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AMERICAN NATIONAL STANDARD

Quality Systems—Model for Quality Assurance in Production, Installation, and Servicing

[Revision of first edition (ANSI/ASQC Q92-1987)]

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 July 18, 1994

Descriptors: quality assurance, quality assurance program, quality systems, production, installation, after-sale services, reference models.

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ASQC Mission: To facilitate continuous improvement and increase customer satisfaction by identifying, communicating, and promoting the use of quality principles, concepts, and technologies; and thereby be recognized throughout the world as the leading authority on, and champion for, quality.

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Contents

Foreword

(This Foreword is not a part of American National Standard *Quality Systems—Model for Quality Assurance in Production, Installation, and Servicing.*)

This American National Standard corresponds to the International Standard ISO 9002:1994. The initial five ISO 9000 series standards, ISO 9000, ISO 9001, ISO 9002, ISO 9003, and ISO 9004, when published in the United States as American National Standards in 1987, were designated as ANSI/ASQC Q90 through ANSI/ASQC Q94 respectively. The five 1987 standards in their 1994 international revisions are now designated ISO 9000-1, ISO 9001, ISO 9002, ISO 9003, and ISO 9004-1 respectively. Their publication as American National Standards are now designated ANSI/ASQC Q9000-1-1994, ANSI/ASQC Q9001-1994, ANSI/ASQC Q9002-1994, ANSI/ASQC Q9003-1994, and ANSI/ASQC Q9004-1-1994 respectively. This new numbering system is intended to emphasize the word-for-word correspondence of the International and American National Standards.

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and nongovernmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization. The American National Standards Institute (ANSI) is the U.S. member body of ISO. ASQC is the U.S. member of ANSI responsible for quality management and related standards.

Users should note that all ANSI/ASQC standards undergo revision from time to time. In the case of International Standards adopted as American National Standards, the revision timing is influenced by the international revision timing. Reference herein to any other standard implies the latest American National Standard revision unless otherwise stated.

Comments concerning this standard are welcome. They should be sent to the sponsor of the standard, American Society for Quality COntrol, 611 East Wisconsin Avenue, P.O. Box 3005, Milwaukee, WI 53201-3005, c/o Standards Administrator.

Introduction

This American National Standard is one of three American National Standards dealing with quality-system requirements that can be used for external quality-assurance purposes. The quality-assurance models, set out in the three American National Standards listed below, represent three distinct forms of quality-system requirements suitable for the purpose of a supplier demonstrating its capability, and for the assessment of the capability of a supplier by external parties.

a) ANSI/ASQC Q9001-1994, *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 design, development, production, installation, and servicing.

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

—for use when conformance to specified requirements is to be assured by the supplier during production, installation, and servicing.

c) ANSI/ASQC Q9003-1994, *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 American National Standard, ANSI/ASQC Q9001-1994, and ANSI/ASQC Q9003-1994 are complementary (not alternative) to the technical (product) specified requirements. They specify requirements which determine what elements quality systems have to encompass, but it is not the purpose of these American National Standards to enforce uniformity of quality systems. They are generic and independent of any specific industry or economic sector. The design and implementation of a quality system will be influenced by the varying needs of an organization, its particular objectives, the products and services supplied, and the processes and specific practices employed.

It is intended that these American National Standards will be adopted in their present form, but on occasions they may need to be tailored by adding or deleting certain quality-system requirements for specific contractual situations. ANSI/ASQC Q9000-1-1994 provides guidance on such tailoring as well as on selection of the appropriate quality-assurance model, *viz.* ANSI/ASQC Q9001-1994, ANSI/ASQC Q9002-1994, or ANSI/ASQC Q9003-1994.

QUALITY SYSTEMS—MODEL FOR QUALITY ASSURANCE IN PRODUCTION, INSTALLATION, AND SERVICING

1 SCOPE

This American National Standard specifies quality-system requirements for use where a supplier's capability to supply conforming product to an established design needs to be demonstrated.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from production through to servicing.

This American National Standard is applicable in situations when

a) the specified requirements for product are stated in terms of an established design or specification, and

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

NOTE 1 For informative references, see annex A.

2 NORMATIVE REFERENCE

The following standard contains provisions which, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the edition indicated was 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 standard indicated below. The American National Standards Institute and members of IEC and ISO maintain registers of currently valid American National Standards and International Standards.

ISO 8402:1994, *Quality management and quality assurance—Vocabulary*

3 DEFINITIONS

For the purposes of this American National Standard, the definitions given in ISO 8402 and the following definitions apply.

3.1 product: Result of activities or processes.

NOTES

2 A product may include service, hardware, processed materials, software, or a combination thereof.

3 A product can be tangible (e.g., assemblies or processed materials) or intangible (e.g., knowledge or concepts), or a combination thereof.

4 For the purposes of this American National Standard, the term "product" applies to the intended product offering only and not to unintended "by-products" affecting the environment. This differs from the definition given in ISO 8402.

3.2 tender: Offer made by a supplier in response to an invitation to satisfy a contract award to provide product.

3.3 contract; accepted order: Agreed requirements between a supplier and customer transmitted by any means.

4 QUALITY-SYSTEM REQUIREMENTS

4.1 Management responsibility

4.1.1 Quality policy

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented, and maintained at all levels of the organization.

4.1.2 Organization

4.1.2.1 Responsibility and authority

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

a) initiate action to prevent the occurrence of any nonconformities relating to product, process, and quality system;

b) identify and record any problems relating to the product, process, and quality system;

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 Resources

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work, and verification activities including internal quality audits.

4.1.2.3 Management representative

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for

a) ensuring that a quality system is established, implemented, and maintained in accordance with this American National Standard, and

b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE 5 The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

4.1.3 Management review

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this American National Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

4.2 QUALITY SYSTEM

4.2.1 General

The supplier shall establish, document, and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this American National Standard. The quality manual shall include or make reference to the quality-system procedures and outline the structure of the documentation used in the quality system.

NOTE 6 Guidance on quality manuals is given in ISO 10013.

4.2.2 Quality-system procedures

The supplier shall

a) prepare documented procedures consistent with the requirements of this American National Standard and the supplier's stated quality policy, and

b) effectively implement the quality system and its documented procedures.

For the purposes of this American National Standard, the range and detail of the procedures that form part of the quality system depend on the complexity of the work, the methods used, and the skills and training needed by personnel involved in carrying out the activity.

NOTE 7 Documented procedures may make reference to work instructions that define how an activity is performed.

4.2.3 Quality planning

The supplier shall define and document how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of a supplier's quality system and shall be documented in a format to suit the supplier's method of operation. The supplier shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects, or contracts:

a) the preparation of quality plans;

b) the identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources, and skills that may be needed to achieve the required quality;

c) ensuring the compatibility of the production process, installation, servicing, inspection, and test procedures, and the applicable documentation;

d) the updating, as necessary, of quality control, inspection, and testing techniques, including the development of new instrumentation;

e) the identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;

f) the identification of suitable verification at appropriate stages in the realization of product;

g) the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element;

h) the identification and preparation of quality records (see 4.16).

NOTE 8 The quality plans referred to (see 4.2.3a) may be in the form of a reference to the appropriate documented procedures that form an integral part of the supplier's quality system.

4.3 CONTRACT REVIEW

4.3.1 General

The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.

4.3.2 Review

Before submission of a tender, or at the acceptance of a contract or order (statement of requirement), the tender, contract, or order shall be reviewed by the supplier to ensure that:

a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the supplier shall ensure that the order requirements are agreed before their acceptance;

b) any differences between the contract or accepted order requirements and those in the tender are resolved;

c) the supplier has the capability to meet the contract or accepted order requirements.

4.3.3 Amendment to a contract

The supplier shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the supplier's organization.

4.3.4 Records

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

NOTE 9 Channels for communication and interfaces with the customer's organization in these contract matters should be established.

4.4 DESIGN CONTROL

The scope of this American National Standard does not include quality-system requirements for design control. This subclause is included to align the clause numbering with ANSI/ASQC Q9001-1994.

4.5 DOCUMENT AND DATA CONTROL

4.5.1 General

The supplier shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this American National Standard including, to the extent applicable, documents of external origin such as standards and customer drawings.

NOTE 10 Documents and data can be in the form of any type of media, such as hard copy or electronic media.

4.5.2 Document and data approval and issue

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document-control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

4.5.3 Document and data changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/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.

4.6 PURCHASING

4.6.1 General

The supplier shall establish and maintain documented procedures to ensure that purchased product (see 3.1) conforms to specified requirements.

4.6.2 Evaluation of subcontractors

The supplier shall:

a) evaluate and select subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality-assurance requirements;

b) define the type and extent of control exercised by the supplier over subcontractors. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product, and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors;

c) establish and maintain quality records of acceptable subcontractors (see 4.16).

4.6.3 Purchasing data

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

a) the type, class, grade, or other precise identification;

b) the title or other positive identification, and applicable issues 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.

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

4.6.4 Verification of purchased product

4.6.4.1 Supplier verification at subcontractor's premises

Where the supplier proposes to verify purchased product at the subcontractor's premises, the supplier shall specify verification arrangements and the method of product release in the purchasing documents.

4.6.4.2 Customer verification of subcontracted product

Where specified in the contract, the supplier's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises and the supplier's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the supplier as evidence of effective control of quality by the subcontractor.

Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

4.7 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

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

Verification by the supplier does not absolve the customer of the responsibility to provide acceptable product.

4.8 PRODUCT IDENTIFICATION AND TRACEABILITY

Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery, and installation.

Where and to the extent that traceability is a specified requirement, the supplier shall establish and maintain documented procedures for unique identification of individual product or batches. This identification shall be recorded (see 4.16).

4.9 PROCESS CONTROL

The supplier shall identify and plan the production, installation, and servicing 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 procedures defining the manner of production, installation, and servicing, where the absence of such procedures could adversely affect quality;

b) use of suitable production, installation, and servicing equipment, and a suitable working environment;

c) compliance with reference standards/codes, quality plans, and/or documented procedures;

d) monitoring and control of suitable process parameters and product characteristics;

e) the approval of processes and equipment, as appropriate;

f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples, or illustrations);

g) suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes 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, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel (see 4.18), shall be specified.

NOTE 11 Such processes requiring prequalification of their process capability are frequently referred to as special processes.

Records shall be maintained for qualified processes, equipment, and personnel, as appropriate (see 4.16).

4.10 INSPECTION AND TESTING

4.10.1 General

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

4.10.2 Receiving inspection and testing

4.10.2.1 The supplier shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements shall be in accordance with the quality plan and/or documented procedures.

4.10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

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

4.10.3 In-process inspection and testing

The supplier shall:

a) inspect and test the product as required by the quality plan and/or documented procedures;

b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 4.10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 4.10.3a.

4.10.4 Final inspection and testing

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

The quality plan and/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 results meet specified requirements.

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

4.10.5 Inspection and test records

The supplier shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

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

4.11 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

4.11.1 General

The supplier shall establish and maintain documented procedures to control, calibrate, and maintain inspection, measuring, and test equipment (including test software) used by the supplier to demonstrate the conformance of product to the specified requirements. Inspection, measuring, and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references such as test hardware are 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, installation, or servicing, 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).

Where the availability of technical data pertaining to the measurement equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the measuring equipment is functionally adequate.

NOTE 12 For the purposes of this American National Standard, the term "measuring equipment" includes measurement devices.

4.11.2 Control procedure

The supplier shall:

a) determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring, and test equipment that is capable of the necessary accuracy and precision;

b) identify all inspection, measuring, and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented;

c) define the process employed for the calibration of inspection, measuring, and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;

d) identify inspection, measuring, and test equipment with a suitable indicator or approved identification record to show the calibration status;

e) maintain calibration records for inspection, measuring, and test equipment (see 4.16);

f) assess and document the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration;

g) ensure that the environmental conditions are suitable for the calibration, inspections, measurements, and tests being carried out;

h) ensure that the handling, preservation, and storage of inspection, measuring, and test equipment is such that the accuracy and fitness for use are maintained;

i) safeguard inspection, measuring, and test facilities, including both test hardware and test software, from adjustments which would invalidate the calibration setting.

NOTE 13 The metrological confirmation system for measuring equipment given in ISO 10012 may be used for guidance.

4.12 INSPECTION AND TEST STATUS

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation, and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 4.13.2)] is dispatched, used, or installed.

4.13 CONTROL OF NONCONFORMING PRODUCT

4.13.1 General

The supplier shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation. This control shall provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned.

4.13.2 Review and disposition of nonconforming product

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,

b) accepted with or without repair by concession,

c) regraded for alternative applications, or

d) rejected or scrapped.

Where required by the contract, the proposed use or repair of product (see 4.13.2b) which does not conform to specified requirements shall be reported for concession to the customer or customer's representative. The description of the nonconformity that has been accepted, and of repairs, shall be recorded to denote the actual condition (see 4.16).

Repaired and/or reworked product shall be reinspected in accordance with the quality plan and/or documented procedures.

4.14 CORRECTIVE AND PREVENTIVE ACTION

4.14.1 General

The supplier shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

4.14.2 Corrective action

The procedures for corrective action shall include:

a) the effective handling of customer complaints and reports of product nonconformities;

b) investigation of the cause of nonconformities relating to product, process, and quality system, and recording the results of the investigation (see 4.16);

c) determination of the corrective action needed to eliminate the cause of nonconformities;

d) application of controls to ensure that corrective action is taken and that it is effective.

4.14.3 Preventive action

The procedures for preventive action shall include:

a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities;

b) determination of the steps needed to deal with any problems requiring preventive action;

c) initiation of preventive action and application of controls to ensure that it is effective;

d) confirmation that relevant information on actions taken is submitted for management review (see 4.1.3).

4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

4.15.1 General

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

4.15.2 Handling

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

4.15.3 Storage

The supplier shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch 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, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

4.15.5 Preservation

The supplier shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

4.15.6 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 CONTROL OF QUALITY RECORDS

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

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration 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 customer or the customer's representative for an agreed period.

NOTE 14 Records may be in the form of any type of media, such as hard copy or electronic media.

4.17 INTERNAL QUALITY AUDITS

The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 4.16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 4.16).

NOTES

15 The results of internal quality audits form an integral part of the input to management review activities (see 4.1.3).

16 Guidance on quality-system audits is given in ANSI/ASQC Q10011-1-1994, ANSI/ASQC Q10011-2-1994, and ANSI/ASQC Q10011-3-1994.

4.18 TRAINING

The supplier shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on 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 a specified requirement, the supplier shall establish and maintain documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

4.20 STATISTICAL TECHNIQUES

4.20.1 Identification of need

The supplier shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.

4.20.2 Procedures

The supplier shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 4.20.1.

ANNEX A (INFORMATIVE)

BIBLIOGRAPHY

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

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

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

[4] ANSI/ASQC Q10011-1-1994, *Guidelines for Auditing Quality Systems—Auditing.*

[5] ANSI/ASQC Q10011-2-1994, *Guidelines for Auditing Quality Systems—Qualification Criteria for Quality Systems Auditors.*

[6] ANSI/ASQC Q10011-3-1994, *Guidelines for Auditing Quality Systems—Management of Audit Programs.*

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[9] ISO 10012-1:1992, *Quality assurance requirements for measuring equipment—Part 1: Metrological confirmation system for measuring equipment.*

[10] ISO 10013:—[1], *Guidelines for developing quality manuals.*

[1] To be published.