 622). All parties who will be affected by the outcome of the project must agree to the project definition.

5.2.2 The project definition includes: (1) present or anticipated problems that indicate that computerization would be advantageous, (2) present capabilities of the equipment and personnel, (3) expected results or improvements from adding the computer, (4) how the modified equipment will fit into future plans for the organization, and (5) budgetary considerations. These will be considered in order as follows:

5.2.2.1 Define the nature of the problem, the reasons for considering computerization, and the needs that the modified equipment will meet.

5.2.2.2 Describe the present situation. An important part of project definition is a realistic assessment of the current capabilities of the organization and of the existing equipment. Even with today's steady decline in the cost of computing power, the installation of a computer may represent a substantial investment of time and money. The project definition must show that the unmodified equipment cannot meet the stated needs. The following points should be considered:

- (1) present work load,
- (2) human resources (number, experience, abilities),
- (3) present cost of operation,
- (4) space available,
- (5) present experience with computerized equipment, if any,
- (6) equipment to be computerized, (age, and degree of amortization), and
- (7) applicable company and consensus standards.

5.2.2.3 Describe the results and improvements expected from installing a computer. Include a list of realistic goals for the modified equipment. These may include increased capabilities, savings in time and money, or expected increases in manpower capability. 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. Where possible the expectations should be defined in measurable terms to facilitate an objective evaluation when the project is completed (see 8.3).

5.2.2.4 Describe the expansion and facility improvement plans for the organization and how this modified equipment will fit into these plans. Few organizations are static in nature. Point out capabilities that may be needed to allow for future needs. A piece of equipment initially dedicated to one specific purpose may need to be flexible enough to be

adapted to other tasks. Long-range plans may help reduce the onset of obsolescence by considering potential new requirements and uses, replacement, possible leasing effects, and advances in the state of the art. Consideration should be given to referencing the appropriate consensus standards for interfaces and data exchange if future plans make it likely that the equipment will be connected to some other system or become a part of a network.

5.2.2.5 Determine what procedures must be followed to obtain necessary financial and technical approvals, such as; relevant organization and statutory requirements, route that the budget request must follow through the organization, approvals required, documentation needed for each level of approval, and necessary lead time at each level. Projects have been delayed and even have failed because people forgot to consider the need for budget, data processing, or other review committee approval.

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

5.3.1 *Present Operations*—Describe how the operations falling under the scope of this project are currently handled. The subsequent subtopics suggest items that may need to be addressed. Treat them as a checklist. These items are not intended to be all inclusive. Appendix X1 contains an example of a more detailed checklist for describing a laboratory instrument that is to be computerized. Some projects may require additional items, and some items listed as follows may be inappropriate.

5.3.1.1 Information on the operation performed by the equipment,

5.3.1.2 Schedule of operation of the equipment,

5.3.1.3 Required inputs for the operation of the equipment,

5.3.1.4 Data collection procedures, if any,

5.3.1.5 Calculations performed, if any,

5.3.1.6 Reports generated, if any,

5.3.1.7 Graphical presentations, if any, and

5.3.1.8 Overall precision and maximum bias obtained or required.

5.3.2 *Desired Functions in the Computerized Equipment*—The following subtopics suggest items that may need to be addressed. Treat them as a checklist. Appendix X2 contains an example of a more detailed checklist. The following should be modified to reflect the nature of the equipment to be computerized.

5.3.2.1 Equipment control requirements,

5.3.2.2 Data collecting methods, if necessary,

5.3.2.3 Calculations required, if necessary,

5.3.2.4 Data output and reports, including graphics, if necessary,

5.3.2.5 Communications capabilities or requirements, and

5.3.2.6 Security, reliability, and safety.

5.3.3 *Potential for System Modification by the User*—Computerization is sometimes undertaken in order to increase the flexibility of equipment. The situation wherein the user must depend on the vendor to adjust the system for