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Standard Guide for Documenting Computerized Systems¹

This standard is issued under the fixed designation E 627; 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 phased, integrated process for documenting computerized systems. System documentation begins with initial system definition, extends through system implementation and evaluation, and continues after the system is placed on-line in an operational mode. Portions of the system documentation are suggested for distribution to various persons involved with the system, depending on their level of involvement and responsibility. The amount of detail to be included in each of these documents is described.

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 622 Guide for Developing Computerized Systems²

E 625 Guide for Training Users of Computerized Systems²

E 919 Specification for Software Documentation for a Computerized System²

E 1013 Terminology Relating to Computerized Systems²

E 1029 Guide for Documentation of Clinical Laboratory Computer Systems²

2.2 Other Standards:

2.2.1 IEEE Standards:

100 Standard Dictionary of Electrical and Electronic Terms³

610 Standard Glossaries of Computer-Related Terminology³

730.1 Standard for Software Quality Assurance Plans³

730.2 Guide for Software Quality Assurance Plans³

1012 Standard for Software Verification and Validation Plans³

1058.1 Standard for Software Project Management Plans³

1063 Standard for Software Under Documentation³

2.2.2 ANSI Standards:

¹ This guide is under the jurisdiction of ASTM Committee E-49 on Computerized Systems and Chemical and Material Information and is the direct responsibility of Subcommittee E49.30 on Development and Acquisition of Computerized Systems.

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² Annual Book of ASTM Standards, Vol 14.01.

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

X 3.172, American National Standard Dictionary for Information Systems⁴

3. Terminology

3.1 The terminology used in this document and others developed by ASTM Committee E-31 on Computerized Systems is defined in Terminology E 1013 and Guide E 622.

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

4. Significance and Use (See Guide E 622, Section 2)

4.1 Guides E 622, E 625 and Specification E 919 prescribe the collection and recording of certain information that should be part of total system documentation. This guide incorporates the requirements contained in the guides listed above, and presents them as a phased, integrated process for documenting computerized systems. It is intended to be used for two purposes: (1) as a model for initial documentation of a system; and (2) as a checklist to ensure that existing system documentation is complete (thereby identifying cases of inadequate documentation).

NOTE 1—ASTM regulations prescribe that all standards be reviewed annually, and after a maximum of five years, must be reapproved or revised, as appropriate. If the current version of any of the referenced standards prescribes documentation not included in this guide, that documentation should be added to what is prescribed by this guide.

NOTE 2—For clinical laboratory systems, use Guide E 1029 to determine the documentation requirements.

4.2 This guide recommends a series of documents that will inform and instruct the parties involved with systems. These parties can include:

Administrative Management (Adm)—Senior executive management, vice-president, department or division head, controller, etc.,

Management (Mgt)—Management and supervisory personnel of the organizational unit for which the computerization project is being done,

Systems Designers (Sys)—Members of the design team,

Vendors (Ven)—Hardware and software suppliers,

Facility Engineering (Fac)—People responsible for buildings, utilities, and other environmental services at the local facility,

Implementors (Imp)—Members of the implementation team,

Operators (Opr)—People using the equipment,

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

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Data Recipients (Rec)—People using the results, and
Maintenance (Mtn)—People servicing the system hardware and software.

Quality Assurance (QA)—People who review the system throughout development to provide a recheck to ensure the system has proper controls add credibility to its results and generally satisfy requirements, guidelines, and environmental and safety aspects of the system (see IEEE 730.1 and 730.2).

4.3 The parties identified in 4.2 may have different titles. Some roles may be combined under other titles. Whatever the titles, it is important that all involved parties be fully informed, information be presented for the appropriate level of knowledge, and none of the items required to document the system be overlooked.

4.4 The information collected during the use of this guide should be selectively disseminated according to each user's needs. It may be bound into separate packages as shown in Table 1. Interested parties are indicated in Table 1 and in the succeeding sections of this guide by the abbreviations defined in 4.2. If some of these parties wish other parts of the documentation, those sections should be provided, subject to the organization's policies. Vendors and outside suppliers of sub-systems need only those portions of the documentation pertaining to their product and how it fits into the overall system.

4.5 Documentation Format:

4.5.1 All project documentation should be in a consistent format. Formats will vary among organizations according to

each organization's policies. System documentation format should contain the following items:

4.5.1.1 Document identification (title page),

4.5.1.2 Table of contents, list of tables, figures, diagrams, and listings,

4.5.1.3 Introduction or overview,

4.5.1.4 *Text Body*—Descriptions of the specific subsystem, procedures, operations, or options,

4.5.1.5 Applicable tables and figures, flowcharts, schematic diagrams, pseudo-code, and program listings of the system being described,

4.5.1.6 References, notes, and letters on special operating characteristics and details referring to pending documentation changes,

4.5.1.7 Index or concordance, and

4.5.1.8 Revision level identification, revision date, and page number on each page.

5. Project Definition (all parties except *Ven*, see Guide E 622, Section 6)

5.1 Purpose:

5.1.1 Project definition defines the scopes of both the computerized system to be developed and the project to develop that system. This is a mutually agreed upon definition of the project, stating the major goals, objectives, and constraints. This first phase of developing a computerized system includes:

TABLE 1 Summary of Recommended Documentation

Section	Documentation	Persons Described in 4.2									
		<i>Adm</i>	<i>Mgt</i>	<i>Sys</i>	<i>Ven</i>	<i>Fac</i>	<i>Imp</i>	<i>Opr</i>	<i>Rec</i>	<i>Mtn</i>	<i>QA</i>
5	Project definition	×	×	×		×	×	×	×	×	×
6	System overview										
6.1	Objectives	×	×	×	×	×	×	×	×	×	×
6.2	Goals and benefits	×	×	×		×	×	×	×		
6.3	Nature of the project	×	×	×			×	×	×		×
6.4	Details of the project		×	×			×	×		×	×
6.5	Non-technical considerations	×	×	×		×	×	×	×		×
6.6	Future requirements	×	×	×	×	×	×	×	×	×	×
7	Functional Requirements										
7.1	Input data		×	×	×		×	×	×	×	×
7.2	Control functions		×	×	×		×			×	×
7.3	Data manipulation and output		×	×	×		×	×	×	×	×
7.4	Operational considerations		×	×	×	×	×	×		×	×
7.5	Human interfaces		×	×	×		×	×		×	×
7.6	Basis for system acceptance	×	×	×	×		×				×
7.7	Basis for system evaluation		×	×	×		×				×
8	Functional design		×	×	×		×			×	×
9	Implementation design										
9.1	Implementation alternatives		×	×			×				×
9.2	Final implementation design	×	×	×	×	×	×	×	×	×	×
9.3	Official approval	×	×	×		×	×			×	×
9.4	Implementation		×	×		×	×			×	×
10	Training program										
10.1	Functional requirements and design		×	×	×		×				×
10.2	Implementation		×	×			×	×	×	×	×
10.3	Evaluation		×	×			×				×
11	Operational documentation		×	×		×		×	×	×	×
12	System evaluation										
12.1	Comparison with requirements		×	×			×				×
12.2	Evaluation process		×	×			×				×
12.3	Potential additional uses		×	×				×	×		×
12.4	Input to definition of future systems			×							×
12.5	Report of evaluation	×	×	×							×
13	Retrospective evaluation	×	×	×						×	×