

**Designation: E 622 – 94 (Reapproved 1999)**AMERICAN SOCIETY FOR TESTING AND MATERIALS
100 Barr Harbor Dr., West Conshohocken, PA 19428
Reprinted from the Annual Book of ASTM Standards. Copyright ASTM**Standard Guide for
Developing Computerized Systems¹**

This standard is issued under the fixed designation E 622; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide covers a process for computerization projects that require design and implementation of new hardware or software. It describes a process for developing computerized systems to meet requirements of both system users and regulatory authorities. This guide covers procedures, considerations, and required documents.

1.2 *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 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
 - E 1206 Guide for Computerization of Existing Equipment²
 - E 1283 Guide for Procurement of Computer-Integrated Manufacturing Systems²
 - E 1340 Guide for Rapid Prototyping of Computerized Systems²
- 2.2 IEEE Standards:**
- 100 Standard Dictionary of Electrical and Electronics Terms³
 - 610 Standard Glossaries of Computer-Related Terminology³

730.1 Standard for Software Quality Assurance Plans³730.2 Guide for Software Quality Assurance Plans³828 Standard for Software Configuration Management Plans³829 Standard for Software Test Documentation³830 Guide to Software Requirements Specifications³982.1 Standard Dictionary of Measures to Produce Reliable Software³982.2 Guide for the Use of Dictionary of Measures to Produce Reliable Software³990 Recommended Practice for Ada as a Program Design Language³1002 Standard Taxonomy for Software Engineering Standards³1008 Standard for Software Unit Testing³1012 Standard for Software Verification and Validation Plans³1016 Recommended Practice for Software Design Descriptions³1028 Standard for Software Reviews and Audits³1042 Guide to Software Configuration Management³1058.1 Standard for Software Project Management Plans³1063 Standard for Software User Documentation³1074 Standard for Developing Software Life Cycle Processes³1228 Standard for Software Safety Plans³**2.3 ANSI Standard:**X3.172 American National Standard Dictionary for Information Systems⁴**2.4 Federal Information Processing Standards:**

FIPS 183, Integration Definition for Function Modeling (IDEFO)

FIPS 184, Integration Definition for Information Modeling (IDEFIX)

3. Terminology

3.1 A distinction is made in this guide between system developers and system users. System developers are people who design and build the system. System users are people who directly interact with the system by making inputs and receiving outputs, or who supply data to or use results from the system.

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This guide incorporates the following ASTM guides in Vol 14.01: E 623, E 624, E 626, E 730, and E 1113. These guides are currently being balloted for withdrawal.

² Annual Book of ASTM Standards, Vol 14.01.

³ Available from IEEE, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331.

⁴ Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.



3.2 The following terms describe phases of a computerization project as well as documents produced in each phase.

3.3 *project definition, n*—(1) a brief statement of what is to be accomplished in a computerization project and why. (2) a written agreement containing a project definition (definition 1). (3) a phase at the beginning of a computerization project in which the project definition (definition 1) is prepared.

3.4 *functional requirements, n*—(1) detailed descriptions of system inputs, system outputs, and transfer functions that are needed to produce outputs from inputs. (2) a document containing functional requirements (definition 1). (3) a phase in a computerization project in which functional requirements (definition 1) are identified, described, and documented.

3.5 *functional design, n*—(1) a detailed description of a system that includes all flows of information, timing diagrams, and state transition diagrams, and that is independent of particular hardware and software. (2) a document containing a functional design (definition 1). (3) a phase in a computerization project in which a functional design (definition 1) is prepared and documented.

3.6 *implementation design, n*—(1) a complete detailed description of a computerized system that specifies all hardware and software components as well as implementation, training, operation, and maintenance procedures. (2) the collection of documents containing an implementation design (definition 1). (3) a phase in a computerization project in which an implementation design (definition 1) is prepared and documented.

3.7 *system assembly, n*—a phase in a computerization project in which system components are built, acquired, programmed, and tested, and the system is assembled, integrated, installed, placed in operation, and accepted (also called “system implementation”).

3.8 *system evaluation, n*—(1) comparison of a working system with its requirements to determine how well the requirements are met, to determine possibilities for growth and improvement, and to preserve the lessons of a computerization project in preparation for the next one. (2) a report of a system evaluation (definition 1). (3) a phase in a computerization project in which a system evaluation (definition 1) is conducted and documented.

3.9 *system documentation, n*—the accumulated documents relating to a computerization project and computerized system, which are prepared as the project proceeds.

Discussion—System documentation is not a separate phase of a computerization project. An important product of each of the project phases is documentation.

3.10 Other computer-related technical terms in this guide are defined in Terminology E 1013, IEEE 100, IEEE 610 series, and ANSI X3.172.

4. Significance and Use

4.1 Significance:

4.1.1 Implementation of computer systems is complex and should be accomplished with a systematic and scientific approach. Many projects that are attempted without a good management plan experience serious problems. Some fail. Others run over budget or take longer than expected. False starts may waste effort and require work to be scrapped. Extensive reworking may be required. Some projects never

achieve the desired objectives of the required level of reliability or performance.

4.1.2 A project requires commitment of resources, which are used with the expectation that certain benefits will be achieved. The feasibility of a project can be characterized by the relationship of costs and benefits (commonly described as the cost-benefit ratio). Resources put into a project include capital and operating funds, time, effort, technical knowledge, and management. The results of a project may include a delivered product, a running system, or a changed environment. The accompanying benefits may include reduced costs, improved quality, greater quantity, or less loss.

4.1.3 Computerization often causes major changes in the operation of the organization served by the computerized system. The system usually changes the way information flows and may cause profound changes in its environment. The full effects of such changes are difficult to predict, and the associated benefits may be difficult to measure. Some benefits of computerization cannot be precisely translated into the familiar units in which costs are expressed.

4.1.4 The necessary technical knowledge for computerization may not reside within the organization that is undertaking the project. Organizations that are technically strong in fields other than computerization should be especially alert for this situation. The necessary technical expertise may have to be developed inside the organization, or hired or contracted from outside (see Appendix X1).

4.1.5 Individuals requesting a system may have no relevant prior experience. They may have had experiences that can lead to wrong ideas about what to expect from a computerized system.

4.1.6 Computerization involves hardware and software. Computer hardware technology has been changing very rapidly and the changes are most apparent in what things cost. The cost of computing power has been reduced by about one third each year since 1980. The rapid decrease in hardware cost means that projects can quickly change from not feasible to feasible. It also means that strategies and approaches for computerization can be quickly outdated.

4.1.7 Software development is very labor-intensive. The cost of custom-developed software increases at least as fast as inflation. Many times the level of satisfaction with custom-developed software is low. Software appears to be infinitely malleable, but producing high-quality software requires experience, skill, and effort. Commercially available software packages are becoming more attractive as complements or alternatives to custom-developed software.

4.1.8 It may be best to gain experience with computerization in small projects that have limited outcomes and limited risks. An organization may wish to undertake some exploratory projects whose chief outcome is knowledge and experience before considering a large project with substantial risk. Be aware, however, that experience in small projects cannot be linearly extrapolated to large projects. Large projects have dimensions that are usually ignored in smaller ones. Large projects require different kinds of management tools and skills, and they involve risks that are caused by the very size of large project teams.



4.2 Use:

4.2.1 This guide focuses on the needs of people who use computerized systems. A successful computerization project is one that meets the expectations and satisfies the needs of system users. System developers and system users need to be involved throughout the computerization project.

4.2.2 This guide applies when some part of the project requires development of new software or hardware. It is appropriate for those systems that will be built from scratch, as well as those configured by integrating various commercial modules. When the project goals can be accomplished by selection and procurement of a commercially available system, to be delivered as a complete working unit, use Guide E 731. To automate existing equipment, use Guide E 1206. Clinical laboratory systems are specifically addressed in Guides E 792 and E 1029. Procurement of computer-integrated manufacturing systems is covered in E1283.

4.2.3 Guide E 1340 describes a rapid prototyping approach that is appropriate for some computerization projects. This guide should be used instead of Guide E 1340 for projects that meet one or more of the following criteria.

4.2.3.1 The system is complex or the implementation is lengthy. This guide (E 622) should be used when the prototyping loop would take too long.

4.2.3.2 The project requirements are well understood and can be written accurately and completely at the start of the project. Rapid prototyping is unnecessary when the system can be correctly specified at the start.

4.2.3.3 The resulting system involves significant safety or economic concerns. Use this guide when operation of partially implemented systems during prototyping cycles would be dangerous or where failures could cause expensive losses.

4.2.4 A large project may need to be divided into smaller subprojects in order to be accomplished. This guide can be used for a large project, for smaller subprojects, or for both. A large project produces an integrated product from its subprojects.

4.2.5 Conventional system life cycles include system development (the phases and activities covered by this guide) as well as operation, maintenance, and retirement. This guide concentrates on system development because decisions made in system development control the range of possibilities for later phases of a system's life. Maintenance, operation, and retirement are discussed in Section 11 and in the appendixes, but they are not covered to the same level of detail as system development.

4.2.6 This guide may also be useful as a tool for training members of a project team. It is written for people with little or no experience in successful computerization projects. Experienced readers may find the checklists in the appendixes most helpful.

5. Overview of System Development

5.1 The process of developing a computerized system can be accomplished in six phases. The phases are diagrammed in Fig. 1 and are described in the following sections.

5.1.1 *Project Definition*, which develops a brief statement of what is to be accomplished and why (Section 6).

5.1.2 *Functional Requirements*, in which all inputs to and

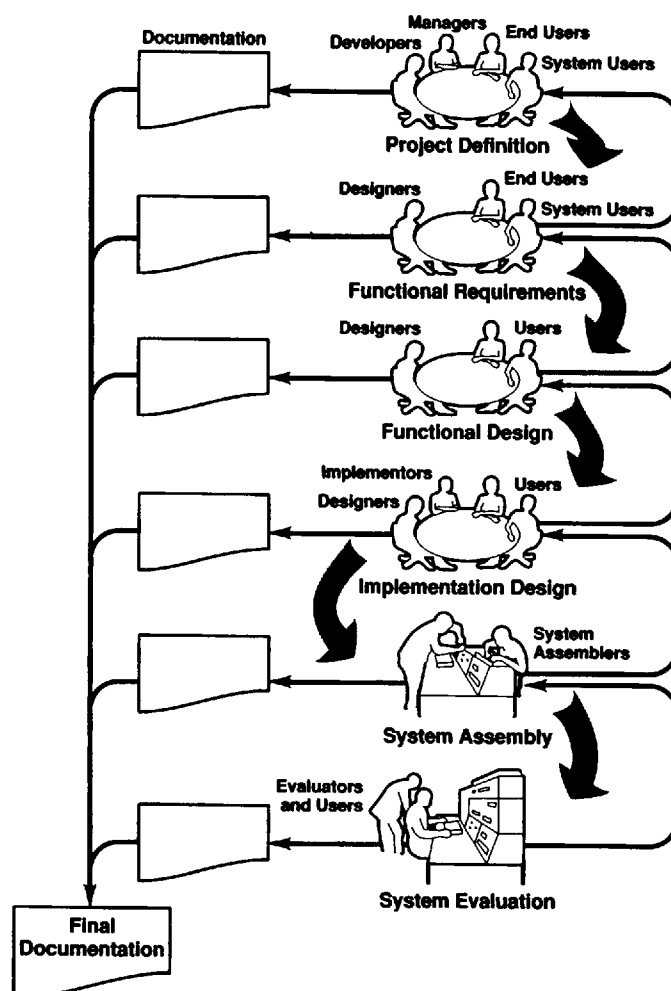


FIG. 1 Conventional Development of a Computerized System

outputs from the system are described in detail. In this phase, transfer functions that are needed to produce the outputs from the inputs are also identified and described (Section 7).

5.1.3 *Functional Design*, which produces detailed descriptions of the system that are independent of particular hardware and software. This includes all flows of information, timing diagrams, and state transition diagrams (Section 8).

5.1.4 *Implementation Design*, in which hardware and software components are selected. Implementation, training, operation, and maintenance procedures are developed in this phase (Section 9).

5.1.5 *System Assembly* (also called "system implementation"), in which system components are built, acquired, programmed, and tested, and the system is assembled, integrated, installed, placed in operation, and accepted (Section 10).

5.1.6 *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 (Section 11).

5.2 System documentation is prepared as the project proceeds. It is not a separate phase. An important product of each of the six phases described in 5.1.1-5.1.6 is documentation that is used in the following phases (see Guide E 627, Specification E 919, Guide E 1029, and IEEE 1063).



5.3 The recommended process is diagrammed in Fig. 1. Although the figure shows that the process is executed as separate phases, many iterations may be required between system designers, implementers, and users during the computerization project. Near the start of the project, system evaluation criteria should be established for intermediate and final implementation stages. All steps should be documented completely as they occur.

5.4 The first three phases produce functional statements that are independent of particular hardware and software. They tell what the system should do and how it should do it. Then the subsequent three phases produce a system that meets the requirements of the organization and the people who will use it. System development problems are often caused by making decisions too early about how to build the system. It is not appropriate to select hardware or software before the implementation design phase.

5.5 System design is a process of translating statements about what a system must do (functional requirements) into detailed engineering statements of how the system will work, within constraints established in the project definition. Functional requirements in system users' terminology are translated into engineering designs and plans. This guide describes two design phases that are adequate for most systems: functional design, which is independent of particular hardware and software, and implementation design, in which hardware and software decisions are taken. Complex systems require more than two design phases. For example, a very large-scale, complex, system development project may involve organizational design, system user job design and task modeling, system architecture design, software architecture design, system user interface design, data modeling and database design, software pseudo-coding, electrical and mechanical interface design, and electrical and mechanical component design.

5.6 It is necessary to assure that the developing system remains true to its original goals and requirements. If this is found to be impossible, then the goals and objectives must be redefined, with the concurrence of the persons who are empowered to authorize the project. As project phases proceed, work products are tested for correctness and checked for consistency with the products of earlier phases and with one another. In smaller projects, this may be done by the project manager. In larger system development projects, which are more difficult to manage, these activities should be assigned to a separate quality assurance function (see IEEE 730.1 and 730.2).

5.7 While quality assurance activities are integrated throughout all project phases, system validation tasks are concentrated in the functional requirements and system assembly phases (see Appendix X2). System validation assures users and purchasers that the system works correctly and can be trusted to produce correct results. For systems that are to be used in settings under legal and regulatory guidelines, validation provides a recheck of system design and capability. This recheck assures that the system has proper controls, adds credibility to its results, and can generally satisfy statutory requirements and field guidelines to protect public and environmental health and safety.

5.8 System documentation (see Guide E 627) should begin with the initial project definition and extend through system design, implementation, evaluation, and operation. Documentation for the various stages of development should be produced for different levels of interest. These interests have been broadly identified as management, system designers, vendors, plant engineering, implementers, operators, data users, and maintenance. It is recognized that each organization is structured to perform its own particular functions. In certain situations, some of the interests identified above may be combined, may be under other titles, or may not exist. It is important, however, that none of the items required to document the system be overlooked.

6. Project Definition

6.1 General Considerations:

6.1.1 A project definition is a brief statement of what is to be accomplished in a computerization project and why. It is also a phase at the beginning of the project, an agreement negotiated during this phase, and a document describing progress and results of this phase. The concepts are not always distinct from one another. This section will explicitly mention the phase, agreement, or document only where it is important to distinguish.

6.1.2 Project definition is the essential first phase in computerization. It defines the scopes of both the computerized system that is to be developed and the project to develop that system.

6.1.3 The primary purpose of the project definition phase is to permit all interested parties to formulate a mutually agreeable definition of the project.

6.1.4 Execution of this phase is very much constrained by the structure of the particular organization and must be carried out in accordance with the established practices of that organization. It is emphasized, however, that a broad participation in this phase greatly facilitates success of the project.

6.1.5 The project definition phase includes four closely related activities: (1) determining feasibility of the project, (2) deciding whether to proceed with computerization, (3) negotiating the project definition agreement, and (4) writing the project definition document.

6.2 Determining Project Feasibility:

6.2.1 Project feasibility involves many factors including: (1) present or anticipated problems or opportunities that indicate a computerized system would be advantageous, (2) present capabilities of the organization's equipment and personnel, (3) expected changes in the present situation that will occur irrespective of computerization, (4) expected results or improvements from installing the computerized system, (5) how the system will fit into future plans for the organization, and (6) budgetary considerations.

6.2.2 Define the nature of the problem, the reasons for considering a computerized system, and the needs that the system will meet. Identify the real problem that the project is intended to solve, and the underlying assumptions that support the problem and the project.

6.2.3 Describe the present situation in the environment where the proposed system would exist. An important part of project definition is a realistic assessment of the current



capabilities of the organization and of existing equipment, if any. The installation of a computerized system may represent substantial investment of time and capital, as well as a future commitment to use the system. The project definition must show that the current personnel, equipment, and other resources do not by themselves meet the stated needs. The following points should be considered:

- 6.2.3.1 Present work load,
- 6.2.3.2 Human resources—number, experience, abilities,
- 6.2.3.3 Present cost of operation,
- 6.2.3.4 Space available,
- 6.2.3.5 Equipment now available, age, and degree of amortization, and
- 6.2.3.6 Present experience with computer services, if any.
- 6.2.4 Describe how the present situation is expected to change, whether or not a computerized system is installed. Consider how each of the items listed in 6.2.3 will change.
- 6.2.5 Describe the results and improvements expected from installing the system. Prepare a list of realistic goals for the system. These may include increased capabilities, savings in time and money, or increases in personnel capability. The word “realistic” is stressed. A project that is justified on the basis of unrealistic goals can jeopardize chances for an unbiased appraisal of future proposals.
- 6.2.6 Describe the expansion and facility improvement plans for the organization and how this system will fit. Few organizations are static in nature. Identify 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 effects of leasing, and advances in the state of the art.
- 6.2.7 Determine what procedures must be followed to obtain necessary administrative, financial, and technical approvals to proceed with the project. Projects have been delayed and even have failed because people forgot to consider the need for budget, data processing, or other review committee approval. Consider the following:
 - 6.2.7.1 Relevant organization and statutory requirements,
 - 6.2.7.2 The route that the budget request must follow through the organization,
 - 6.2.7.3 Approvals required,
 - 6.2.7.4 Documentation needed for each level of approval, and
 - 6.2.7.5 Necessary lead time at each level.
- 6.3 *Deciding Whether to Computerize:*
 - 6.3.1 In deciding whether to proceed, consider the following different alternatives and approaches to computerization:
 - 6.3.1.1 Improved management and coordination of existing manual systems,
 - 6.3.1.2 Improved manual system,
 - 6.3.1.3 Additional people or equipment,
 - 6.3.1.4 Limited computerization using microcomputers,
 - 6.3.1.5 Procurement of a commercially available system (see Guide E 731),

6.3.1.6 Development of a custom system with an outside contractor, and

6.3.1.7 Development of a custom system with internal resources.

6.3.2 Estimate total costs and total benefits of the different approaches and alternatives. Consider costs of all of the resources required and the value of all of the benefits to be achieved. Costs for purchased components can usually be estimated to within $\pm 25\%$ in the project definition phase. Developed components are much more difficult to estimate accurately.

6.3.3 This is the only time in the project definition phase when it is appropriate to consider specific hardware and software for a proposed computerized system. It is only appropriate here insofar as necessary to estimate costs and benefits. Do not start to develop a functional specification at this stage, and do not become prematurely committed to a particular system configuration or supplier.

6.3.4 Consider the risks of different approaches and alternatives. Calculate the ratio of benefits to costs for different approaches and determine what value of the ratio is acceptable. Consider costs and benefits that cannot be quantified, and how to evaluate them.

6.3.5 Decide whether to proceed with the project.

6.4 *Negotiating the Agreement:*

6.4.1 A project definition agreement must be accepted by all parties who will be affected by the system and the project. The first step in negotiating an agreement is to identify all of the parties. They include administrative management, financial management, technical management, people who will maintain the system, people who will use it, maintenance supervisors, operating supervisors, and people who will use products or results produced by the system.

6.4.2 It may be necessary to revise the project definition agreement several times in order to satisfy conflicting desires of all parties. Do not decide details of how the computerized system will work in the project definition phase. Early decisions constrain later ones. Details must be purposefully postponed until the full scope of the project is understood.

6.4.3 The project definition agreement must cover the following issues:

- 6.4.3.1 What is to be accomplished in the project.
- 6.4.3.2 What is the real problem to be solved.
- 6.4.3.3 Why the project is to be accomplished.
- 6.4.3.4 Specific outcomes expected from the project, including the major functions of the required system.
- 6.4.3.5 Measurable benefits associated with the outcomes of 6.4.3.4.
- 6.4.3.6 Estimated costs of the project.
- 6.4.3.7 Justification for the project, that is, relationship of benefits and costs.
- 6.4.3.8 Important assumptions that support the project and the problem that it is expected to solve.
- 6.4.3.9 Important constraints on how the project can be done.
- 6.4.3.10 Bounds of the project.
- 6.4.3.11 Risks and their causes.
- 6.4.3.12 Timing of the phases of the project.

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6.4.3.13 Identification by name and position of all parties who agree to the project definition.

6.5 The Project Definition Document:

6.5.1 The project definition document is produced in the project definition phase of the project. It contains the information gathered in determining whether the project is feasible, formal project requests and approvals, and the project definition agreement.

6.5.2 It is important to have a written project definition agreement and to renegotiate any changes to it. All parties to the original project definition agreement should agree to changes. Computerization is never easy; it can become impossible when the project targets move in ways that have not been predicted.

6.5.3 If the project definition agreement exceeds one page, prepare a one-page summary of what is to be accomplished and why. This serves as an introduction to the system and the project to develop it.

6.5.4 If a large project is divided into smaller subprojects, write a project definition for each part.

6.5.5 The form of the project definition document may be determined by organizational requirements. For example, part or all of the document may become part of the project request or approval. If multiple projects are competing for resources, the project definition document may be required to conform to a uniform consistent format in order to simplify comparison and evaluation.

7. Functional Requirements

7.1 General Considerations:

7.1.1 Functional requirements are detailed descriptions of system inputs, system outputs, and transfer functions that are needed to produce outputs from inputs. They are collected in a document that is also called functional requirements, which is prepared in a phase in a computerization project called functional requirements. The concepts are closely related to one another. This section focuses on the functional requirements document and the information that should be in it. The phase or document will be explicitly mentioned where it is useful to distinguish between them.

7.1.2 Functional requirements describe what a system is required to do in sufficient detail that the system developers can use them to prepare a functional design or to select a commercially available system. The functional requirements documents contain an overview of the project and its objectives, as well as financial, time, and personnel resource constraints. They describe the required control functions, sources and characteristics of the input data, data manipulation and output requirements, technical requirements, human-computer interactions, and basis for system evaluation.

7.1.3 Information for the functional requirements document is supplied by managers, supervisors, people who will use the computerized system, users of results produced by the system, and software and hardware specialists who will maintain the system. The documents are written in the system users' terminology.

7.1.4 Statements describing how the functional requirements are to be met must be postponed until the functional design phase of the project. The functional requirements

should not specify any particular hardware or software. Those choices are made in the implementation design phase.

7.1.5 Functional requirements are organized in a top-down fashion. General requirements for a computerized system are established first, then more detailed requirements are established from the general requirements.

7.1.6 A product of the functional requirements phase of a computerization project is one or more documents that describe the functional requirements of the system. In large projects involving many subsystems, separate documents describing the functional requirements of each logical entity may be most appropriate. If this is the case, a more general functional requirements document is also required to describe the overall project and to show how the subsystems fit together.

7.1.7 The functional requirements documents are used by system developers to prepare a functional design (see Section 8) or to select a commercially available system (see Guide E 731). When functional requirements are released from the user organization to an outside supplier, it may be necessary to remove certain information. For example, financial and budget data is not normally released to potential bidders. If the functional requirements contain proprietary information, outside suppliers may be required to sign nondisclosure agreements before receiving them.

7.1.8 The level of detail in this section is appropriate for computerization of a single process, procedure, test, experiment, function, or operation in an existing facility. It is suitable for both real-time systems and for systems that process data in other than real time. For new facilities, multiple-use systems, or complex systems as described in 7.1.6, the outline in Appendix X3 should be retained and the details modified to meet the needs of the project. In any case, enough detail should be provided for those who will use the functional requirements document to produce a functional design. Consider the nature of the project and the levels of expertise and experience of the individuals involved.

7.1.9 Paragraphs 7.2 and 7.3 can be used by experienced system developers as a checklist, or by less experienced people as a detailed guide. The major headings and subheadings in the following sections may be used as an outline for the functional requirements documents (see Appendix X3).

7.2 Overview of the System—Information in this section describes the context and constraints of the system.

7.2.1 Objective—State the objective of the project (or portion of the total project) covered by this functional requirements document. This must be consistent with the project definition.

7.2.2 Specific Goals and Expected Benefits—Provide a detailed list of objectives and expected benefits of computerization. Assign priorities to each item on a scale from 1 (lowest) to 10 (highest). Be specific so that this list can be used for subsequent evaluation.

7.2.3 Nature of the Project—Provide a description of the process, procedure, test, experiment, function, or operation to be computerized. Provide background references. Describe any alternate methods that may be used to produce the desired result.



7.2.3.1 Describe each piece of equipment to be computerized in the project. List the name, model, and manufacturer. To the extent that the system must deal with data acquisition and reduction or equipment control, provide the following:

- (1) Description of the equipment functions.
- (2) List of the transducers, sensors, indicators, controls, activators, and actuators (see also 7.3.1 and following).
- (3) Communication standards, formats, and protocols that are used by the equipment.
- (4) Drawings or sketches that show the physical locations of the equipment and other components of the system.

7.2.3.2 Describe operating conditions and procedures including sequence, timing, and scheduling of operations (see Appendix X4 and Appendix X5).

7.2.3.3 Describe changes and enhancements that the computerized system is to make in the operating conditions and procedures described in 7.2.3.2.

7.2.4 Nontechnical Considerations:

7.2.4.1 *Financial Considerations*—Provide the following information:

- (1) Guidelines for investment in new equipment.
- (2) Guidelines for initial noncapital investment (cite organizational directives for equipment rental or lease).
- (3) Guidelines for continuing maintenance, supplies, operating costs, etc.
- (4) Depreciation of available equipment.
- (5) Budget for future expansion of software and hardware.
- (6) Budget for training personnel.
- (7) Budget for start-up costs including installation, facilities modification, etc.
- (8) Required rate of return on investment.
- (9) Overhead.
- (10) Other financial constraints.

7.2.4.2 *Time and Effort for System Development*—Provide the following information:

- (1) Date by which the system must be operational.
- (2) Desired timetable for completion of important milestones in the project.
- (3) Personnel resources that can be made available for each part of the project (in-house, consultants, etc.). Be specific about skills.

7.2.4.3 *Operational Support*—Describe the personnel who will be available for continuing operation of the system, including operators, engineers, technicians, programmers, etc.

7.2.5 *Future Requirements*—Provide the following projections for future expansion or future uses of the system:

- 7.2.5.1 Additional control functions.
- 7.2.5.2 Additional data processing.
- 7.2.5.3 Additional equipment to be interfaced.
- 7.2.5.4 Anticipated future use of the system.
- 7.2.5.5 Other future alternatives.

7.3 *Functional Requirements of the System*—This section describes the system to be implemented.

7.3.1 *Desired Control Functions*:

7.3.1.1 *Nature of Control Functions*—Describe the following:

- (1) All control functions, such as instructions to the operator, management or auditing checks, on/off control of alarms, set

points for analog controllers, direct digital controls, digital outputs to controllers, etc.

- (2) Parameters required for each run or series of runs.

(3) Control functions that are based on analysis of inputs. Some control may need to be completed in real-time. Other corrections to parameters may be implemented between runs. Some control decisions are made within the system, others by intervention from outside the system. For those controls that are made outside the system, identify the source (another system, an operator, etc.).

7.3.1.2 *Electrical and Mechanical Requirements*, if appropriate. Describe the following (if they are requirements that the system must meet and not values to be determined by the system design):

- (1) Current and voltage levels required for each control function.

- (2) Electrical precision and accuracy required.

- (3) Mechanical precision and accuracy required.

7.3.1.3 *Critical Timing Requirements for Performing Control Functions*—Describe the following:

- (1) External events with which control functions must be synchronized.

- (2) Duration of imposed control functions.

- (3) Maximum and minimum repetition rates for control functions.

- (4) Time scales for control, including minimum and maximum duration of run times, duration of a typical run, and intervals between runs.

7.3.2 *Sources and Characteristics of Input Data* (see Appendix X6)—Describe the following:

7.3.2.1 System inputs that originate as signals from transducers, including the source, nature, and significant features of each input signal.

7.3.2.2 Data that enter the system in electronic form from other equipment.

7.3.2.3 Operator inputs.

7.3.2.4 Other inputs.

7.3.2.5 Data for which the method of input is to be specified as part of the system design.

7.3.2.6 Maximum and minimum values, significant digits, accuracy required, and units for the numeric data.

7.3.2.7 Known or anticipated relationships between data inputs.

7.3.2.8 Minimum and maximum number of discrete data values to be obtained and kept.

7.3.3 *Data Manipulation and Output*:

7.3.3.1 *Transfer Functions and Data Manipulation*—Provide the following information:

- (1) What the initial raw data represents.

- (2) Final forms of results to which the raw data will be transformed. (Maxima or minima, slopes, inflection points, etc.)

- (3) Length of time that raw, intermediate, final and summary data must remain available to the operator, supervisor, auditor, or other system users.

- (4) Stepwise procedure for converting the raw data to final form. Indicate what information must be supplied in addition to the raw measurements.

(5) Accuracy. State how close the results must be to the “true” value, in relative or absolute terms. Give the accuracy needed and the accuracy desired.

(6) Precision. State the desired and required reproducibility of results. Indicate what deviations are acceptable among repeated measurements.

7.3.3.2 Data Output Requirements—Provide the following information:

(1) Nature of report or data outputs. State whether a complete report or a single piece of data is required. If complete reports are needed, give specific details, for example, “Each report will contain a 7 by 10-in. plot and one 8½ by 11-in. page of tables and other numerical results.” List the number of copies needed for each report.

(2) Which data or results are to be reported.

(3) Format in which data are to be presented.

(4) Where the results should be displayed.

(5) How the results should be recorded or displayed, for example, paper, magnetic tape, display screen, etc. Sometimes more than one method is required. If results are to be transmitted to other equipment, computers, or systems, a special format and protocol may be required.

7.3.3.3 Timing of Data Reduction and Outputs—Provide the following information:

(1) List of results that are used for control functions.

(2) Additional inputs required for data reduction. Give the detail of operator prompting needed and the flexibility desired, based upon assumed levels of operator experience (see also 7.3.2).

(3) Length of time for retaining data for later processing or output (see also 7.3.3.1(3)).

(4) Maximum allowable time between completion of data collection and report of results.

(5) Desired frequency of reports or data outputs.

7.3.3.4 Comparison of Results—Provide the following information:

(1) Number of current and prior measurements to be included.

(2) Criteria for comparison. Indicate if, how, and why these criteria may change.

(3) Actions to be taken if similarities or differences are found, and timing of such actions.

7.3.4 Operational Considerations:

7.3.4.1 Availability and Reliability Requirements—Provide the following information:

(1) Time schedule during which the system is expected to be available for routine use (hours or shifts per day, days per week, etc.).

(2) Frequency of system maintenance. (This must be consistent with 7.3.4.1(I).)

(3) Plans for continuing operations in case of failure of the computerized system.

(4) Maximum acceptable time for the system to be out of service for repair.

(5) Requirements for data reliability and availability during planned and unplanned time out-of-service.

(6) Requirements for data recovery after system has been out of service.

7.3.4.2 Safety Considerations—Provide the following information:

(1) Possible modes of failure of external or interface equipment that would result in data failure. State how such conditions can be recognized by software or hardware tests.

(2) Safety hazards to operators and equipment that are associated with system failure.

(3) Any other hazardous conditions that may involve the system.

(4) Acceptable or possible results of system failure.

7.3.4.3 System Environment—Provide the following information:

(1) Characteristics of available primary power sources (frequency, voltage, current, power, interruptability, etc., stability of voltage and frequency).

(2) Range of ambient temperature.

(3) Range of ambient humidity.

(4) Heat removal capability.

(5) Corrosive atmosphere considerations.

(6) Electromagnetic radiation considerations.

(7) Altitude considerations.

(8) Acoustical noise considerations.

(9) Other environmental considerations.

7.3.4.4 Specific Hardware or Software Implementation Requirements:

(1) Requirements to use existing computer equipment or programs, or both.

(2) Constraints on modification of existing equipment.

(3) Other specific implementation requirements.

7.3.4.5 Security—Specify required protection against the following kinds of threats:

(1) Unauthorized access or use.

(2) False triggering.

(3) Falsification of data.

(4) Monitoring.

(5) Interference or jamming.

(6) Physical attack.

(7) Fire and flood.

(8) Earthquake, volcanic eruption, etc.

7.3.4.6 System Modifications:

(1) Requirements for altering, improving, and reprogramming the system.

(2) Requirements for testing the system after changes are made.

(3) Responsibility for making and testing changes.

(4) Responsibility for updating documentation (including users’ manuals) to reflect changes.

7.3.4.7 Other Operational Considerations—Provide a list of all additional operational considerations.

7.3.5 Human-computer Interactions:

7.3.5.1 Level of Education, Training, and Experience, for each person who will interact with the system—Provide information for the following:

(1) Operation, including managers and operators.

(2) Maintenance, including engineers, technicians, and programmers.

(3) Users of the reported results.

7.3.5.2 Desired Levels of Human Interactions—Provide

descriptions for each category as in 7.3.5.1. Break these down into the various groups of system users. Be specific with regard to such possible interactions as program revision or updating, simple passive response to system queries, no operator interaction, etc.

7.3.5.3 Information that Must be Accessible to Each Group of System Users—Provide detailed description for each category as in 7.3.5.1.

7.3.5.4 Security Considerations—Restrictions on what information may be accessible to whom and at what times.

7.3.6 System Validation Plan:

7.3.6.1 Prepare a system validation plan (IEEE 1012) as part of the functional requirements, setting criteria for system acceptance. For each feature and attribute required by the functional requirements, describe a method of testing the feature or attribute (see 10.7). The system validation plan must include quantifiable criteria such as accuracy, precision, production rate, throughput, etc.

7.3.6.2 If the functional requirements are modified, the system validation plan should also be modified to describe testing of added or changed features or to remove testing of deleted features.

7.3.6.3 In the system validation plan, document the procedure for handling failed tests. At the minimum, the procedure should cover number of retests allowed before the system is not accepted, how successful and failed tests and retests should be recorded and reported, notifications of failed tests or retests, and procedure for software and hardware modifications or repairs after system validation has started.

7.3.6.4 Guidelines and regulations are emerging for computerized systems that are to be used (1) in settings that must meet formal quality or accreditation requirements, (2) in regulated industries, or (3) in settings that are otherwise under legal or regulatory authority. When these resources are available, they should be used to complement, modify, or replace the system validation requirements of this guide. Recommendations in this guide describe good practice for system development and should be used where other regulatory or contractual requirements have not been established.

8. Functional Design

8.1 General Considerations:

8.1.1 A functional design is a detailed description of a system that includes all flows of information, timing diagrams, and state transition diagrams, and which is independent of particular hardware and software. It is contained in a document that is also called a functional design. The term also applies to a phase in a computerization project in which a functional design is prepared and documented. The concepts are not distinct from one another. This section will explicitly mention the phase or document where it is important to distinguish between them.

8.1.2 A functional design is an exact, concise description of the functions required in a proposed computerized system. Functional requirements (Section 7) describe what a system must do. The functional design describes how the system will accomplish that task. A functional design translates the functional requirements into a concise form characterized by inputs, functions, and outputs.

8.1.3 Preparation of a functional design follows the development of functional requirements and is usually undertaken by the same persons who prepare and document the requirements.

8.1.4 A functional design is usually expressed in diagrams that are characterized by inputs, outputs, and transfer functions. They show the processes the system must use to accomplish the functional requirements.

8.1.5 Paragraph 8.3 provides a procedure for the preparation of a functional design and a graphical representation for design diagrams. The procedure is not unique. Other approaches are discussed in 8.4.

8.1.6 This is the last phase of the project that is independent of particular hardware and software.

8.2 Characteristics of a Functional Design:

8.2.1 The functional design must be exact. All essential information must be included so that the functional design is logical and accurate. Sufficient information must be presented to define exactly how the system will accomplish its mission.

8.2.2 The functional design should be concise, at the same time reflecting the interrelationships or hierarchy of steps within the system. If one attempts to include too much information in a single diagram, it becomes unwieldy and difficult to follow. Multiple functional diagrams should be included for complex systems.

8.2.3 The basic concept of a functional design diagram is shown in Fig. 2. Each element is formatted in the same way showing inputs, functions, and outputs from left to right in the design element. The format should show the flow and transformation of specific data by a specific function.

8.2.3.1 Functional design diagrams are composed of multiple elements, each depicting a function and the associated data inputs and outputs.

8.2.3.2 Each diagram contains a brief description of each input, function, and output and the reference codes identifying text locations, tables, or figures in the functional requirements document where more information can be found.

8.2.3.3 In addition, each function is identified by a number in the upper left-hand corner of the function rectangle (see Fig. 3). When major functions are decomposed into lower-level functions, this identifying number can be subdivided to indicate multiple lower-level functions associated with a single high-level function. For example, high-level function 3 may be divided into multiple lower-level functions 3.1 through 3.6 (see Fig. 4).

8.3 Preparation of a Functional Design:

8.3.1 The following steps are used to prepare a functional design. These steps are not always carried out in this order, but they are performed in a way to efficiently prepare an exact and concise design.

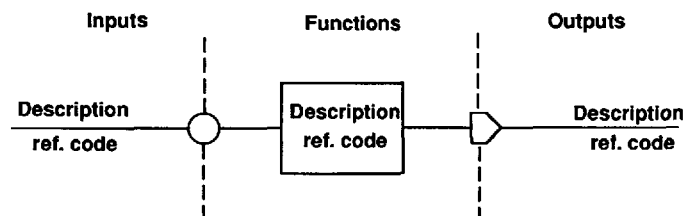


FIG. 2 Structure of One Element of a Functional Design Diagram

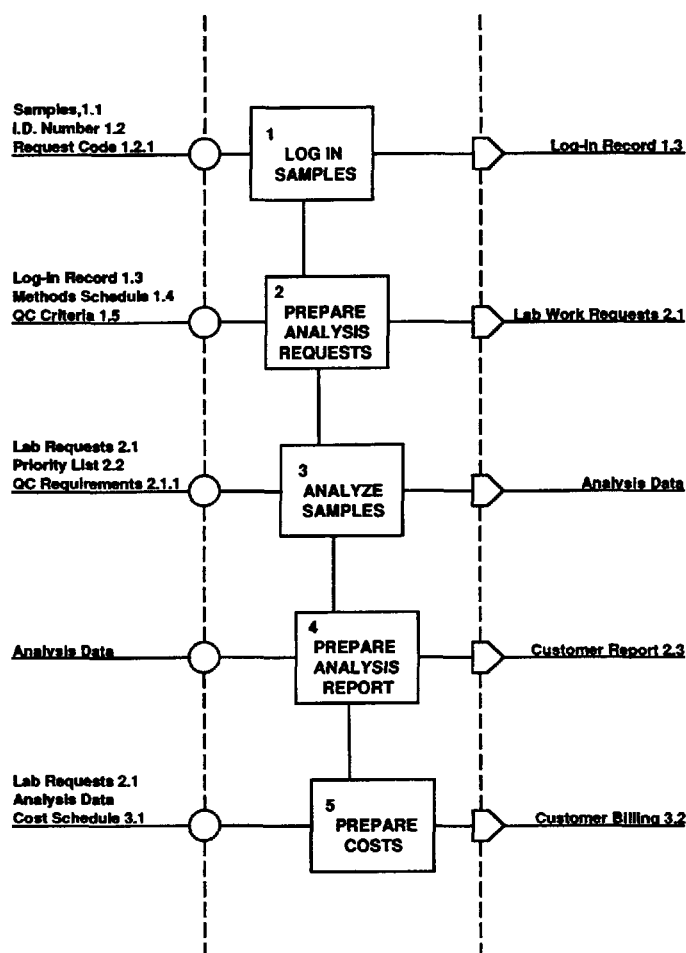


FIG. 3 High-Level Functional Design Diagram: Example of Major Operations in a Chemical Analysis Laboratory

8.3.1.1 Review and Verification of the Project Definition and Functional Requirements:

(1) Carefully review and verify the project definition, especially the goals and constraints that have been placed on the project. This ensures close conformity with the project objectives.

(2) Review the functional requirements documents. Verify the characteristics and relationships of all components of the system. Identify all processes and functions of the system, their interrelationships, and the temporal order of events.

8.3.1.2 Decomposition of the System:

(1) Determine the overall structure of the system to be automated, including the higher- and lower-level processes, the individual functions making up each process, and the interdependencies of the functions and processes within the system. This information can be extracted from the functional requirements document.

(2) Divide the system into unique parts so that the hierarchy of processes and functions can be clearly identified. This step can be carried out by preparing a series of tables containing the high-level processes of the system. These should be followed by additional tables that show the orderly decomposition of the high-level processes into lower-level functions.

(3) During or following decomposition, identify and tabulate the inputs and outputs for each process and function. Include in

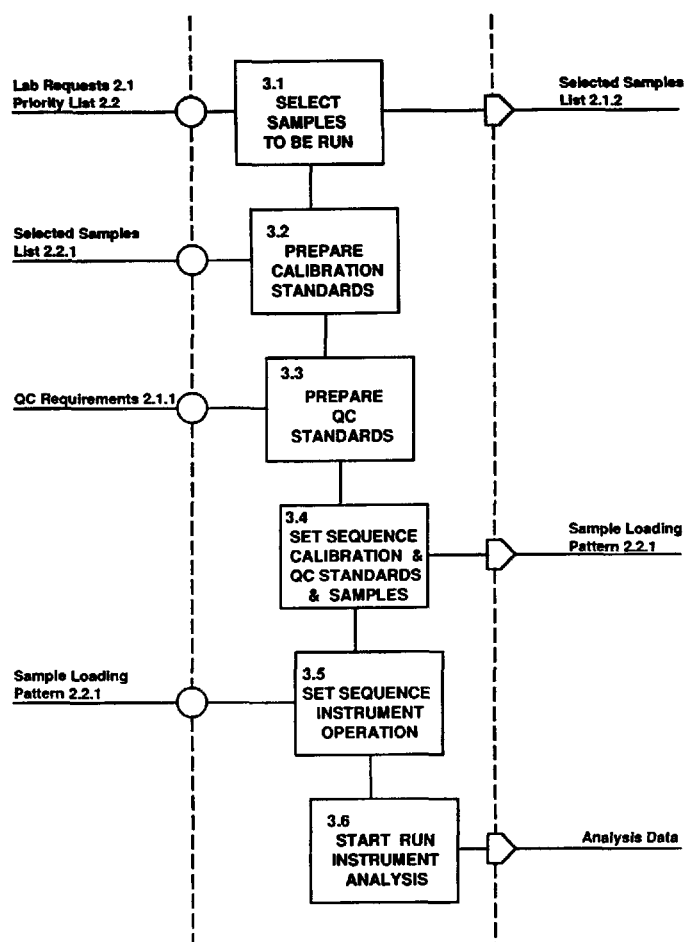


FIG. 4 Lower-Level Functional Design Diagram: Example of Sample Analysis Subfunctions

the tabulation the specific reference codes that indicate where the detailed input, output, and functional information can be found in the functional requirements document. Careful attention to system decomposition is vital and constitutes a major part of the work required to prepare the functional design diagrams.

(4) Document errors, omissions, and irrelevant parts of the project definition and functional requirements as they are found, to use as input for the iteration described in 8.3.2.

8.3.1.3 Preparation of the Functional Design Diagrams:

(1) Fig. 2 illustrates the simplest element of a functional design diagram. Most designs are composed of many elements with multiple inputs, functions, and outputs. Fig. 3 is a high-level functional design diagram showing major operations in a chemical analysis laboratory. There are five high-level processes identified by the numbers 1 through 5 in the upper left-hand corner of the functional rectangle. Brief descriptions are inserted for each input, function, and output along with reference codes indicating where detailed information for each can be obtained in the functional requirements. Fig. 4 is a lower-level diagram illustrating the subfunctions associated with Process 3 in the high-level diagram (Fig. 3).

(2) Prepare a functional design diagram of the high-level processes that make up the overall system. For guidance, refer to Fig. 3. Include as many elements as needed to identify the major processes in the system. Six elements have been found to