

ANSI/ASQC D1160-1995

AMERICAN NATIONAL STANDARD

Formal Design Review

AMERICAN SOCIETY FOR QUALITY CONTROL
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Introduction

The objective of conducting design reviews during the development cycle is to ensure that products or services satisfy specified dependability, life, safety, endurance, environment, electromagnetic compatibility, and performance requirements at a minimum cost and are deliverable within a prescribed schedule.

Design review enhances the development of products or processes through cost reduction, delivery schedule improvements, and better quality, performance, and safety. It can be employed by both supplier and customer.

Design review is an advisory activity. It is intended primarily to provide synergistic verification of the work of the development team, and only secondarily to provide input to the creative process. Design review should thus be considered a refining procedure and not a creative one.

Design reviews, regardless of frequency or depth, cannot replace good product definitions, design specifications, design, and engineering. Used as a control process, design review can provide the necessary verification of the successful completion of the design effort at a given time.

Design review should not be confused with day-to-day management of a project. The manager of the project carries the design responsibility and the final decisions should be his/hers. Design review is an independent activity, and, when properly done, increases confidence that design and engineering activities were carried out with due regard to all pertinent requirements throughout the product life cycle.

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Formal Design Review

*Prepared by
American Society for Quality Control Standards Committee
for
American National Standards Committee Z-1 on Quality Assurance*

An American National Standard Approved on September 11, 1995

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FORMAL DESIGN REVIEW

1 SCOPE

This American National Standard makes recommendations for the implementation of design review procedures as a means of stimulating product and/or process improvement. It includes guidelines for planning and conducting design reviews and specific details concerning contributions by reliability, maintenance, maintenance support, and availability specialists. This American National Standard also includes subclauses on contributions by other specialists dealing with related subjects such as quality, environment, safety (product and user), human factors, and legal matters.

In addition to the common understanding of "product," it is expedient to include other aspects, e.g., hardware and software, catalog listings, specifications describing the item, shipping package, installation and assembly, instructions and operating manuals, labels and warnings, maintenance, spare parts lists, warranties, sales brochures, and advertising literature.

2 REFERENCES

2.1 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent edition of the standards listed below. The American National Standards Institute and members of IEC and ISO maintain registers of currently valid American National Standards and International Standards.

IEC 50(191):1990, *International Electrotechnical Vocabulary (IEV), Chapter 191: Dependability and quality of service*.

ANSI/ISO/ASQC-A8402, *Quality Management and Quality Assurance—Vocabulary*.

2.2 Related documents

The following are listed in this document but are not shown in the IEC 1160 standard on Formal Design

Review. These are for the reader's use, but are not a part of the international standard.

IEC 319:1978, *Presentation of reliability data on electronic components (or parts)*.

IEC 362:1971, *Guide for the collection of reliability, availability, and maintainability data from field performance of electronic items*.

IEC 409:1981, *Guide for the inclusion of reliability clauses into specifications for components (or parts) for electronic equipment*.

IEC 605:1978, *Equipment reliability testing series of standards for different conditions*.

IEC 706-1:1982, *Guide on maintainability of equipment, Part 1: Sections One, Two and Three—Introduction, requirements and maintainability program*.

IEC 706-2:1990, *Guide on maintainability of equipment, Part 2: Section Five—Maintainability studies during the design phase*.

IEC 706-3:1987, *Guide on maintainability of equipment, Part 3: Sections Six and Seven—Verification and collection, analysis and presentation of data*.

IEC 812:1985, *Procedure for failure mode and effects analysis (FMEA)*.

IEC 863:1986, *Presentation of reliability, maintainability and availability predictions*.

IEC 1014:1989, *Programs for reliability growth*.

IEC 1025:1990, *Fault tree analysis (FTA)*.

IEC 1070:1991, *Compliance test procedures for steady-state availability*.

IEC 1078:1991, *Analysis techniques for dependability—Reliability block diagram method*.

ANSI/ISO/ASQC Q9000-1-1994, *Quality Management and Quality Assurance Standards—Guidelines for Selection and Use*.

ANSI/ISO/ASQC Q9001-1994, *Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*.

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ANSI/ISO/ASQC Q9002-1994, *Quality Systems—Model for Quality Assurance in Production, Installation, and Servicing*.

ANSI/ISO/ASQC Q9003-1994, *Quality Systems—Model for Quality Assurance in Final Inspection and Test*.

ANSI/ISO/ASQC Q9004-1-1994, *Quality Management and Quality System Elements—Guidelines*.

3 DEFINITIONS

For the purpose of this American National Standard the terms and definitions of IEC(50)191:1990 apply together with the following additional definitions.

3.1 formal design review: A formal and independent examination of an existing or proposed design for the purpose of detection and remedy of deficiencies in the requirements and design which could affect such things as reliability performance, maintainability performance, maintenance support performance requirements, fitness for the purpose, and the identification of potential improvements.

NOTE: Design review by itself is not sufficient to ensure proper design [IEV 191-17-13].

NOTE: Design can relate to a product, process, or procedure.

3.2 action item: A question to be resolved before the formal design review is completed.

3.3 recommendation: A specific proposal to change a product, process, or schedule, to be acted upon or formally rejected before the design review is completed.

4 APPLICATION OF FORMAL DESIGN REVIEW

Every organization should adopt a comprehensive design review program as presented in this American National Standard, or else tailor a more limited one involving specific needs.

The design review should be incorporated into the overall operating procedures and integrated with product safety, electromagnetic compatibility, quality, and reliability programs.

Limitations of size and resources of the organization, project value, product benefits, risks, and complexity, all influence the review process. In smaller organizations, it

may be necessary to supplement staff with personnel from suppliers, consultants, and other outside advisors.

5 MANAGEMENT OF THE PROCESS

5.1 Policy statement

Each organization, e.g., corporation, plant, division, agency, project, as appropriate, should issue a policy statement governing the practice of design reviews authorized by the chief operating officer of the organization.

The policy statement should include the following:

—Formal design review should be conducted for all new products, processes, and applications, and for revisions to existing products and manufacturing processes which would affect function, performance, safety, dependability, electromagnetic compatibility, ability to cost, or other characteristics affecting the product and/or process, users, observers, or the population at large;

—Design reviews should be conducted at appropriate intervals to consider changes in technology which may affect the specified characteristics.

A senior member of management should be responsible for executing the policy on design review and implementing the policy statement by developing specific procedures and practices in accordance with this American National Standard.

5.2 Precautions

Care should be taken to prevent the design review process from dictating the ultimate design by directing the detailed engineering work. Decisions are made every day which bear on the product or process under review. If each decision were subjected to an independent review, the review team would, in essence, design the product, requiring an excessive time. Conversely, if the first formal design review occurred only just before production, its benefit would be questionable. At that point, no corrective action could be taken, short of stopping the project because of a critical problem with potentially catastrophic consequences.

6 FORMAL DESIGN REVIEWS DURING LIFE CYCLE PHASES

6.1 Types

This American National Standard adopts the philosophy that an appropriate type of design review should be conducted before taking any major decisions.