CERTIFICATE

By Authority Of
THE UNITED STATES OF AMERICA
Legally Binding Document

By the Authority Vested By Part 5 of the United States Code § 552(a) and Part 1 of the Code of Regulations § 51 the attached document has been duly INCORPORATED BY REFERENCE and shall be considered legally binding upon all citizens and residents of the United States of America. *HEED THIS NOTICE*: Criminal penalties may apply for noncompliance.

Document Name: ASQC Q9004-1: Quality Management and Quality Systems Elements-Guidelines

CFR Section(s): 24 CFR 200.935(d)(4)(ii)(A)(5)

Standards Body: American Society for Quality Control

APPROVED

Official Incorporator:

THE EXECUTIVE DIRECTOR
OFFICE OF THE FEDERAL REGISTER
WASHINGTON, D.C.

ADOPTION NOTICE

ANSI/ASQC Q9004-1, "Quality Management and Quality System Elements--Guidelines," was adopted on 15 September 1994 for use by the Department of Defense (DoD). Proposed changes by DoD activities must be submitted to the DoD Adopting Activity: Office of the Assistant Secretary of the Air Force for Acquisition, Deputy Assistant Secretary for Management Policy and Program Integration, Manufacturing and Quality Division, ATTN: SAF/AQXM, 1060 Air Force Pentagon, Washington, DC 20330-1060. DoD activities may obtain copies of this standard from the Standardization Document Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 19111-5094. The private sector and other Government agencies may purchase copies from The American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.

Custodians:
Army - AR
Navy - OS
Air Force - 05

Adopting Activity:
Air Force - 05
(Project QCIC-0188)

AREA QCIC

DISTRIBUTION STATEMENT A: Approved for public release; distribution is unlimited.

AMERICAN NATIONAL STANDARD

Quality Management and Quality System Elements—Guidelines

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 management, quality systems, components, general conditions.

American National Standards: 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 an American National Standard does not in any respect preclude anyone, whether he or she has approved the standard or not, from manufacturing, 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 edition.

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 publication. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

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.

10 9 8 7 6 5 4 3 2 1

Printed in the United States of America

Printed on acid-free recycled paper

Published by:

ASQC
611 East Wisconsin Avenue
Milwaukee, Wisconsin 53202

Contents

Page

1 Scope 1

2 Normative references 1

3 Definitions 1

4 Management responsibility 2

5 Quality-system elements 5

6 Financial considerations of quality systems 7

7 Quality in marketing 8

8 Quality in specification and design 8

9 Quality in purchasing 11

10 Quality of processes 12

11 Control of processes 13

12 Product verification 15

13 Control of inspection, measuring, and test equipment 15

14 Control of nonconforming product 16

15 Corrective action 17

16 Postproduction activities 17

17 Quality records 18

18 Personnel 19

19 Product safety 20

20 Use of statistical methods 20

Annex
A Bibliography 21

Foreword

(This Foreword is not a part of American National Standard *Quality Management and Quality System Elements—Guidelines.)*

This American National Standard corresponds to the International Standard ISO 9004-1:1994. 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

0.1 GENERAL

ANSI/ASQC Q9004-1-1994 and all the International Standards in the ISO 9000 family are generic and independent of any specific industry or economic sector. Collectively they provide guidance for quality management and models for quality assurance.

The International Standards in the ISO 9000 family describe what elements quality systems should encompass, but not how a specific organization should implement these elements. Because the needs of organizations vary, it is not the purpose of these International Standards or the corresponding American National Standards to enforce uniformity of quality systems. The design and implementation of a quality system will be influenced by the particular objectives, products, processes, and individual practices of the organization.

A primary concern of any organization should be the quality of its products. (See 3.5 for the definition of "product" which includes service.)

In order to be successful, an organization should offer products that:

a) meet a well-defined need, use, or purpose;

b) satisfy customers' expectations;

c) comply with applicable standards and specifications;

d) comply with requirements of society (see 3.3);

e) reflect environmental needs;

f) are made available at competitive prices;

g) are provided economically.

0.2 ORGANIZATIONAL GOALS

In order to meet its objectives, the organization should ensure that the technical, administrative, and human factors affecting the quality of its products will be under control, whether hardware, software, processed materials, or services. All such control should be oriented towards the reduction, elimination, and, most importantly, prevention of quality nonconformities.

A quality system should be developed and implemented for the purpose of accomplishing the objectives set out in the organization's quality policy.

Each element (or requirement) in a quality system varies in importance from one type of activity to another and from one product to another.

In order to achieve maximum effectiveness and to satisfy customer expectations, it is essential that the quality system be appropriate to the type of activity and to the product being offered.

0.3 MEETING CUSTOMER/ORGANIZATION NEEDS AND EXPECTATIONS

A quality system has two interrelated aspects, as follows.

a) **The customer's needs and expectations**
For the customer, there is a need for confidence in the ability of the organization to deliver the desired quality as well as the consistent maintenance of that quality.

b) **The organization's needs and interests**
For the organization, there is a business need to attain and to maintain the desired quality at an optimum cost; the fulfillment of this aspect is related to the planned and efficient utilization of the technological, human, and material resources available to the organization.

Each of the above aspects of a quality system requires objective evidence in the form of information and data concerning the quality of the system and the quality of the organization's products.

0.4 BENEFITS, COSTS, AND RISKS

Benefit, cost, and risk considerations have great importance for both the organization and customer. These considerations are inherent aspects of most products. The possible effects and ramifications of these considerations are given in a to c.

a) **Benefit considerations**

For the customer, consideration has to be given to reduced costs, improved fitness for use, increased satisfaction, and growth in confidence.

For the organization, consideration has to be given to increased profitability and market share.

b) **Cost considerations**

For the customer, consideration has to be given to safety, acquisition cost, operating, maintenance, downtime and repair costs, and possible disposal costs.

For the organization, consideration has to be given to costs due to marketing and design deficiencies, including unsatisfactory product, rework, repair, replacement, reprocessing, loss of production, warranties, and field repair.

c) **Risk considerations**

For the customer, consideration has to be given to risks such as those pertaining to the health and safety of people, dissatisfaction with product, availability, marketing claims, and loss of confidence.

For the organization, consideration has to be given to risks related to deficient products which lead to loss of image or reputation, loss of market, complaints, claims, liability, and waste of human and financial resources.

0.5 CONCLUSIONS

An effective quality system should be designed to satisfy customer needs and expectations while serving to protect the organization's interests. A well-structured quality system is a valuable management resource in the optimization and control of quality in relation to benefit, cost, and risk considerations.

QUALITY MANAGEMENT AND QUALITY SYSTEM ELEMENTS—GUIDELINES

1 SCOPE

ANSI/ASQC Q9004-1-1994 provides guidance on quality management and quality-system elements.

The quality-system elements are suitable for use in the development and implementation of a comprehensive and effective in-house quality system, with a view to ensuring customer satisfaction.

ANSI/ASQC Q9004-1-1994 is not intended for contractual, regulatory, or certification use. Consequently, it is not a guideline for the implementing of ANSI/ASQC Q9001, ANSI/ASQC Q9002-1994, and ANSI/ASQC Q9003-1994. ISO 9000-2 should be used for that purpose.

The selection of appropriate elements contained in this part of ANSI/ASQC Q9004-1-1994 and the extent to which these elements are adopted and applied by an organization depends upon factors such as the market being served, nature of the product, production processes, and customer and consumer needs.

References in ANSI/ASQC Q9004-1-1994 to a "product" should be interpreted as applicable to the generic product categories of hardware, software, processed materials or service (in accordance with the definition of "product" in ISO 8402).

NOTES

1 For further guidance, see ISO 9004-2 and ISO 9004-3.

2 For informative references, see annex A.

2 NORMATIVE REFERENCES

The following standards contain provisions which, through reference in this text, constitute provisions of ANSI/ASQC Q9004-1-1994. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on ANSI/ASQC Q9004-1-1994 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

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

3 DEFINITIONS

This revision of ANSI/ASQC Q94-1987 has improved the harmonization of terminology with other American National Standards in the ANSI/ASQC Q9000 series and with other International Standards in the ISO 9000 family. Table 1 shows the supply-chain terminology used in these American National Standards.

Thus, the term "subcontractor" is used rather than the term "supplier" in ANSI/ASQC Q9004-1-1994 to avoid confusion with the meaning of the term "supplier" in ANSI/ASQC Q9000-1-1994 and ANSI/ASQC Q9001-1994. See ANSI/ASQC Q9000-1-1994 for a fuller explanation of the basis for usage of these terms.

For the purposes of ANSI/ASQC Q9004-1-1994, the definitions given in ISO 8402 apply.

For the convenience of users of ANSI/ASQC Q9004-1-1994, the following definitions are quoted from ISO 8402.

Table 1 — Relationships of organizations in the supply chain

ANSI/ASQC Q9000-1-1994	Subsupplier	→	supplier or organization	→ customer
ANSI/ASQC Q9001-1-1994 ANSI/ASQC Q9002-1994 ANSI/ASQC Q9003-1994	Subcontractor	→	supplier	→ customer
ANSI/ASQC Q9004-1-1994	Subcontractor	→	organization	→ customer

3.1 organization: Company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

3.2 customer: Recipient of a product provided by the supplier.

NOTES

3 In a contractual situation, the customer is called the "purchaser."[1)]

4 The customer may be, for example, the ultimate consumer, user, beneficiary, or purchaser.

5 The customer can be either external or internal to the organization.

3.3 requirements of society: Obligations resulting from laws, regulations, rules, codes, statutes, and other considerations.

NOTES

6 "Other considerations" include protection of the environment, health, safety, security, and conservation of energy and natural resources.

7 All requirements of society should be taken into account when defining the requirements for quality.

8 Requirements of society include jurisdictional and regulatory requirements. These may vary from one jurisdiction to another.

3.4 quality plan: Document setting out the specific quality practices, resources, and sequence of activities relevant to a particular product, project, or contract.

NOTES

9 A quality plan usually makes reference to the parts of the quality manual applicable to the specific case.

10 Depending on the scope of the plan, a qualifier may be used, for example, quality assurance plan, quality management plan.

3.5 product: Result of activities or processes.

NOTES

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

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

13 A product can be intended (e.g., offering to customers) or unintended (e.g., pollutant or unwanted effects).

3.6 service: Result generated by activities at the interface between the supplier and the customer and by supplier internal activities to meet the customer needs.

NOTES

14 The supplier or the customer may be represented at the interface by personnel or equipment.

15 Customer activities at the interface with the supplier may be essential to the service delivery.

16 Delivery or use of tangible products may form part of the service delivery.

17 A service may be linked with the manufacture and supply of tangible product.

4 MANAGEMENT RESPONSIBILITY

4.1 General

The responsibility for and commitment to a quality policy belongs to the highest level of management. Quality management encompasses all activities of the overall management function that determine the quality policy, objectives, and responsibilities, and implement them by means such as quality planning, quality control, quality assurance, and quality improvement within the quality system.

4.2 Quality policy

The management of an organization should define and document its quality policy. This policy should be consistent with other policies within the organization. Management should take all necessary measures to ensure that its quality policy is understood, implemented, and reviewed at all levels of the organization.

4.3 Quality objectives

4.3.1 Management should document objectives and commitments pertaining to key elements of quality, such as fitness for use, performance, safety, and dependability.

1) The recommended harmonized term is "customer" as shown in Table 1 of ANSI/ASQC Q9004-1-1994. The term "purchaser" was used in ANSI/ASQC Q91-1987, ANSI/ASQC Q92-1987, and ANSI/ASQC Q93-1987.

4.3.2 The calculation and evaluation of costs associated with all quality elements and objectives should always be an important consideration, with the objective of minimizing quality losses.

4.3.3 Appropriate levels of management should document specific quality objectives consistent with quality policy as well as other objectives of the organization.

4.4 Quality system

4.4.1 A quality system is the organizational structure, procedures, processes, and resources needed to implement quality management.

4.4.2 The organization's management should develop, establish, and implement a quality system to accomplish the stated policies and objectives.

4.4.3 The quality system should be structured and adapted to the organization's particular type of business and should take into account the appropriate elements outlined in ANSI/ASQC Q9004-1-1994.

4.4.4 The quality system should function in such a manner as to provide confidence that:

a) the system is understood, implemented, maintained, and effective;

b) the products actually do satisfy customer needs and expectations;

c) the needs of both society and the environment have been addressed;

d) emphasis is placed on problem prevention rather than dependence on detection after occurrence.

5 QUALITY-SYSTEM ELEMENTS

5.1 Extent of application

5.1.1 The quality system typically applies to, and interacts with, all activities pertinent to the quality of a product. It will involve all phases in the life-cycle of a product and processes, from initial identification of market needs to final satisfaction of requirements. Typical phases are:

a) marketing and market research;

b) product design and development;

c) process planning and development;

d) purchasing;

e) production, or provision of services;

f) verification;

g) packaging and storage;

h) sales and distribution;

i) installation and commissioning;

j) technical assistance and servicing;

k) after sales;

l) disposal or recycling at the end of useful life.

NOTE 18 Figure 1 gives a schematic representation of the typical life-cycle phases of a product.

5.1.2 In the context of interacting activities within an organization, marketing and design should be emphasized as especially important for

—determining and defining customer needs, expectations, and other product requirements, and

—providing the concepts (including supporting data) for producing a product to documented specifications at optimum cost.

5.2 STRUCTURE OF THE QUALITY SYSTEM

5.2.1 General

Input from the market should be used to improve new and existing products and to improve the quality system.

Management is ultimately responsible for establishing the quality policy and for decisions concerning the initiation, development, implementation, and maintenance of the quality system.

5.2.2 Responsibility and authority

Activities contributing to quality, whether directly or indirectly, should be defined and documented, and the following actions taken.

a) General and specific quality-related responsibilities should be explicitly defined.

b) Responsibility and authority delegated to each activity contributing to quality should be clearly established. Responsibility, organizational freedom, and authority to act should be sufficient to attain the assigned quality objectives with the desired efficiency.

c) Interface control and coordination measures between different activities should be defined.

d) In organizing a well-structured and effective quality system, emphasis should be placed on the identification

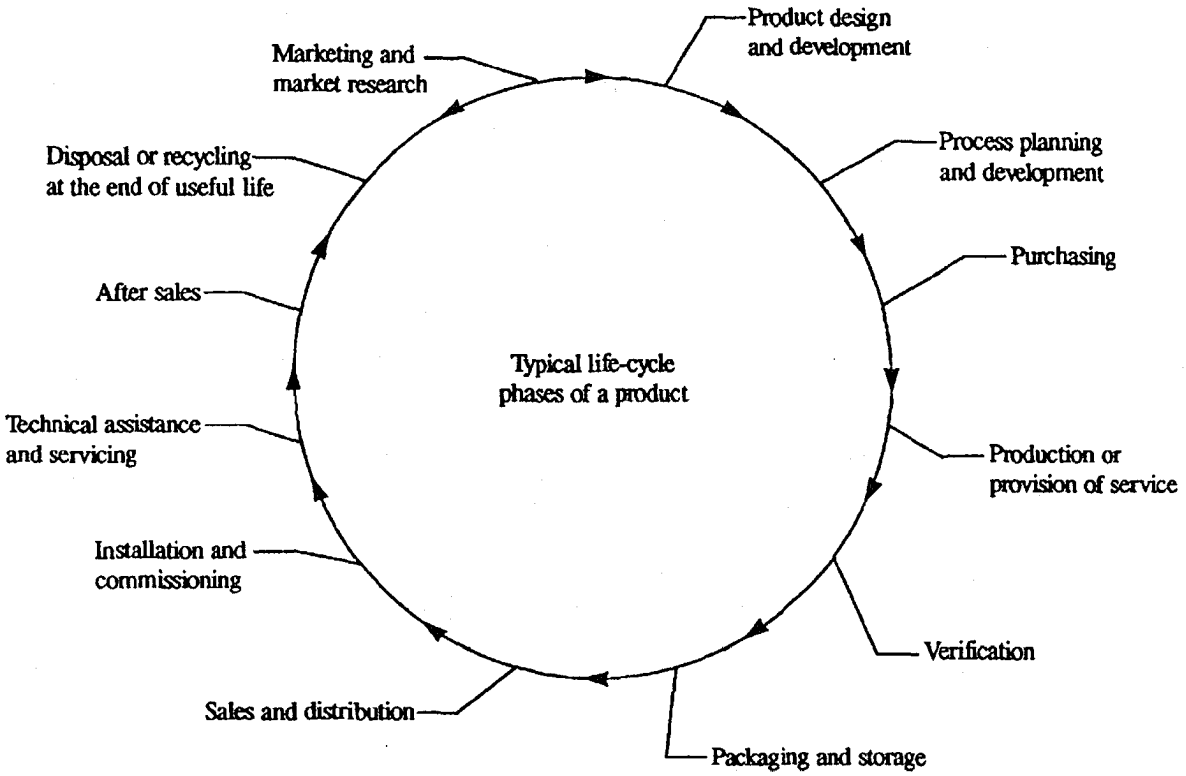

Figure 1 — Main activities having an impact on quality

of potential or actual quality problems and the implementation of preventive or corrective action (see clauses 14 and 15).

5.2.3 Organizational structure

Functions related to the quality system should be clearly established within the overall organizational structure. The lines of authority and communication should be defined.

5.2.4 Resources and personnel

Management should identify resource requirements, and provide sufficient and appropriate resources essential to the implementation of the quality policy and the achievement of quality objectives. For example, these resources can include:

a) human resources and specialized skills;

b) design and development equipment;

c) manufacturing equipment;

d) inspection, test, and examination equipment;

e) instrumentation and computer software.

Management should determine the level of competence, experience, and training necessary to ensure the capability of personnel (see clause 18).

Management should identify quality-related factors affecting market position and objectives relative to products, processes, or associated services, in order to allocate organization resources on a planned and timely basis.

Programs and schedules covering these resources and skills should be consistent with the organization's overall objectives.

5.2.5 Operational procedures

The quality system should be organized in such a way that adequate and continuous control is exercised over all activities affecting quality.

The quality system should emphasize preventive actions that avoid occurrence of problems, while maintaining the ability to respond to and correct failures, should they occur.

Documented operational procedures coordinating different activities with respect to an effective quality system should be developed, issued, and maintained to implement the quality policy and objectives. These documented procedures should specify the objectives and performance of the various activities having an impact on quality (see Figure 1).

All documented procedures should be stated simply, unambiguously, and understandably, and should indicate methods to be used and criteria to be satisfied.

5.2.6 Configuration management

The quality system should include documented procedures for configuration management to the extent appropriate. This discipline is initiated early in the design phase and continues through the whole life-cycle of a product. It assists in the operation and control of design, development, production, and use of a product, and gives management visibility of the state of documentation and product during its life-time.

Configuration management can include: configuration identification, configuration control, configuration status accounting, and configuration audit. It relates to several of the activities described in ANSI/ASQC Q9004-1-1994.

5.3 Documentation of the quality system

5.3.1 Quality policies and procedures

All the elements, requirements, and provisions adopted by an organization for its quality system should be documented in a systematic, orderly, and understandable manner in the form of policies and procedures. However, care should be taken to limit documentation to the extent pertinent to the application.

The quality system should include adequate provision for the proper identification, distribution, collection, and maintenance of all quality documents.

5.3.2 Quality-system documentation

5.3.2.1 The typical form of the main document used to demonstrate or describe a documented quality system is a "quality manual." For further guidance, see ISO 10013.

5.3.2.2 The primary purpose of a quality manual is to define an outline structure of the quality system while serving as a permanent reference in the implementation and maintenance of that system.

5.3.2.3 Documented procedures should be established for making changes, modifications, revisions, or additions to the contents of a quality manual.

5.3.2.4 Supporting the quality manual are documented quality-system procedures (e.g., design, purchasing, and process work instructions). These documented procedures can take various forms, depending on

—the size of the organization,

—the specific nature of the activity, and

—the intended scope and structure of the quality manual.

Documented procedures may apply to one or more parts of the organization.

5.3.3 Quality plans

For any product or process, management should ensure that documented quality plans are prepared and maintained. These should be consistent with all other requirements of the organization's quality system, and should ensure that specified requirements for a product, project, or contract are met. A quality plan may be a part of a larger overall plan. A quality plan is particularly necessary for a new product or process, or when there is significant change to an existing product or process.

Quality plans should define:

a) the quality objectives to be attained (e.g., characteristics or specifications, uniformity, effectiveness, aesthetics, cycle time, cost, natural resources, utilization, yield, and dependability);

b) the steps in the processes that constitute the operating practice of the organization (a flowchart or similar diagram can be used to demonstrate the elements of the process);

c) the specific allocation of responsibilities, authority, and resources during the different phases of the project;

d) the specific documented procedures and instructions to be applied;

e) suitable testing, inspection, examination, and audit programs at appropriate stages (e.g., design and development);

f) a documented procedure for changes and modifications in a quality plan as projects proceed;

g) a method for measuring the achievement of the quality objectives;

h) other actions necessary to meet the objectives.

Quality plans may be included or referenced in the quality manual, as appropriate.

To facilitate achievement of the objectives of a quality plan, documented operational control as described in ANSI/ASQC Q9004-1-1994 should be used.

5.3.4 Quality records

Quality records, including charts pertaining to design, inspection, testing, survey, audit, review, or related results, should be maintained as important evidence to demonstrate conformance to specified requirements and the effective operation of the quality system (see clause 17).

5.4 Auditing the quality system

5.4.1 General

Audits should be planned and carried out to determine if the activities and related results of the organization's quality system comply with planned arrangements, and to determine the effectiveness of the quality system. All elements should be internally audited and evaluated on a regular basis, considering the status and importance of the activity to be audited. For this purpose, an appropriate audit program should be established and implemented by the organization's management.

5.4.2 Audit program

The audit program should cover:

a) planning and scheduling the specific activities and areas to be audited;

b) assignment of personnel with appropriate qualifications to conduct audits;

c) documented procedures for carrying out audits, including recording and reporting the results of the quality audit and reaching agreement on timely corrective actions on the deficiencies found during the audit.

Apart from planned and systematic audits, other factors necessitating audits can be organizational changes, market feedback, nonconformity reports, and surveys.

5.4.3 Extent of audits

Objective evaluations of quality-system activities by competent personnel should include the following activities or areas:

a) organizational structures;

b) administrative, operational, and quality-system procedures;

c) personnel, equipment, and material resources;

d) work areas, operations, and processes;

e) products being produced (to establish the degree of conformance to standards and specifications);

f) documentation, reports, and record keeping.

Personnel conducting audits of quality-system elements should be independent of those having direct responsibilities for the specific activities or areas being audited. An audit plan should be prepared and documented to include the items listed in a to f.

5.4.4 Audit reporting

Audit observations, conclusions, and agreements on timely corrective action should be recorded and submitted for appropriate action by the management responsible for the area audited, and communicated for the information of management with executive responsibility for quality.

The following items should be covered in the audit report:

a) all examples of nonconformities or deficiencies;

b) appropriate and timely corrective action.

5.4.5 Follow-up action

Implementation and effectiveness of corrective actions resulting from previous audits should be assessed and documented.

NOTE 19 For further guidance on quality auditing, qualifications of auditors and management of audit programs, see ANSI/ASQC Q10011-1-1994, ANSI/ASQC Q10011-2-1994, and ANSI/ASQC Q10011-3-1994.

5.5 REVIEW AND EVALUATION OF THE QUALITY SYSTEM

The organization's management should provide for independent review and evaluation of the quality system at defined intervals. The reviews of the quality policy and objectives should be carried out by top management, and the review of supporting activities should be carried out by management with executive responsibilities for quality and other appropriate members of management, utilizing competent independent personnel as decided on by the management.

Reviews should consist of well-structured and comprehensive evaluations which include:

a) results from internal audits centred on various elements of the quality system (see 5.4.3);

b) the overall effectiveness in satisfying the guidance of ANSI/ASQC Q9004-1-1994 and the organization's stated quality policy and objectives;

c) considerations for updating the quality system in relation to changes brought about by new technologies, quality concepts, market strategies, and social or environmental conditions.

Observations, conclusions, and recommendations reached as a result of review and evaluation should be documented for necessary action.

5.6 Quality improvement

When implementing a quality system, the management of an organization should ensure that the system will facilitate and promote continuous quality improvement.

Quality improvement refers to the actions taken throughout the organization to increase the effectiveness and efficiency of activities and processes to provide added benefits to both the organization and its customers.

In creating an environment for quality improvement, consideration should be given to:

a) encouraging and sustaining a supportive style of management;

b) promoting values, attitudes, and behavior that foster improvement;

c) setting clear quality-improvement goals;

d) encouraging effective communication and teamwork;

e) recognizing successes and achievements;

f) training and educating for improvement.

NOTE 20 Further guidance is given in ISO 9004-4.

6 FINANCIAL CONSIDERATIONS OF QUALITY SYSTEMS

6.1 General

It is important that the effectiveness of a quality system be measured in financial terms. The impact of an effective quality system upon the organization's profit and loss statement can be highly significant, particularly by improvement of operations, resulting in reduced losses due to error and by making a contribution to customer satisfaction.

Such measurement and reporting can provide a means for identifying inefficient activities, and initiating internal improvement activities.

By reporting quality-system activities and effectiveness in financial terms, management will receive the results in a common business language from all departments.

6.2 Approaches to financial reporting of quality-system activities

6.2.1 General

Some organizations find it useful to report the financial benefits using systematic quality financial reporting procedures.

The approach(es) to financial reporting selected and used by particular organizations will be dependent upon their individual structures, their activities, and the maturity of their quality systems.

6.2.2 Approaches

There are various approaches to gathering, presenting, and analyzing the elements of financial data. The approaches given in a to c have been found to be useful, but do not exclude others, or adaptations or combinations of them.

a) **Quality-costing approach**

This approach addresses quality-related costs, which are broadly divided into those arising from internal operations and external activities.

Cost elements for internal operations are analyzed according to the PAF (prevention, appraisal, failure) costing model.

Prevention and appraisal costs are considered as investments, while failure costs are considered as losses. The components of the costs are:

1) prevention: efforts to prevent failures;

2) appraisal: testing, inspection, and examination to assess whether requirements for quality are being fulfilled;

3) internal failure: costs resulting from a product failing to meet the quality requirements prior to delivery (e.g., re-performing a service, reprocessing, rework, retest, scrap);

4) external failure: costs resulting from a product failing to meet the quality requirements after delivery (e.g., product maintenance and repair, warranties and returns, direct costs and allowances, product recall costs, liability costs).

b) **Process-cost approach**
This approach analyzes the costs of conformity and the costs of nonconformity for any process, both of which can be the source of savings. These are defined as:

1) cost of conformity: cost to fulfill all of the stated and implied needs of customers in the absence of failure of the existing process;

2) cost of nonconformity: cost incurred due to failure of the existing process.

c) **Quality-loss approach**
This approach focuses on internal and external losses due to poor quality and identifies tangible and intangible loss types. Typical external intangible losses are loss of future sales due to customer dissatisfaction. Typical internal intangible losses arise from lower work efficiency due to rework, poor ergonomics, missed opportunities, etc. Tangible losses are internal and external failure costs.

6.3 Reporting

The financial reporting of quality activities should be regularly provided to and monitored by management, and be related to other business measures such as "sales," "turnover," or "added value" in order to provide for a realistic, entrepreneurial

—evaluation of the adequacy and effectiveness of the quality system,

—identification of additional areas requiring attention and improvement, and

—establishment of quality and cost objectives for the following period.

The elements of financial quality reports are in many cases already available in the organization, but in other forms. Their reporting as a financial quality report can require regrouping of individual elements from other reports.

7 QUALITY IN MARKETING

7.1 Marketing requirements

The marketing function should establish adequately defined and documented requirements for the quality of the product. Particularly at this early stage in the product life-cycle, it is important to consider the requirements for all the elements of the total product, whether hardware, software, processed materials, or services. In fact, all products involve some element of service, and many products involve several generic product categories. The marketing function should:

a) determine the need for a product;

b) define the market demand and sector, so that product grade, quantity, price, and timing can be determined;

c) determine specific customer requirements, or review general market needs; actions include assessment of any unstated expectations or biases held by customers;

d) communicate all customer requirements within the organization;

e) ensure that all relevant organizational functions agree that they have the capability to meet customer requirements.

7.2 Defining product specification

The marketing function should provide the organization with a formal statement or outline of product requirements. Specific customer and general market requirements and expectations should be translated into a preliminary set of specifications as the basis for subsequent design work. Among the elements that may be included are the following requirements:

a) performance characteristics (e.g., environmental and usage conditions and dependability);

b) sensory characteristics (e.g., style, color, taste, smell);

c) installation, arrangement layout or fit;

d) applicable standards and statutory regulations;

e) packaging;

f) quality verification and/or assurance.

7.3 Customer feedback information

The marketing function should establish an information-monitoring and feedback system on a continuous basis. All information pertinent to the customers' use of and satisfaction with the quality of a product should be analyzed, collated, interpreted, verified, and reported in accordance with documented procedures. Such information will help to determine the nature and extent of product problems in relation to customer experience and expectations. In addition, the feedback information can lead to management action resulting in product improvement or to new product offerings (see also 8.8, 8.9, clause 15, and 16.6).

8 QUALITY IN SPECIFICATION AND DESIGN

8.1 Contribution of specification and design to quality

The specification and design function should provide for the translation of customer needs into technical specifications

for materials, products, and processes. This should result in a product that provides customer satisfaction at an acceptable price that gives a satisfactory financial return for the organization. The specification and design should be such that the product is producible, verifiable, and controllable under the proposed production, installation, commissioning, or operational conditions.

8.2 Design planning and objectives (defining the project)

8.2.1 Management should prepare plans that define the responsibility for each design and development activity inside and/or outside the organization, and ensure that all those who contribute to design are aware of their responsibilities in relation to the full scope of the project.

8.2.2 In its delegation of responsibilities and authority for quality, management should ensure that design functions provide clear and definitive technical data for procurement, the execution of work, and verification of conformance of products and processes to specification requirements.

8.2.3 Management should establish time-phased design programs with holdpoints appropriate to the nature of the product and process. The extent of each phase, and the position of the holdpoints at which evaluations of the product or the process will take place, can depend upon several elements, such as

—the product's application,

—its design complexity,

—the extent of innovation and technology being introduced, and

—the degree of standardization and similarity with past proven designs.

8.2.4 In addition to customer needs, consideration should be given to the requirements relating to safety, environmental, and other regulations, including items in the organization's quality policy which may go beyond existing statutory requirements (see also 3.3).

8.2.5 The design should unambiguously and adequately define characteristics important to quality, such as the acceptance criteria. Both fitness for purpose and safeguards against misuse should be considered. Product definition can also include dependability and serviceability through a reasonable life expectancy, including benign failure and safe disposability, as appropriate.

8.3 Product testing and measurement

The methods of measurement and test, and the acceptance criteria applied to evaluate the product and processes during both the design and production phases, should be specified. These should include the following:

a) performance target values, tolerances, and attribute features;

b) acceptance criteria;

c) test and measurement methods, equipment, and computer software (see clause 13).

8.4 Design review

8.4.1 General

At the conclusion of each phase of design development, a formal, documented, systematic, and critical review of the design results should be planned and conducted. This should be distinguished from a project progress meeting. Participants at each design review should include representatives of all functions affecting quality, as appropriate to the phase being reviewed. The design review should identify and anticipate problem areas and inadequacies, and initiate corrective actions to ensure that the final design and supporting data meet customer requirements.

8.4.2 Elements of design reviews

As appropriate to the design phase and product, the elements outlined in a to c should be considered.

a) **Items pertaining to customer needs and satisfaction**

1) comparison of customer needs expressed in the product specification with technical specifications for materials, products, and processes;

2) validation of the design through prototype tests;

3) ability to perform under expected conditions of use and environment;

4) unintended uses and misuses;

5) safety and environmental compatibility;

6) compliance with regulatory requirements, national and International Standards, and organization practices;

7) comparisons with competitive designs;

8) comparison with similar designs, especially analysis of the history of internal and external problems to avoid repeating problems.

b) **Items pertaining to product specification**

1) dependability and serviceability requirements;

2) permissible tolerances and comparison with process capabilities;

3) product acceptance criteria;

4) installability, ease of assembly, storage needs, shelf-life, and disposability;

5) benign failure and fail-safe characteristics;

6) aesthetic specifications and acceptance criteria;

7) failure mode and effect analysis, and fault tree analysis;

8) ability to diagnose and correct problems;

9) labeling, warnings, identification, traceability requirements, and user instructions;

10) review and use of standard parts.

c) **Items pertaining to process specification**

1) ability to produce product conforming to the design, including special process needs, mechanization, automation, assembly, and installation of components;

2) capability to inspect and test the design, including special inspection and test requirements;

3) specification of materials, components, and subassemblies, including approved supplies and subcontractors as well as availability;

4) packaging, handling, storage, and shelf-life requirements, especially safety factors relating to incoming and outgoing items.

8.4.3 Design verification

All designs should be verified to ensure that product specifications are fulfilled (see 7.2). In addition to design review, design verification should include one or more of the following methods:

a) performing alternative calculations, made to verify the correctness of the original calculations and analyses;

b) testing and demonstrations (e.g., by model or prototype tests); if this method is adopted, the test programs should be clearly defined and the results documented;

c) independent verification, to verify the correctness of the original calculations and/or other design activities.

8.5 Design qualification and validation

The design process should provide periodic evaluation of the design at significant stages. Such evaluation can take the form of analytical methods, such as FMEA (failure mode and effect analysis), fault tree analysis, or risk assessment, as well as inspection and test of prototype models and/or actual production samples. The amount and degree of testing (see 8.3) should be related to the identified risks. Independent evaluation can be used, as appropriate, to verify original calculations, provide alternative calculations, or perform tests. A number of samples should be examined by tests and/or inspection to provide adequate statistical confidence in the results. The tests should include the following activities:

a) evaluation of performance, durability, safety, reliability, and maintainability under expected storage and operational conditions;

b) inspections to verify that all design features conform to defined user needs and that all authorized design changes have been accomplished and recorded;

c) validation of computer systems and software.

The results of all tests and evaluations should be documented regularly throughout the qualification test-cycle. Review of test results should include nonconformity and failure analysis.

8.6 Final design review and production release

The final design should be reviewed and the results appropriately documented in specifications and drawings, which then form the design baseline. Where appropriate, this should include a description of initial test units and any modifications made to correct deficiencies identified during the qualification test programmes. The total document package that defines the design baseline (output) should require approval at appropriate levels of management affected by or contributing to the product. This approval constitutes the production release and signifies that the design can be realized.

8.7 Market-readiness review

A determination should be made as to whether the organization has the capability to deliver the new or redesigned product. Depending upon the type of product, the review can cover the following points:

a) availability and adequacy of installation, operation, maintenance, and repair manuals;

b) existence of adequate distribution and customer after-sales service;

c) training of field personnel;

d) availability of spare parts;

e) field trials;

f) satisfactory completion of qualification tests;

g) physical inspection of early production units and their packaging and labeling;

h) evidence of process capability to meet specification on production equipment.

8.8 Design-change control

The quality system should include documented procedures for controlling the release, change, and use of documents that define the design input and the design baseline (output), and for authorizing the necessary work to be performed to implement changes and modifications that can affect product during its entire life-cycle, including changes in software and service instructions. The procedures should provide for various necessary approvals, specified points and times for implementing changes, removing obsolete drawings and specifications from work areas, and verification that changes are made at the appointed times and places. These procedures should handle emergency changes necessary to prevent production or delivery of nonconforming product. Consideration should be given to instituting formal design reviews and validation testing when the magnitude, complexity, or risk associated with the change warrant such actions.

8.9 Design requalification

Periodic evaluation of product should be performed in order to ensure that the design is still valid. This should include a review of customer needs and technical specifications in the light of field experiences, field performance surveys, or new technology and techniques. The evaluation should also consider process modifications. The quality system should ensure that any production and field experience indicating the need for design change is fed back for analysis. Care should be taken that design changes do not cause degradation of product quality for example, and that proposed changes are evaluated for their impact on all product characteristics in the original product specification.

8.10 Configuration management in design

This discipline may be initiated once the requirements have been defined, but is most useful during the design phase. It continues through the whole life-cycle of a product (see 5.2.6).

9 QUALITY IN PURCHASING

9.1 General

Purchases become part of the organization's product and directly affect the quality of its product. All purchasing activities should be planned and controlled by documented procedures. Purchased services such as testing, calibration, and subcontracted processing should also be included. A close working relationship and feedback system should be established with each subcontractor. In this way, continual quality improvements can be maintained and disputes avoided or settled quickly. This close working relationship and feedback system will benefit both parties.

The quality system for purchasing should include the following elements as a minimum:

a) The applicable issue of specifications, drawings, purchase documents and other technical data (see 9.2);

b) selection of qualified subcontractors (see 9.3);

c) agreement on quality assurance (see 9.4);

d) agreement on verification methods (see 9.5);

e) provisions for settlement of disputes (see 9.6);

f) receiving inspection procedures (see 9.7);

g) receiving controls (see 9.7);

h) receiving quality records (see 9.8).

9.2 Requirements for specifications, drawings, and purchase documents

The successful purchase of supplies begins with a clear definition of the requirements. Usually these requirements are contained in contract specifications, drawings, and purchase documents which are provided to the subcontractor.

The purchasing activity should develop documented procedures to ensure that the requirements for the supplies are clearly defined, communicated, and, most importantly, are completely understood by the subcontractor. These methods may include documented procedures for the preparation of specifications, drawings, and purchase documents, meetings with subcontractors prior to the release of the purchase document, and other activities appropriate for the supplies being procured.

Purchasing documents should contain data clearly describing the product ordered. Typical elements are as follows:

a) precise identification of type, class, and grade;

b) inspection instructions and applicable issue of specifications;

c) quality-system standard to be applied.

Purchasing documents should be reviewed and approved for accuracy and completeness prior to release.

9.3 Selection of acceptable subcontractors

Each subcontractor should have a demonstrated capability to furnish product which meets all the requirements of the specifications, drawings, and purchase documents.

The methods of establishing this capability can include, but are not limited to, any combination of the following:

a) on-site evaluation of subcontractor's capability and/or quality system;

b) evaluation of product samples;

c) past history with similar products;

d) test results of similar products;

e) published experience of other users.

9.4 Agreement on quality assurance

The organization should develop a clear agreement with subcontractors for the assurance of product supplied. This can be achieved by one or more of the following:

a) reliance on subcontractor's quality system;

b) submission of specified inspection/test data and process-control records with shipments;

c) 100% inspection/testing by the subcontractor;

d) lot acceptance inspection/testing by sampling by the subcontractor;

e) implementation of a formal quality system by the subcontractor as specified by the organization; in certain cases, a formal quality-assurance model may be involved (see ANSI/ASQC Q9001-1994, ANSI/ASQC Q9002-1994, and ANSI/ASQC Q9003-1994 for further information);

f) periodic evaluation of subcontractor quality practices by the organization or by a third party;

g) in-house receiving inspection or sorting.

9.5 Agreement on verification methods

A clear agreement should be developed with the subcontractor on the methods by which conformance to requirements will be verified. Such agreements may also include the exchange of inspection and test data with the aim of furthering quality improvements. Reaching agreement can minimize difficulties in the interpretation of requirements as well as inspection, test, or sampling methods.

9.6 Provisions for settlement of disputes

Systems and procedures should be established by which settlement of disputes regarding quality can be reached with subcontractors. Provisions should exist for dealing with routine and nonroutine matters.

A very important aspect of these systems and procedures is the provision of improved communication channels between the organization and the subcontractor on matters affecting quality.

9.7 Receiving inspection planning and control

Appropriate measures should be established to ensure that received materials are properly controlled. These procedures should include quarantine areas or other appropriate methods to prevent unintended use or installation of nonconforming materials (see 14.3).

The extent to which receiving inspection will be performed should be carefully planned. The characteristics to be inspected should be based on the cruciality of the product. The capability of the subcontractor should also be considered, taking into account the factors listed in 9.3. The level of inspection should be selected so as to balance the costs of inspection against the consequences of inadequate inspection.

It is also necessary to ensure, before the incoming product arrives, that all the necessary tools, gauges, meters, instruments, and equipment are available and properly calibrated. Personnel should be adequately trained.

9.8 Quality records related to purchasing

Appropriate quality records related to product received should be maintained. This will ensure the availability of historical data to assess subcontractor performance and quality trends.

In addition, it may be useful, and in certain instances essential, to maintain records of lot identification for the purposes of traceability.

10 QUALITY OF PROCESSES

10.1 Planning for process control

10.1.1 Planning of processes should ensure that these proceed under controlled conditions in the specified manner and sequence. Controlled conditions include appropriate controls for materials, approved production, installation, and servicing equipment, documented procedures or quality plans, computer software, reference standards/codes, suitable approval of processes and personnel, as well as associated supplies, utilities, and environments.

The operation of processes should be specified to the necessary extent by documented work instructions.

Process-capability studies should be conducted to determine the potential effectiveness of a process (see 10.2).

Common practices that can be beneficially applied throughout the organization should be documented and referenced in all appropriate procedures and instructions. These should describe the criteria for determining satisfactory work completion and conformity to specification and standards of good workmanship. Workmanship criteria should be stipulated in the clearest practical manner by written standards, photographs, illustrations, and/or representative samples.

10.1.2 Verification of the quality status of a hardware product, process, software, processed material, service, or environment should be considered at important points in the production sequence to minimize effects of errors and to maximize yields. The use of control charts and statistical sampling procedures and plans are examples of techniques employed to facilitate process control (see also 12.2).

10.1.3 Monitoring and control of processes should relate directly to finished product specifications or to an internal requirement, as appropriate. If verification of the process variables through some measurement procedure is not physically or economically practical or feasible, then verification will have to depend primarily on verification of final product characteristics. In all cases, relationships between in-process controls, their specifications, and final product specifications should be developed, communicated to the personnel concerned, and then documented.

10.1.4 All in-process and final verifications should be planned and specified. Documented test and inspection procedures should be maintained for each quality characteristic to be checked. These should include the specific equipment to perform such checks and tests, and the specified requirements and workmanship criteria.

10.1.5 The appropriate methods of cleaning and preserving, and the details of packing, including moisture elimination, cushioning, blocking, and crating, should be established and maintained in documented procedures.

10.1.6 Efforts to develop new methods for improving process quality should be encouraged.

10.2 Process capability

Processes should be verified as being capable of producing product in accordance with specifications. Operations associated with product or process characteristics that can have a significant effect on product quality should be identified. Appropriate control should be established to ensure that these characteristics remain within the specification, or that appropriate modifications or changes are made.

Verification of processes should include material, equipment, computer system and software, procedures, and personnel.

10.3 Supplies, utilities and environment

Where important to product quality characteristics, auxiliary materials and utilities, such as water, compressed air, electrical power, and chemicals used for processing, should be controlled and verified periodically to ensure uniformity of effect on the process. Where environmental conditions, such as temperature, humidity and cleanliness, are important to product quality, appropriate limits should be specified, controlled, and verified.

10.4 Handling

The handling of product requires proper planning, control, and a documented system for incoming, in-process, and final product; this applies not only during delivery but up to the time of being put into use.

The methods of handling of product should provide for the correct selection and use of suitable pallets, containers, conveyors, and vehicles to prevent damage or deterioration due to vibration, shock abrasion, corrosion, temperature, or any other conditions occurring during the production or delivery processes.

11 CONTROL OF PROCESSES

11.1 General

Product quality should be addressed in each phase of the life-cycle (see 5.1.1).

11.2 Material control, traceability, and identification

11.2.1 Material control

All materials and parts should conform to specified requirements before being introduced into a process. However, in determining the amount and nature of receiving inspection necessary, consideration should be given to

cost impact and the effect that substandard material quality will have on production flow.

In-process product, including that in in-process inventory stockrooms, should be appropriately stored, segregated, handled, and preserved to maintain its suitability. Special consideration should be given to shelf-life and deterioration control, including assessment of product in stock at appropriate intervals. (For final product storage, see 16.1.)

11.2.2 Traceability

Where traceability of product is important, appropriate identification should be maintained throughout the process, from receipt and during all stages of production, delivery, and installation, to ensure traceability to original material identification and verification status (see 11.7 and 14.2).

11.2.3 Identification

The marking and labeling of materials should be legible, durable and in accordance with specifications. Materials should be uniquely identified from the time of initial receipt, to delivery and installation at the final destination. The identification should be in accordance with documented procedures, and should be recorded. This should enable a particular product to be identified in the event that a recall or special inspection becomes necessary.

11.3 Equipment control and maintenance

All equipment, including fixed machinery, jigs, fixtures, tooling, templates, patterns, and gauges, should be proved for accuracy prior to use. Special attention should be paid to computers used in controlling processes, and especially the maintenance of the related software (see 13.1).

Equipment should be appropriately stored and adequately protected between use, and verified or recalibrated at appropriate intervals to ensure that the requirements concerning accuracy (trueness and precision) are fulfilled.

A program of preventive maintenance should be established to ensure continued process capability. Special attention should be given to equipment characteristics that contribute to product quality.

11.4 Process-control management

Processes which are important to product quality should be planned, approved, monitored, and controlled. Particular consideration should be given to product characteristics which cannot be easily or economically measured, and those requiring special skills.

Process variables should be monitored, controlled, and verified at appropriate frequencies to assure:

a) the accuracy and variability of equipment used;

b) the skill, capability, and knowledge of operators;

c) the accuracy of measurement results and data used to control the process;

d) process environment and other factors affecting quality, such as time, temperature, and pressure;

e) appropriate documentation of process variables, equipment, and personnel.

In some cases, for example where process deficiencies may become apparent only after the product is in use, the results of processes cannot be directly verified by subsequent inspection or test of the product itself. Such processes require prequalification (validation) to ensure process capability and control of all critical variables during process operation.

11.5 Documentation

Documentation should be controlled as specified by the quality system (see 5.3 and 17.3).

11.6 Process-change control

Those responsible for authorization of process changes should be clearly designated and, where necessary, customer approval should be sought. As with design changes, all changes to production tooling or equipment, materials, or processes should be documented. The implementation should be covered by defined procedures.

A product should be evaluated after any change to verify that the change instituted had the desired effect upon product quality. Any changes in the relationship between process and product characteristics resulting from the change should be documented and appropriately communicated.

11.7 Control of verification status

Verification status of product output should be identified. Such identification should be suitable means, such as stamps, tags, notations, or inspection records that accompany the product, or by computer entries or physical location. The identification should distinguish among unverified, conforming, or nonconforming product. It should also identify the organizational unit responsible for verification.

11.8 Control of nonconforming product

Provision should be made for the identification and control of all nonconforming products and materials (see clause 14).

12 PRODUCT VERIFICATION

12.1 Incoming materials and parts

The method used to ensure quality of purchased materials, component parts and assemblies that are received into the production facility will depend on the importance of the item to quality, the state of control and information available from the subcontractor, and impact on costs (see clause 9, in particular 9.7 and 9.8).

12.2 In-process verification

Verification, typically by inspections or tests, should be considered at appropriate points in the process to verify conformity. Location and frequency will depend on the importance of the characteristics and ease of verification during processing. In general, verification should be made as close as possible to the point of realization of the characteristic.

Verifications for hardware products may include the following:

a) set-up and first-piece inspection;

b) inspections or tests by machine operator;

c) automatic inspection or test;

d) fixed inspection stations at intervals throughout the process;

e) monitoring specific operations by patrolling inspectors.

Product should not be released for further use until it has been verified in accordance with the quality plan, except under positive recall procedures.

12.3 Finished product verification

To augment inspections and tests made during processing, two forms of verification of finished product are available. Either or both of the following may be used, as appropriate.

a) Acceptance inspections or tests may be used to ensure that finished product conforms to the specified requirements. Reference may be made to the purchase order to verify that the product to be shipped agrees in type and quantity. Examples include 100% inspection of items, lot sampling, and continuous sampling.

b) Product-quality auditing of sample units selected as representative of completed lots may be either continuous or periodic.

Acceptance inspection and product-quality auditing may be used to provide rapid feedback for corrective action of product, process, or the quality system. Nonconforming product should be reported and reviewed, removed, or segregated, and repaired, accepted with or without concession, reworked, regraded, or scrapped (see clause 14). Repaired and/or reworked products should be reinspected or retested.

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

13 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

13.1 Measurement control

Control should be maintained over all measuring systems used in the development, production, installation, and servicing of product to provide confidence in decisions or actions based on measurement data. Control should be exercised over gauges, instruments, sensors, special test equipment, and related test software. In addition, manufacturing jigs, fixtures such as test hardware, comparative references, and process instrumentation that can affect the specified characteristics of a product or process should be suitably controlled (see 11.3).

Documented procedures should be established to monitor and maintain the measurement process itself in a state of statistical control, including equipment, procedures, and operator skills. Inspection, measuring, and test equipment, including test software, should be used in conjunction with documented procedures to ensure that measurement uncertainty is known and is consistent with the required measurement capability. Appropriate action should be taken when accuracy is not adequate to measure properly the process and product.

13.2 Elements of control

The procedures for control of inspection, measuring, and test equipment and test methods should include, as appropriate:

a) suitable specification and selection, including range, accuracy, and robustness, under specified environmental conditions;

b) initial calibration prior to first use in order to validate the required accuracy (accuracy and precision); the software and procedures controlling automatic test equipment should also be tested;

c) periodic recall for adjustment, repair, and recalibration, considering the manufacturer's specification, the results of prior calibration, and the method and extent of use, to maintain the required accuracy in use;

d) documentary evidence covering unique identification of instruments, frequency of recalibration, calibration status, and procedures for recall, handling, preservation, and storage, adjustment, repair, calibration, installation, and use;

e) traceability to reference standards of known accuracy and stability, preferably to nationally or internationally recognized standards; where such standards do not exist, the basis used for calibration should be documented.

13.3 Subcontractor measurement controls

The control of measuring and test equipment and test methods may be extended to all subcontractors.

13.4 Corrective action

Where measuring processes are found to be out of control, or where inspection, measuring, and test equipment are found to be out of calibration, appropriate action is necessary. Evaluation should be made to determine the effects on completed work and to what extent reprocessing, retesting, recalibration, or complete rejection may be necessary. In addition, investigation of cause is important in order to avoid recurrence. This can include review of calibration methods and frequency, training, and adequacy of test equipment.

13.5 Outside testing

The facilities of outside organizations may be used for inspection, measurement, testing, or calibration to avoid costly duplication or additional investment, provided that the conditions given in 13.2 and 13.4 are satisfied. (For further information, see ISO 10012-1.)

14 CONTROL OF NONCONFORMING PRODUCT

14.1 General

The steps for dealing with nonconforming product should be established and maintained in documented procedures. The objectives of procedures for nonconformity control are to prevent the customer from inadvertently receiving nonconforming product and to avoid the unnecessary costs of further processing nonconforming product. The steps outlined in 14.2 to 14.7 should be taken as soon as indications occur that materials, components, or completed product do not, or may not, conform to the specified requirements.

14.2 Identification

Suspected nonconforming items or lots should be immediately identified and the occurrence(s) recorded.

Provision should be made as necessary to examine or reexamine previous lots.

14.3 Segregation

The nonconforming items should be segregated, when practical, from the conforming items and adequately identified to prevent further unintended use of them until the appropriate disposition is decided.

14.4 Review

Nonconforming product should be subjected to review by designated persons to determine whether it can be accepted with or without repair by concession, repaired, reworked, regraded, or scrapped. Persons carrying out the review should be competent to evaluate the effects of the decision on interchangeability, further processing, performance, dependability, safety, and aesthetics (see 9.7 and 11.8).

14.5 Disposition

Disposition of nonconforming product should be taken as soon as practicable. A decision to accept such product should be documented, together with the reason for doing so, in authorized waivers, with appropriate precautions.

14.6 Action

Action should be taken as soon as possible to prevent unintended use or installation of nonconforming product. This action can include review of other product designed or processed following the same procedures as the product found to be nonconforming, and/or previous lots of the same product.

For work in progress, corrective action should be instituted as soon as practical in order to limit the costs of repair, reworking, or scrapping. Repaired, reworked, and/or modified product should be reinspected or retested to verify conformance with specified requirements.

In addition, it may be necessary to recall completed product, whether in a finished product warehouse, in transit to distributors, in their stores, or already in use (see 11.2). Recall decisions are affected by considerations of safety, product liability, and customer satisfaction.

14.7 Avoidance of recurrence

Appropriate steps should be taken to avoid the recurrence of nonconformity (see 15.5 and 15.6).

15 CORRECTIVE ACTION

15.1 General

The implementation of corrective action begins with the detection of a quality-related problem and involves taking measures to eliminate or minimize the recurrence of the problem. Corrective action also presupposes the repair, reworking, recall, or scrapping of unsatisfactory product. The need for action to eliminate the cause of nonconformities can originate from sources such as:

a) audits (internal and/or external);

b) process-nonconformity reports;

c) management reviews;

d) market feedback;

e) customer complaints.

Specific actions to eliminate the causes of either an existing nonconformity or a potential nonconformity are given in steps 15.2 to 15.8.

15.2 Assignment of responsibility

The responsibility and authority for instituting corrective action should be defined as part of the quality system. The coordination, recording, and monitoring of corrective action related to all aspects of the quality system should be assigned within the organization. The analysis and implementation may involve a variety of functions, such as design, purchasing, engineering, processing, and quality control.

15.3 Evaluation of importance

The significance of a problem affecting quality should be evaluated in terms of its potential impact on such aspects as processing costs, quality-related costs, performance, dependability, safety, and customer satisfaction.

15.4 Investigation of possible causes

Important variables affecting the capability of the process to meet specified requirements should be identified. The relationship of cause and effect should be determined, with all potential causes considered. The results of the investigation should be recorded.

15.5 Analysis of problem

In the analysis of a quality-related problem, the root cause or causes should be determined before corrective action is planned. Often the root cause is not obvious, thus requiring careful analysis of the product specifications and of all related processes, operations, quality records, servicing reports, and customer complaints. Statistical methods can be useful in problem analysis (see clause 20).

Consideration should be given to establishing a file listing nonconformities to help identify those problems having a common source, contrasted with those that are unique occurrences.

15.6 Elimination of causes

Appropriate steps should be taken to eliminate causes of actual or potential nonconformities. Identification of the cause or potential causes may result in changes to production, packing, service, transit or storage processes, a product specification, and/or revision of the quality system. Action should be initiated to a degree appropriate to the magnitude of the problem and to avoid the recurrence of nonconformities.

15.7 Process controls

Sufficient controls of processes and procedures should be implemented to avoid recurrence of the problem. When the corrective action is implemented, its effect should be monitored in order to ensure that desired goals are met.

15.8 Permanent changes

Permanent changes resulting from corrective action should be recorded in work instructions, production-process documentation, product specifications, and/or the quality-system documentation. It may also be necessary to revise the procedures used to detect and eliminate potential problems.

16 POSTPRODUCTION ACTIVITIES

16.1 Storage

Appropriate storage methods should be specified to ensure shelf-life and to avoid deterioration. Storage conditions and the condition of product in stock should be checked at appropriate intervals for compliance with specified

requirements and to detect any loss, damage, or deterioration of product (see also 10.1.5 and 10.4).

16.2 Delivery

Provision for protection of the quality of product is important during all phases of delivery. All product, in particular product with limited shelf-life or requiring special protection during transport or storage, should be identified and procedures established, documented, and maintained to ensure that deteriorated product is not shipped and put into use.

16.3 Installation

Installation procedures, including warning notices, should contribute to proper installations and should be documented. They should include provisions which preclude improper installation or factors degrading the quality, reliability, safety, and performance of any product or material.

16.4 Servicing

16.4.1 Special-purpose tools or equipment for handling and servicing products during or after installation should have their design and function validated, as for any new product (see 8.5).

16.4.2 Inspection, measuring, and test equipment used in the field should be controlled (see clause 13).

16.4.3 Documented procedures and associated instructions for field assembly and installation, commissioning, operation, administration of spares or parts lists, and servicing of any product should be comprehensive and be established and supplied in a timely manner. The suitability of instructions for the intended reader should be verified.

16.4.4 Adequate logistic back-up, to include technical advice, spares or parts supply, and competent servicing, should be assured. Responsibility should be clearly assigned and agreed among subcontractors, distributors, and customers.

16.5 After sales

Consideration should be given to the establishment of an early warning system for reporting instances of product failure of shortcomings, to ensure rapid corrective action.

Information on complaints, the occurrence and modes of failure, or any problem encountered in use should be made available for review and corrective action in the design, processing, and/or use of the product.

16.6 Market feedback

A feedback system regarding performance in use should exist to monitor the quality characteristics of products throughout the life-cycle. This system can permit the analysis, on a continuing basis, of the degree to which the product satisfies customer requirements or expectations on quality, including safety and dependability.

17 QUALITY RECORDS

17.1 General

The organization should establish and maintain documented procedures as a means for identification, collection, indexing, access, filing, storage, maintenance, retrieval, and disposition of pertinent quality records. Policies should be established concerning availability and access of records to customers and subcontractors. Policies concerning documented procedures should also be established for changes and modifications in various types of documents.

17.2 Quality records

The quality system should require that sufficient records be maintained to demonstrate conformance to specified requirements and verify effective operation of the quality system. Analysis of quality records provides an important input for corrective action and improvement. The following are examples of the types of quality records, including charts, requiring control:

—inspection reports,

—test data,

—qualification reports,

—validation reports,

—survey and audit reports,

—material review reports,

—calibration data, and

—quality-related cost reports.

Quality records should be retained for a specified time, in such a manner as to be readily retrievable for analysis, in order to identify trends in quality measures and the need for, and the effectiveness of, corrective action.

While in storage, quality records should be protected in suitable facilities from damage, loss and deterioration (e.g., due to environmental conditions).

17.3 Quality-records control

The quality system should require that sufficient documentation be available to follow and demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent subcontractor documentation should be included. All documentation should be legible, dated (including revision dates), clean, readily identifiable, retrievable, and maintained in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss. Records may be in the form of any type of media such as hard copy, electronic media, etc.

In addition, the quality system should provide a method for defining retention times, removing and/or disposing of documentation when that documentation has become outdated.

The following are examples of the types of documents requiring control:

—drawings,

—specifications,

—inspection procedures and instructions,

—test procedures,

—work instructions,

—operation sheets,

—quality manual (see 5.3.2),

—quality plans,

—operational procedures, and

—quality-system procedures.

18 PERSONNEL

18.1 Training

18.1.1 General

The need for training of personnel should be identified, and documented procedures for providing that training should be established and maintained. Appropriate training should be provided to all levels of personnel within the organization performing activities affecting quality. Particular attention should be given to the qualifications, selection, and training of newly recruited personnel and personnel transferred to new assignments. Appropriate records of training should be maintained.

18.1.2 Executive and management personnel

Training should be given which will provide executive management with an understanding of the quality system, together with the tools and techniques needed for full executive management participation in the operation of the system. Executive management should also be aware of the criteria available to evaluate the effectiveness of the system.

18.1.3 Technical personnel

Training should be given to the technical personnel to enhance their contribution to the success of the quality system. Training should not be restricted to personnel with primary quality assignments, but should include assignments such as marketing, purchasing, and process and product engineering. Particular attention should be given to training in statistical techniques, such as those listed in 20.2.

18.1.4 Process supervisors and operating personnel

All process supervisors and operating personnel should be trained in the procedures and skills required to perform their tasks, i.e.

—the proper operation of instruments, tools and machinery they have to use,

—reading and understanding the documentation provided,

—the relationship of their duties to quality, and

—safety in the workplace.

As appropriate, personnel should be certified in their skills, such as welding. Training in basic statistical techniques should also be considered.

18.2 Qualification

The need to require and document qualifications of personnel performing certain specialized operations, processes, tests, or inspections should be evaluated and implemented where necessary, in particular for safety-related work. The need to assess periodically and/or require demonstrations of skills and/or capability should be addressed. Considerations should also be given to appropriate education, training, and experience.

18.3 Motivation

18.3.1 General

Motivation of personnel begins with their understanding of the tasks they are expected to perform and how those tasks support the overall activities. Personnel should be

made aware of the advantages of proper job performance at all levels, and of the effects of poor job performance on other people, customer satisfaction, operating costs, and the economic well-being of the organization.

18.3.2 Applicability

Efforts to encourage personnel toward quality of performance should be directed not only at production workers, but also at personnel in marketing, design, documentation, purchasing, inspection, test, packing and shipping, and servicing. Management, professional, and staff personnel should be included.

18.3.3 Quality awareness

The need for quality should be emphasized through an awareness program which can include introduction and elementary programs for new personnel, periodic refresher programs for long-standing personnel, provision for personnel to initiate preventive and corrective actions, and other procedures.

18.3.4 Measuring quality

Where appropriate, objective and accurate means of measuring quality achievements should be developed. These may be publicized to let personnel see for themselves what they, as a group or as individuals, are achieving. This can encourage them to improve quality. Recognition of performance should be provided.

19 PRODUCT SAFETY

Consideration should be given to identifying safety aspects of products and processes with the aim of enhancing safety. Steps can include:

a) identifying relevant safety standards in order to make the formulation of product specifications more effective;

b) carrying out design evaluation tests and prototype (or model) testing for safety and documenting the test results;

c) analyzing instructions and warnings to the user, maintenance manuals, and labeling and promotional material in order to minimize misinterpretation, particularly regarding intended use and known hazards;

d) developing a means of traceability to facilitate product recall (see 11.2, 14.2 and 14.6);

e) considering development of an emergency plan in case recall of a product becomes necessary.

20 USE OF STATISTICAL METHODS

20.1 Applications

Identification and correct application of modern statistical methods are important elements to control every phase of the organization's processes. Documented procedures should be established and maintained for selecting and applying statistical methods to:

a) market analysis;

b) product design;

c) dependability specification, longevity, and durability prediction;

d) process-control and process-capability studies;

e) determination of quality levels in sampling plans;

f) data analysis, performance assessment, and nonconformity analysis;

g) process improvement;

h) safety evaluation and risk analysis.

20.2 Statistical techniques

Specific statistical methods for establishing, controlling, and verifying activities include, but are not limited to, the following:

a) design of experiments and factorial analysis;

b) analysis of variance and regression analysis;

c) tests of significance;

d) quality-control charts and cusum techniques;

e) statistical sampling.

NOTE 21 Guidance on the International Standards to be used for the statistical techniques that are identified may be found in ISO/TR 13425 and ISO Handbook 3. For guidance on dependability applications, reference should be made to ISO 9000-4 and to IEC publications.

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

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

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

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

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

[8] ISO 9000-2:1993, *Quality management and quality assurance standards—Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003.*

[9] ISO 9000-3:1991, *Quality management and quality assurance standards—Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software.*

[10] ISO 9000-4:1993, *Quality management and quality assurance standards—Part 4: Guide to dependability programme management.*

[11] ISO 9004-2:1991, *Quality management and quality system elements—Part 2: Guidelines for services.*

[12] ISO 9004-3:1993, *Quality management and quality system elements—Part 3: Guidelines for processed materials.*

[13] ISO 9004-4:1993, *Quality management and quality system elements—Part 4: Guidelines for quality improvement.*

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

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

[16] ISO Handbook 3:1989, *Statistical methods.*

1) To be published.