

**AMERICAN NATIONAL STANDARD**

**Quality Systems-Model for Quality  
Assurance in  
Design/Development, Production, Installation,  
and Servicing**

**AMERICAN SOCIETY FOR QUALITY CONTROL  
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# **AMERICAN NATIONAL STANDARD**

## **Quality Systems-Model for Quality Assurance in Design/Development, Production, Installation, and Servicing**

**Sponsor: American Society for Quality Control**

## Abstract

Quality Systems-Model for Quality Assurance in Design/Development, Production, Installation, and Servicing specifies quality system requirements for use where a contract between two parties requires the demonstration of a supplier's capability to design and supply product.

**AMERICAN NATIONAL STANDARD:** An American National Standard implies a consensus of those substantially concerned with its scope and provisions. An American National Standard is intended as a guide to aid the manufacturer, the consumer, and the general public. The existence of a American National Standard does not in any respect preclude anyone, whether he has approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. American National Standards are subject to periodic review, and users are cautioned to obtain the latest editions.

**CAUTION NOTICE:** This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of approval. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

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**Approved June 19, 1987**  
**American National Standards Institute, Inc.**

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**Forward**

(This Forward is not a part of American National Standard Quality Systems- Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.)

Guidance concerning the selection of this standard or others in the ANSI/ASQC Q91-94 series is contained in ANSI/ASQC Q90-1987.

Rather than Independently revising and extending its current Generic Guidelines for Quality Systems (ANSI/ASQC Z1.15-1979) the Standards Committee has elected to join other nations in adopting standards fully consistent with the "ISO 9000-9004 Series" of Quality Management and Quality Assurance Standards, since the latter were in agreement with the efforts of the ANSI/ASQC revision team.

These five ISO standards (ISO 9000-9004) were prepared by Technical Committee ISO/TC 176 on Quality Assurance in the interest of harmonizing the large number of national and international standards in this field. In addition to input from other countries, such as U.S. standards as ANSI/ASQC Z1.15 and ANSI/ASQC Z1.8 were considered in the source material used in developing these ISO standards. The ANSI/ASQC Q90 through Q94 standards are technically equivalent to the ISO 9000-9004 series, but incorporate customary American language usage and spelling.

Users should note that all ANSI/ASQC standards undergo revision from time to time, and that any reference herein to any other standard implies the latest revision, unless otherwise stated.

Comments concerning this standard will be welcome. They should be sent to the standard's sponsor. American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, Wisconsin 53202.

## **ANSI/ASQC Standard Q91-1987**

# **QUALITY SYSTEMS-MODEL FOR QUALITY ASSURANCE IN DESIGN/ DEVELOPMENT, PRODUCTION, INSTALLATION, AND SERVICING**

### **0.0 INTRODUCTION**

This standard is one of the series of three Standards dealing with quality systems that can be used for external quality assurance purposes. The alternative quality assurance models, set out in three Standards listed below, represent three distinct forms of functional or organizational capability suitable for two-party contractual purposes:

- ANSI/ASQC Q91-1987. Quality Systems-Model for Quality Assurance in Design/Development, Production, Installation, and Servicing.

- For use when conformance to specified requirements is to be assured by the supplier during several stages which may include design/development, production, installation, and servicing.

- ANSI/ASQC Q92-1987. Quality Systems-model for Quality Assurance in Production and Installation.

- For use when conformance to specified requirements is to be assured by the supplier during production and installation.

- ANSI/ASQC Q93-1987. Quality Systems-Model for Quality Assurance in Final Inspection and Test.

- For use when conformance to specified requirements is to be assured by the supplier solely at final inspection and test.

It is emphasized that the quality system requirements specified in this Standard. Standards Q92 and Q93 are complementary (not alternative) to the technical (product/service) specified requirements. These Standards are technically equivalent to the International Standards ISO 9001, 9002, and 9003 respectively.

It is intended that these Standards will normally be adopted in their present form, but on occasions they may need to be tailored for specific contractual situations. Q90 provides guidance on such tailoring as well as selection of the appropriate quality assurance model, namely Q91, Q92, or Q93.

## **1.0 SCOPE AND FIELD OF APPLICATION**

### **1.1 Scope**

This Standard specifies quality system requirements for use where a contract between two parties requires the demonstration of a supplier's capability to design and supply product.

The requirements specified in this Standard are aimed primarily at preventing nonconformity at all stages from design to servicing.

### **1.2 Field of Application**

This Standard is applicable in contractual situations when:

a) the contract specifically requires design effort and the product requirements are stated principally in performance terms or they need to be established.

b) confidence in product conformance can be attained by adequate demonstration of certain supplier's capabilities in design, development, production, installation, and servicing.

## **2.0 REFERENCES**

ANSI/ASQC A3. QUALITY SYSTEMS TERMINOLOGY  
ISO 8402-1986. QUALITY-VOCABULARY  
ANSI/ASQC Q90-1987 QUALITY MANAGEMENT AND QUALITY Assurance Standards-Guidelines for Selection and Use.  
ISO 9000-1987, Quality Management and Quality Assurance Standards- Guidelines for Selection and Use.

## **3.0 DEFINITIONS**

For the purposes of this Standard, the definitions given in ANSI/ASQC A3 apply.

NOTE: For the purposes of this Standard, the term "product" is also used to denote "service" as appropriate.

## **4.0 QUALITY SYSTEM REQUIREMENTS**

### **4.1 Management Responsibility**

#### **4.1.1 Quality Policy**

The supplier's management shall define and document its policy and objectives for, and commitment to quality. The supplier shall ensure that this policy is understood, implemented, and maintained at all levels in the organization.

## **4.1.2 Organization**

### **4.1.2.1 Responsibility and Authority**

The responsibility, authority, and the interrelation of all personnel who manage, perform, and verify work affecting quality shall be defined; particularly for personnel who need the organizational freedom and authority to:

- a) initiate action to prevent the occurrence of product nonconformity;
- b) identify and record any product quality problems;
- c) initiate, recommend, or provide solutions through designated channels;
- d) verify the implementation of solutions;
- e) control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

### **4.1.2.2 Verification Resources and Personnel**

The supplier shall identify in-house verification requirements provide adequate resources, and assign trained personnel for verification activities (see 4.18).

Verification activities shall include inspection, test, and monitoring of the design, production, installation, and servicing of the process and/or product: design reviews and audits of the quality system, processes, and/or product shall be carried out by personnel independent of those having direct responsibility for the work being performed.

### **4.1.2.3 Management Representative**

The supplier shall appoint a management representative who, irrespective of other responsibilities, shall have defined authority and responsibility for ensuring that the requirements of this Standard are implemented and maintained.

## **4.1.3 Management Review**

The quality system adopted to satisfy the requirements of this Standard shall be reviewed at appropriate intervals by the supplier's management to ensure its continuing suitability and effectiveness. Records of such reviews shall be maintained (see 4.16).

**NOTE:** Management reviews normally include assessment of the results of internal quality audits, but are carried out by, or on behalf of the supplier's management, namely management personnel having direct responsibility for the system (see 4.17).

## 4.2 Quality System

The supplier shall establish and maintain a documented quality system as a means of ensuring that product conforms to specified requirements. This shall include:

- a) the preparation of documented quality system procedures and instructions in accordance with the requirements of this standard;
- b) the effective implementation of the documented quality system procedures and instructions.

**NOTE:** In meeting specified requirements, timely consideration needs to be given to the following activities:

- a) the preparation of quality plans and a quality manual in accordance with the specified requirements;
- b) the identification and acquisition of any controls, processes, inspection equipment, fixtures, total production resources, and skills that may be needed to achieve required quality;
- c) the updating, as necessary, of quality control, inspection, and testing techniques, including the development of the new instrumentation;
- d) the identification of any measurement requirement involving capability that exceeds the know state of the art in sufficient time for the needed capability to be developed;
- e) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;
- f) the compatibility of the design, the production process, installation, inspection and test procedures, and the applicable documentation;
- g) the identification and preparation of quality records (see 4.16).

## 4.3 Contract Review

The supplier shall establish and maintain procedures for contract review and for the coordination of these activities. Each contract shall be reviewed by the supplier to ensure that:

- a) the requirements are adequately defined and documented;
- b) any requirements differing from those in the tender are resolved;
- c) the supplier has the capability to meet contractual requirements.

Records of such contract reviews shall be maintained (see 4.16).

**NOTE:** The contract review activities, interfaces, and communication within the supplier's organization should be coordinated with the purchaser's organization, appropriate.

## **4.4 Design Control**

### **4.4.1 General**

The supplier shall establish and maintain procedures to control and verify the design of the product in order to ensure that the specified requirements are met.

### **4.4.2 Design and Development Planning**

The supplier shall draw up plans that identify the responsibility for each design and development activity. The plans shall describe or reference these activities and shall be updated as the design evolves.

#### **4.4.2.1 Activity Assignment**

The design and verification activities shall be planned and assigned to qualified staff equipped with adequate resources.

#### **4.4.2.2 Organizational and Technical Interfaces**

Organizational and technical interfaces between different groups shall be identified and the necessary information documented, transmitted, and regularly reviewed.

### **4.4.3 Design Input**

Design input requirements relating to the product shall be identified, documented, and their selection reviewed by the supplier for adequacy.

Incomplete, ambiguous, or conflicting requirements shall be resolved with those responsible for drawing up these requirements.

### **4.4.4 Design Output**

Design output shall be documented and expressed in terms of requirements, calculations, and analyses.

Design Output Shall:

- a)** meet the design output requirements;
- b)** contain or reference acceptance criteria;
- c)** conform to appropriate regulatory requirements whether or not these have been stated in the input information;
- d)** identify those characteristics of the design that are crucial to the safe and proper functioning of the product.

#### **4.4.5 Design Verification**

The supplier shall plan, establish, document, and assign to competent personnel functions for verify the design.

Design verification shall establish that design output meets the design input requirement (see 4.4.4) by means of design control measures such as:

- a) holding and recording design reviews (see 4.16):
- b) undertaking qualification tests and demonstrations:
- c) carrying out alternative calculations:
- d) comparing the new design with a similar proven design, if available.

#### **4.4.6 Design Changes**

The supplier shall establish and maintain procedures for the identification, documentation, and appropriate review and approval of all changes and modifications.

### **4.5 Document Control**

#### **4.5.1 Document Approval and Issue**

The supplier shall establish and maintain procedures to control all documents and data that relate to the requirements of this Standard. These documents shall be reviewed and approved for adequacy by authorized personnel prior to issue.

This control shall ensure that:

- a) the pertinent issues of appropriate documents are available at all locations where operations are essential to the effective functioning of the quality system are performed:
- b) obsolete documents are promptly removed from all points of issue or use.

#### **4.5.2 Document Changes/Modifications**

Changes to documents shall be reviewed and approved by the same functions/organizations that performed the original review and approval unless specifically designated otherwise. The designated organizations shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

A master list or equivalent document control procedure shall be established to identify the current revision of documents in order to preclude the use of non-applicable documents.

Documents shall be re-issued after a practical number of changes have been made.

## **4.6 Purchasing**

### **4.6.1 General**

The supplier shall ensure that purchased product conforms to specified requirements.

### **4.6.2 Assessment of Sub-Contractors**

The supplier shall select sub-contractors on the basis of their ability to meet sub-contract requirements, including quality requirements. The supplier shall establish and maintain records of acceptable sub-contractors (see 4.16).

The selection of sub-contractors, and the type and extent of control exercise by the supplier, shall be dependent upon the type of product and, where appropriate on records of subcontractors' previously demonstrated capability and performance.

The supplier shall ensure that quality system controls are effective.

### **4.6.3 Purchasing Data**

Purchasing documents shall contain data clearly describing the product ordered, including where applicable:

- a) the type, class, style, grade, or other precise identification:
- b) the title or other positive identification, and applicable issue of specifications, drawings, process requirements, inspection instructions, and other relevant technical data, including requirements for approval or qualification of product, procedures, process equipment and personnel:
- c) the title, number, and issue of the quality system Standard to be applied to the product.

The supplier shall review and approve purchasing documents for adequacy of specified requirements prior to release.

### **4.6.4 Verification of Purchased Product**

Where specified in the contract, the purchaser or the purchaser's representative shall be afforded the right to verify at source or upon receipt that purchased product conforms to specified requirements. Verification of the purchaser shall not absolve the supplier of the responsibility to provide acceptable product nor shall it preclude subsequent rejection.

When the purchaser or the purchaser's representative elects to carry out verification at the sub-contractor's plant, such verification shall not be used by the supplier as evidence of effective control of quality by the sub-contractor.

## **4.7 Purchaser Supplied Product**

The supplier shall establish and maintain procedures for verification storage, and maintenance of purchaser supplied product provided for incorporation into supplies. Any such product that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the purchaser (see 4.16).

**NOTE:** Verification by the supplier does not absolve the purchaser of the responsibility to provide acceptable product.

## **4.8 Product Identification and Traceability**

Where appropriate, the supplier shall establish and maintain procedures for identifying the product from applicable drawings, specifications, or other documents, during all stages of production, delivery, and installation. Where, and to the extent that, traceability is a specified requirement, individual product or batches shall have a unique identification. This identification shall be recorded (see 4.16).

## **4.9 Process Control**

### **4.9.1 General**

The supplier shall identify and plan the production and, where applicable, installation processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

- a) documented work instructions defining the manner of production and installation, where the absence of such instructions would adversely affect quality use of suitable production and installation equipment, suitable working environment compliance with reference standards/codes, and quality plans;
- b) monitoring and control of suitable process and product characteristics during production and installation;
- c) the approval of processes and equipment, as appropriate;
- d) criteria for workmanship which shall be stipulated, to the greatest practicable extent, in written standards or by means of representative samples.

### **4.9.2 Special Processes**

These are processes, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use. Accordingly, continuous monitoring and/or compliance with documented procedures is required to ensure that the specified requirements are met. These processes shall be qualified and shall also comply with requirements of 4.9.1. Records shall be maintained for qualified processes, equipment, and personnel as appropriate.

## **4.10 Inspection and Testing**

### **4.10.1 Receiving Inspection and Testing**

4.10.1.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.1.2) until it has been inspected or otherwise verified as confirming to specified requirements. Verification shall be in accordance with the quality plan or documented procedures.

4.10.1.2 Where incoming product is released for urgent production purposes it shall be positively identified and recorded (see 4.16) in order to permit immediate recall and replacement in the event of nonconformance to be specified requirements.

**NOTE:** In determining the amount and nature of receiving inspection, consideration should be given to the control exercised at source and documented evidence and quality conformance provided.

### **4.10.2 In-Process Inspection and Testing**

The supplier shall:

- a) inspect, test, and identify product as required by the quality plan or documented procedure;
- b) establish product conformance to specified requirements by use of process monitoring and control methods;
- c) hold product until the required inspection and test have been completed or necessary reports have been received and verified except when product is released under positive recall procedures (see 4.10.1). Release under positive recall procedures shall not preclude the activities outlined in 4.10.2 a),
- d) identify nonconforming product.

### **4.10.3 Final Inspection and Testing**

The quality plan or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the data meets specified requirements.

The supplier shall carry out all final inspection and testing in accordance with the quality plan or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

No product shall be dispatched until all the activities specified in the quality plan or documented procedures have been satisfactorily completed and the associated data and documentation is available and authorized.

#### **4.10.4 Inspection and Test Records**

The supplier shall establish and maintain records which give evidence that the product has passed inspection and/or test with defined acceptance criteria (see 4.16).

#### **4.11 Inspection, Measuring, and Test Equipment**

The supplier shall control, calibrate, and maintain inspection, measuring, and test equipment, whether owned by the supplier, on loan, or provided by purchaser, to demonstrate the conformance of product to the specified requirements. Equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.

The supplier shall:

- a)** identify the measurements to be made, the accuracy required, and select the appropriate inspection, measuring, and test equipment;
- b)** identify, calibrate, and adjust all inspection, measuring and equipment, and devices that can effect product quality at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standards-where no such standards exist, the basis used for calibration shall be documented;
- c)** establish, document, and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;
- d)** ensure that the inspection, measuring, and test equipment is capable of accuracy and precision necessary;
- e)** identify inspection, measuring, and test equipment with a suitable indicator or approved identification record to show the calibration status;
- f)** maintain calibration records for inspection, measuring, and test equipment (see 4.16);
- g)** assess and document the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration;
- h)** ensure that the environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out;
- i)** ensure that the handling, preservation, and storage of inspection, measuring, and test equipment is such that the accuracy and fitness for use is maintained;
- j)** safeguard inspection, measuring, and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

Where test hardware (e.g., jigs, fixtures, templates, patterns) or test software is used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product prior to release for use during production and installation and shall be rechecked at prescribed intervals. The supplier shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 4.16). Measurement design data shall be made available, when required by the purchaser or his representative, for verification that it is functionally adequate.

## **4.12 Inspection and Test Status**

The inspection and test status of product shall be identified by using markings, authorized stamps, tags, labels, routing cards, inspection records, test software, physical location, or other suitable means, which indicate the conformance or non-conformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as necessary, throughout production and installation of the product to ensure that only product that has passed the required inspections and tests is dispatched, used, or installed.

Records shall identify the inspection authority responsible for release of conforming product (see 4.16).

## **4.13 Control of Nonconforming Product**

The supplier shall establish and maintain procedures to ensure that product that does not conform to specified requirements is prevented from inadvertent use or installation. Control shall provide for identification, documentation, evaluation, segregation when practical, disposition of non-conforming product, and for notification to the functions concerned.

### **4.13.1 Nonconformity Review and Disposition**

The responsibility for review and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be reviewed in accordance with documented procedures, It may be:

- a)** reworked to meet the specified requirements, or
- b)** accepted with or without repair by concession, or
- c)** re-graded for alternative applications, or
- d)** rejected or scraped.

Where required by the contract, the proposed use or repair of product (see 4.13,1 b) which does not conform the specified requirements shall be reported for concession to the purchaser or the purchaser's representative. The description of nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).

Repaired and reworked product shall be re-inspected in accordance with documented procedures.

## **4.14 Corrective Action**

The supplier shall establish, document, and maintain procedures for:

- a)** investigating the cause of nonconforming product and the corrective action needed to prevent recurrence;
- b)** analyzing all processes, work operations, concessions, quality records, service reports, and customer complaints to detect and eliminate potential causes of nonconforming product;
- c)** initiating preventative actions to deal with problems to a level corresponding to the risks encountered;

- d) applying controls to ensure that corrective actions are taken and that they are effective;
- e) implementing and recording changes in procedures resulting from corrective action.

## **4.15 Handling, Storage, Packaging, and Delivery**

### **4.15.1 General**

The supplier shall establish, document, and maintain procedures for handling, storage, packaging, and delivery of product.

### **4.15.2 Handling**

The supplier shall provide methods and means of handling that prevent damage or deterioration.

### **4.15.3 Storage**

The supplier shall provide secure storage areas or stock rooms to prevent damage or deterioration of product, pending use, or delivery. Appropriate methods for authorizing receipt and the dispatch to and from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

### **4.15.4 Packaging**

The supplier shall control packing, preservation, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements and shall identify, preserve, and segregate all product from the time of receipt until the supplier's responsibility ceases.

### **4.15.5 Delivery**

The supplier shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

## **4.16 Quality Records**

The supplier shall establish and maintain procedures for identification, collection, indexing, filing, storage, maintenance, and disposition of quality records.

Quality records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system. Pertinent sub-contractor quality records shall be an element of these data.

All quality records shall be legible and identifiable to the product involved. Quality records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a

suitable environment to minimize deterioration or damage and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the purchaser or the purchaser's representative for and agreed period.

#### **4.17 Internal Quality Audits**

The supplier should carry out a comprehensive system of planned and documented internal quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.

Audits shall be scheduled on the basis of the status and importance of the activity.

The audits and follow-up shall be carried out in accordance with documented procedures.

The results of the audits shall be documented and brought to attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on the deficiencies found by the audit (see 4.1.3).

#### **4.18 Training**

The supplier shall establish and maintain procedures for identifying the training needs and provide for the training of all personnel performing activities effecting quality. Personnel performing specific assigned tasks shall be qualified to the basis of appropriate education, training, and/or experience as required. Appropriate records of training shall be maintained (see 4.16).

#### **4.19 Servicing**

Where servicing is specified in the contract, the supplier shall establish and maintain procedures for performing and verifying that servicing meets the specified requirements.

#### **4.20 Statisical Techniques**

Where appropriate, the supplier shall establish procedures for identifying adequate statistical techniques required for verifying the acceptability of process capability and product characteristics.

# **Contents**

ANSI/ASQC Q91-1987, Quality Systems-Model for Quality Assurance  
in Design/Development, Production, Installation, and Servicing

0.0 Introduction

1.0 Scope and Field of Application

2.0 References

3.0 Definitions

4.0 Quality Systems Requirements

4.1 Management Responsibility

4.2 Quality System

4.3 Contract Review

4.4 Design Control

4.5 Document Control

4.6 Purchasing

4.7 Purchaser Supplied Product

4.8 Product Identification and Traceability

4.9 Process Control

4.10 Inspection and Testing

4.11 Inspection, Measuring, and Test Equipment

4.12 Inspection and Test Status

4.13 Control of Nonconforming Product

4.14 Corrective Action

4.15 Handling, Storage, Packaging, and Delivery

4.16 Quality Records

4.17 Internal Quality Audits

4.18 Training

4.19 Servicing

4.20 Statistical Techniques