INTERNATIONAL STANDARD

ISO 9004-3

First edition
1993-06-15

Quality management and quality system elements —

Part 3:
Guidelines for processed materials

Gestion de la qualité et éléments de système qualité —
Partie 3: Lignes directrices pour les matériels fabriqués

Reference number
ISO 9004-3:1993(E)

Contents

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Foreword

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 non-governmental, 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9004-3 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Sub-Committee SC 2, *Quality systems*.

ISO 9004 consists of the following parts, under the general title *Quality management and quality system elements*:

— *Part 1: Guidelines*

— *Part 2: Guidelines for services*

— *Part 3: Guidelines for processed materials*

— *Part 4: Guidelines for quality improvement*

— *Part 5: Guidelines for quality plans*

— *Part 6: Guide to quality assurance for project management*

— *Part 7: Guidelines for configuration management*

Part 1 is a revision of ISO 9004:1987.

Annex A of this part of ISO 9004 is for information only.

Introduction

0.1 General

A primary concern of any company or organization should be the quality of its products and services.

In order to be successful, a company should offer products or services that

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

b) satisfy customers' expectations;

c) comply with applicable standards and specifications;

d) comply with statutory (and other) requirements of society;

e) are made available — at competitive prices;

f) are provided at a cost which will yield a profit.

0.2 Organizational goals

In order to meet its objectives, the company should organize itself in such a way that the technical, administrative and human factors affecting the quality of its products and services will be under control. All such control should be oriented towards the reduction, elimination and, most importantly, prevention of quality deficiencies.

With processed materials, control of the process itself is of primary concern.

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

Each element (or requirement) in a quality system will vary in importance from one type of activity to another and from one product or service 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 process, product or service being offered.

0.3 Meeting company/customer needs

A quality system has two inter-related aspects.

a) **The company's needs and interests**

For the company, there is a business need to attain and to maintain the desired quality at an optimum cost; the fulfilment of this quality aspect is related to the planned and efficient utilization of the technological, human and material resources available to the company.

b) **The customer's needs and expectations**

For the customer, there is a need for confidence in the ability of the company to deliver the desired quality as well as the consistent maintenance of that quality.

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 company's products.

0.4 Risks, costs and benefits

Risk, cost and benefit considerations have great importance for both company and customer. These considerations are inherent aspects of most products and services. The possible effects and ramifications of these considerations are given as follows.

a) **Risk considerations**

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

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

b) **Cost considerations**

For the company: Consideration has to be given to costs due to marketing and design deficiencies, including unsatisfactory materials, rework, repair, replacement, reprocessing, loss of production, warranties and field repair.

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

c) **Benefit considerations**

For the company: Consideration has to be given to increased profitability and market share.

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

0.5 Conclusions

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

This page intentionally left blank

Quality management and quality system elements —

Part 3:
Guidelines for processed materials

1 Scope

This part of ISO 9004 gives guidance on the application of quality management to processed materials.

The selection of appropriate elements contained in this part of ISO 9004 and the extent to which these elements are adopted and applied by a company depend upon factors such as the market being served, the nature of the product, production processes and consumer needs.

This part of ISO 9004 is not intended to be used as a checklist for compliance with a set of requirements.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9004. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9004 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.

ISO 8402:—[1], *Quality management and quality assurance — Vocabulary.*

ISO 9004:1987, *Quality management and quality system elements — Guidelines.*

3 Definitions

For the purposes of this part of ISO 9004, the definitions given in ISO 8402 and ISO 9004 and the following definition apply.

3.1 processed materials: Products (final or intermediate) prepared by transformations, consisting of solids, liquids, gases, or combinations thereof, including particulate materials, ingots, filaments or sheet structures.

NOTE 1 Processed materials are typically delivered in bulk systems, such as pipelines, drums, bags, tanks, cans or rolls.

4 Management responsibility

4.1 General

The responsibility for and commitment to a quality policy belongs to the highest level of management. Quality management is that aspect of the overall management function which determines and implements quality policy.

4.2 Quality policy

The management of a company should develop and state its corporate quality policy. This policy should be consistent with other company policies. Management should take all necessary measures to ensure that its corporate quality policy is understood, implemented and maintained.

4.3 Quality objectives

4.3.1 For a corporate quality policy, management should define objectives pertaining to key elements of quality, such as fitness for use, performance, safety and reliability. Objectives pertaining to process control, process capability, process performance, safety and reliability of the process should also be defined.

1) To be published. (Revision of ISO 8402:1986)

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, where necessary, should define specialized quality objectives consistent with corporate quality policy as well as other corporate objectives.

4.4 Quality system

4.4.1 Management should develop, establish and implement a quality system as the means by which stated policies and objectives might be accomplished.

4.4.2 The quality system should be structured and adapted to the company's particular type of business and should take into account the appropriate elements outlined in this part of ISO 9004.

4.4.3 The quality system should function in such a manner as to provide proper confidence that

a) the system is well understood and effective;

b) the products or services actually do satisfy customer expectations;

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

5 Quality system principles

5.1 Quality system elements

5.1.1 The quality system typically applies to, and interacts with, all activities pertinent to the quality of a product, process or service. It involves all phases from initial identification to final satisfaction of requirements and customer expectations. These phases and activities may include the following:

a) marketing and market research;

b) technical research and development;

c) design/specification engineering and product development;

d) procurement;

e) process planning and development;

f) production process measurement, control and adjustment;

g) production;

h) process maintenance;

i) inspection, testing and examination;

j) packaging and storage;

k) sales and distribution;

l) customer use;

m) technical assistance;

n) disposal after use.

See figure 1 for a schematic representation of the quality system elements.

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

a) determining and defining customer needs, expectations and the product requirements;

b) providing the concepts (including back-up data) for producing a product or service to defined specifications at optimum cost.

5.2 Structure of the quality system

5.2.1 General

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

5.2.2 Quality responsibility and authority

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

a) General and specific responsibilities should be explicitly defined.

b) Responsibility and authority delegated to each activity contributing to quality should be clearly established; that authority and responsibility 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) Management may choose to delegate the responsibility for internal quality assurance and for external quality assurance where necessary; the persons so delegated should be independent of the activities reported on.

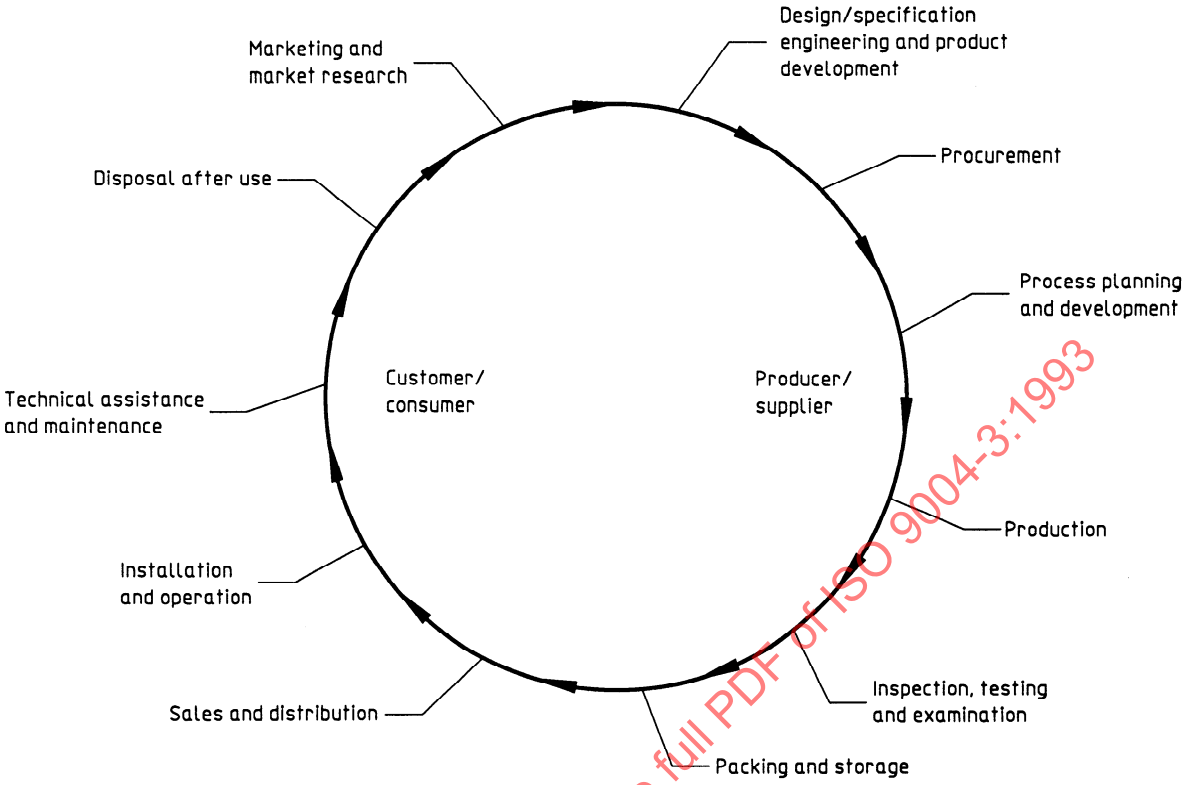

Figure 1 — Quality loop

e) In organizing a well-structured and effective quality system, emphasis should be placed on the identification of actual or potential quality problems and the initiation of remedial or preventive measures.

5.2.3 Organizational structure

The organizational structure pertaining to the quality system should be clearly established within the overall management of a company. The lines of authority and communication should be defined.

5.2.4 Resources and personnel

Management should provide sufficient and appropriate resources essential to the implementation of quality policies and the achievement of quality objectives. These resources may 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 factors affecting market position and objectives relative to new products, processes or services (including new technologies) in order to allocate company resources on a planned and timely basis.

Programmes and schedules covering these resources and skills should be consistent with the company'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.

It should emphasize preventive actions that avoid occurrence of problems, whilst not sacrificing the ability to respond to and correct failures should they occur.

Operational procedures coordinating different activities with respect to an effective quality system should be developed, issued and maintained to implement corporate quality policies and objectives. These procedures should lay down the objectives and performance of the various activities having an impact on

quality (e.g. design, development, procurement, production and sales).

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

5.3 Documentation of the system

5.3.1 Quality policies and procedures

All the elements, requirements and provisions adopted by a company for its quality system should be documented in a systematic and orderly manner in the form of written policies and procedures. Such documentation should ensure a common understanding of quality policies and procedures (i.e. quality programmes/plans/manuals/records).

The quality system should include adequate provision for the proper identification, distribution, collection and maintenance of all quality documents and records. However, care should be taken to limit documentation to the extent pertinent to the application. (See clause 17.)

5.3.2 Quality manual

5.3.2.1 The typical form of the main document used in drawing up and implementing a quality system is a "Quality Manual".

5.3.2.2 The primary purpose of a quality manual is to provide an adequate description of the quality management system while serving as a permanent reference in the implementation and maintenance of that system.

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

5.3.2.4 In larger companies, the documentation relating to the quality management system may take various forms, including the following:

a) a corporate quality manual;

b) divisional quality manuals;

c) specialized quality manuals (e.g. design, development, procurement, project, work instructions).

5.3.3 Quality plans

For projects relating to new products, services or processes, management should prepare, as appropriate, written quality plans consistent with all other requirements of a company's quality management system.

Quality plans should define the following:

a) the quality objectives to be attained;

b) the specific allocation of responsibilities and authority during the different phases of the project;

c) the specific procedures, methods and work instructions to be applied;

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

e) a method for making changes and modifications to a quality plan as projects proceed;

f) other measures necessary to meet objectives.

A quality plan may form part of a detailed operating procedure.

5.3.4 Quality records

Quality records and charts pertaining to design, inspection, testing, survey, audit, review or related results are important constituents of a quality management system (see 17.2 and 17.3).

5.4 Auditing the quality system

5.4.1 General

All elements, aspects and components pertaining to a quality system should be internally audited and evaluated on a regular basis. Audits should be carried out in order to determine whether various elements within a quality system are effective in achieving stated quality objectives. For this purpose, an appropriate audit plan should be formulated and established by company management. (For further details, see parts 1, 2 and 3 of ISO 10011.)

5.4.2 Audit plan

The format of the audit plan should cover the following points:

a) specific activities and areas to be audited;

b) qualifications of personnel carrying out the audits;

c) the basis for carrying out the audits (e.g. organizational changes, reported deficiencies, routine checks and surveys);

d) procedures for reporting audit findings, conclusions and recommendations.

5.4.3 Carrying out the audit

Objective evaluations of quality system elements by competent personnel may include the following activities or areas:

a) organizational structures;

b) administrative and operational procedures;

c) personnel, equipment and material resources;

d) work areas, operations and processes;

e) items being produced (to establish conformance to standards and specifications);

f) documentation, reports and record-keeping.

Personnel carrying out audits of quality system elements should be independent of the specific activities or areas being audited.

5.4.4 Reporting and follow-up of audit findings

Audit findings, conclusions and recommendations should be submitted in documentary form for consideration by appropriate members of company management.

The following items should be covered in the reporting and follow-up of audit findings:

a) specific examples of non-compliance or deficiencies should be documented in the audit report; possible reasons for such deficiencies, where evident, may be included;

b) implementation and effectiveness of corrective actions suggested in previous audits should be assessed;

c) appropriate corrective actions may be suggested if requested.

5.5 Review and evaluation of the quality system

Provision should be made by company management for independent review and evaluation of the quality system. Such reviews should be carried out by appropriate members of company management or by competent independent personnel, as decided on by company management.

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

a) findings of audits centred on various elements of the quality system (see 5.4.3);

b) the overall effectiveness of the quality system in achieving stated quality objectives;

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

Findings, conclusions and recommendations reached as a result of review and evaluation should be submitted in documentary form for necessary action by company management.

6 Economics — Quality-related cost considerations

6.1 General

The impact of quality upon the profit-and-loss statement can be highly significant, particularly in the long term. It is, therefore, important that the effectiveness of a quality system be measured in a businesslike manner. The main objective of quality cost reporting is to provide means for evaluating effectiveness and establishing the basis for internal improvement programmes.

6.2 Selecting appropriate elements

A portion of total business costs is earmarked for meeting the quality objectives. In practice, the combination of selected elements from this portion of total costs can provide the necessary information for marshalling efforts towards achieving quality goals. It is now common practice to identify and measure "quality costs". Both the costs of activities directed at achieving appropriate quality and the resultant costs from inadequate control should be identified.

6.3 Types of quality-related costs

6.3.1 General

Quality costs can be broadly divided into operating quality costs (see 6.3.2) and external assurance quality costs (see 6.3.3).

6.3.2 Operating quality costs

Operating quality costs are those costs incurred by a business in order to attain and ensure specified quality levels. These include the following.

a) **Prevention and appraisal costs (or investments)**

— prevention: costs of efforts to prevent failures;

— appraisal: costs of testing, inspection and examination to assess whether the specified quality is being maintained;

b) **Failure costs (or losses)**

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

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

6.3.3 External assurance quality costs

External assurance quality costs are those costs relating to the demonstration and proof required as objective evidence by customers, including particular and additional quality assurance provisions, procedures, data, demonstration tests and assessments (e.g. the cost of testing for specific safety characteristics by recognized independent testing bodies).

6.4 Management visibility

Quality costs should be regularly reported to and monitored by management and be related to other cost (ratio) measures, such as sales, turnover or added value, so as to

a) evaluate the adequacy and effectiveness of the quality management system;

b) identify additional areas requiring attention;

c) establish quality and cost objectives.

7 Quality in marketing

7.1 Marketing requirements

The marketing function should take the lead in establishing quality requirements for the product. It should

a) determine the need for a product or service;

b) accurately define the market demand and sector, since doing so is important in determining the grade, quality, quantity, price and timing estimates for the product or service;

c) accurately determine customer requirements by a review of contract or market needs; actions include an assessment of any unstated expectations or biases held by customers;

d) communicate all customer requirements clearly and accurately within the company.

7.2 Product brief

The marketing function should provide the company with a formal statement or outline of product requirements (e.g. a product brief). The product brief translates customer requirements and expectations into a preliminary set of specifications as the basis for subsequent design/development work. (See note 2.) Among the elements that may be included in the product brief are the following requirements:

a) performance characteristics such as strength, durability, corrosion resistance, thermal resistance and workability, as well as other measurable properties of the process output;

b) sensory characteristics (e.g. visual, taste, touch, smell);

c) safety and environment considerations;

d) applicable standards and statutory regulations;

e) packaging, transportation, handling or storage;

f) quality assurance/verification.

NOTE 2 The use of the term "design/development" includes

— development of product designs that meet customer requirements (development of new products or enhancement of existing products);

— development of a process design that meets product requirements.

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 quality of a product or service should be analysed, collated, interpreted and communicated in accordance with defined procedures. Such information will help to determine the nature and extent of product or service problems in relation to customer experience and expectations. In addition, feedback information may provide clues to possible design changes as well as appropriate management action. (See also 8.8, 8.9 and 16.3.)

7.4 Joint development

In developing new products and materials, the quality requirements submitted in advance by users are frequently shown qualitatively rather than specified accurately and quantitatively. In such cases, joint development may be carried out in collaboration with customers to clarify the requirements by iterating the process of shipment of samples, trial use and evaluation.

8 Quality in specification and design/development

8.1 Contribution of specification and design to quality

The specification and design/development function should provide for the translation of customer needs from the product brief into technical specifications for materials, products and processes. This should result in a product that provides customer satisfaction at an acceptable price that enables a satisfactory return on investment for the enterprise. The product and process specification should be such that the material is producible, verifiable and controllable for the proposed products, materials, method of processing, transporting, storing or operating involved.

8.2 Planning and objectives of design/development (defining the project)

8.2.1 Management should specifically assign responsibilities for various design duties to activities inside and/or outside the organization and ensure that all those who contribute to design are aware of their responsibilities for achieving quality.

8.2.2 In its delegation of responsibilities 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. Responsibilities apply both in the process of research and development and at the stage of continuous or batch operations.

8.2.3 Management should establish time-phased design/development programmes with checkpoints appropriate to the nature of the product. The extent of each phase and the stages at which evaluations of the product and process will take place may be in general as follows, although they depend on the product's application, its design complexity, the extent of innovation and technology being introduced, the degree of standardization and similarity with past proven designs. The stages may include:

a) research and development at a laboratory stage;

b) trial at the plant to assure that the pilot plant output can be scaled-up to predict the commercial plant output;

c) tentative use by a customer or in the market;

d) initial production at a commercial plant;

e) mass production;

f) design of monitoring and process control systems.

8.2.4 In addition to customer needs, due consideration should be given to the requirements relating to safety, product liability, environmental and other regulations, including items in the company's quality policy which may go beyond existing statutory requirements.

8.2.5 The quality aspects of the design/development should be unambiguous and adequately define characteristics important to quality, such as the acceptance and rejection criteria. Both fitness for purpose and safeguards against misuse should be considered. Product definition may include process capability, durability, reliability, processability, homogeneity, impurities, foreign substances, changes in quality over time, deterioration, safety and disposability.

8.2.6 At the time of establishment and modification of the process, experiments should be performed in order to understand the technical condition of the new or modified process related to the quality of products. Attention should be paid to the necessary maintenance programme for the process, including the removal of deficiencies found, and also to establishing future maintenance needs.

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. Parameters should include the following:

a) performance target values, tolerances and attribute features;

b) method of sampling and preparation of samples;

c) method of measurement and analysis;

d) acceptance and rejection criteria;

e) requirements for test and measurement accuracy.

8.4 Process and product design qualification and validation

The design process should provide periodic evaluation of the design at significant stages. Evaluation should include trial samples from pilot plant and commercial plant. Such evaluation can take the form of analytical methods, such as Fault Modes and Effect Analysis (FMEA), Fault Tree Analysis (FTA) or risk assessment, as well as inspection or test of prototype and/or actual production samples. The amount and degree of testing should be related to the risks identified in the design plan (see 8.2). Independent evaluation may be employed, as appropriate, to verify original calculations, provide alternative calculations or perform tests. Adequate numbers 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) validation of performance, durability, safety, reliability and maintainability under expected storage and operational conditions;

b) verification that all design features are as intended 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 defect and failure analysis.

8.5 Review in design/development

8.5.1 General

At the conclusion of each phase of design/development, a formal, documented, systematic and critical review of the design/development results should be conducted. This review should include those aspects concerning the quality of product and manufacturing processes involved. The design/development 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.

8.5.2 Elements of process and product design reviews

Review teams should be set up with all relevant functions/disciplines represented in order to have the totality of the design/development evaluated. Inasmuch as the design of the process is of particular importance in the manufacture of processed material, product requirements and process requirements should be considered at the same time. As appropriate to the design/development phase and product, the following elements outlined below should be considered.

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

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

2) validation of the process and product design through small-scale trial and sample tests;

3) durability and effectiveness of the product under expected conditions of processing and use;

4) considerations of unintended uses and misuses;

5) safety and environmental compatibility;

6) compliance with regulatory requirements, national and international standards and corporate practices;

7) comparisons with competitive products;

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

b) **Items pertaining to product specification and service requirements:**

1) reliability, serviceability and maintainability requirements;

2) permissible tolerances and comparison with process capability;

3) product acceptance/rejection criteria;

4) handling, package, transportation, storage needs, shelf-life and disposability;

5) benign failure characteristics;

6) aesthetic specifications, such as surface aspects and impurity criteria;

7) limits on foreign substances;

8) labelling, warnings, identification, traceability requirements and user instructions.

c) **Items pertaining to process specifications and service requirements:**

1) producibility of 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 sub-assemblies, including approved supplies and suppliers as well as availability;

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

5) quality characteristics affected by scaling-up of the process from the trial plant in a small size to the mass-production plant in a large size;

6) identification and control of the process parameters affecting the quality of products;

7) identification and control of the external elements such as impurities which affect quality;

8) grasp and sufficiency of process capability to meet the required tolerance;

9) such analyses as FMEA and FTA for the manufacturing processes and facilities;

10) ease of operation, control and maintenance;

11) matters relating to trial runs;

12) education and training in advance, with the aim of ensuring the manufacturing and servicing activities;

13) evaluation of manufacturing costs.

8.5.3 Design verification

Design verification may be undertaken independently or in support of design reviews by applying the following methods:

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

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

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

8.6 Approval for commercial production

Development process review concerning the product's quality and manufacturing process should be appropriately documented in product specification and manufacturing engineering standards. The total document package that defines the product quality and the manufacturing methods should require approval at appropriate levels of management affected by or contributing to the product.

"Approval" also signifies that the new product can be manufactured using the planned process. This "approval" constitutes the production release and signifies concurrence that the design can be realized.

8.7 Market readiness review

The quality system should provide for a review to determine whether production capability and field support are adequate for the new or redesigned product. Depending upon the type of product, the review may cover the following points:

a) availability and adequacy of documented procedures for handling, transportation, storage and distribution;

b) existence of an adequate distribution and customer service organization;

c) training of field personnel;

d) field trials;

e) certification of the satisfactory completion of qualification tests;

f) physical inspection of early production units and their packaging and labelling;

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

8.8 Change control of product and process specification

The quality system should provide a procedure for controlling the release, change and use of documents that define the specification of products and processes, and for authorizing the necessary work to be performed to implement changes that may affect the product or process during its entire life-cycle. 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. This control process is referred to as "change control". These procedures should handle emergency changes necessary to prevent production of nonconforming product. Consideration should be given to instituting formal specification and process reviews and validation testing when the magnitude, complexity or risk associated with the change warrant such actions.

8.9 Requalification of product and process specifications

Periodic re-evaluation of a product should be performed in order to ensure that the product and process are still valid with respect to all specified requirements. 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 review 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 product quality degradation and that proposed changes are evaluated for their impact on all specified product quality characteristics.

9 Quality in procurement

9.1 General

Purchased raw materials and auxiliary materials such as water, chemicals and gases can become an ingredient of the company's product and can directly affect the quality of its product. Thorough consideration should be given to the process capability of the manufacturing facilities when specifying raw and auxiliary materials. Quality of services such as calibration and special processes should also be considered. The procurement of purchased supplies should be planned and controlled. The purchaser should establish a close working relationship and feedback system with each supplier. In this way, a programme of continual quality improvements can be maintained and quality disputes avoided or settled quickly. This close working relationship and feedback system will benefit both the purchaser and the supplier.

The procurement quality programme should include the following elements as a minimum for both external and internal suppliers:

a) requirements for specification, drawings and purchase orders (see 9.2);

b) selection of qualified suppliers (see 9.3);

c) agreement on quality assurance (see 9.4);

d) agreement on verification methods (see 9.5);

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

f) receiving inspection plans when appropriate (see 9.7);

g) receiving controls (see 9.7);

h) receiving quality records (9.8).

9.2 Requirements for specifications, drawings and purchase orders

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

The procuring activity should develop appropriate methods to ensure that the requirements for the supplies are clearly defined, communicated and, most importantly, are completely understood by the supplier. These methods may include written procedures for the preparation of specifications, drawings and purchase orders, supplier and purchaser conferences prior to purchase order release, and other methods appropriate for the supplies being procured.

Purchasing documents should contain data clearly describing the product or service ordered. Elements that may be included are as follows:

a) precise identification of grade;

b) inspection instructions and applicable specifications;

c) quality system standard to be applied;

d) requirements for evidence of process control from the supplier (e.g. control charts);

e) precise descriptions of chemical composition and physical properties;

f) packaging, labelling, transportation and delivery timing requirements;

g) laboratory method specifications and analysis instructions;

h) advance notification when the supplier intends making changes to the material composition or process.

These requirements should also apply to "internal" suppliers. It may be found useful to prepare formal supply agreements within a company.

Purchasing documents should be reviewed for accuracy and completeness before release.

NOTE 3 When purchasing machinery or equipment, consideration should be given to specifying their process capabilities.

9.3 Selection of qualified suppliers

Each supplier should have a demonstrated capability to furnish supplies which can meet all the requirements of the specifications, drawings and purchase order.

The methods of establishing this capability may include any combination of the following:

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

b) evaluation of product samples;

c) past history with similar supplies;

d) test results of similar supplies;

e) statistical data relevant to the consistency of the supplier's process;

f) published experience of other users.

9.4 Agreement on quality assurance

A clear understanding should be developed with the supplier on quality assurance for which the supplier is responsible. The assurance to be provided by the supplier may vary as follows:

a) the purchaser relies on the supplier's quality assurance system;

b) the supplier submits specified inspection/test data or process control records with shipments;

c) the supplier carries out 100 % inspection/testing;

d) the supplier carries out lot acceptance inspection/testing by sampling;

e) the supplier implements a formal quality assurance system as specified by the purchaser;

f) the supplier provides nothing — the purchaser relies on receiving inspection or in-house sampling analysis.

The assurance provisions should be commensurate with the needs of the purchaser's business and should avoid unnecessary costs. In certain cases, formal quality assurance systems may be involved (see ISO 9000, ISO 9001, ISO 9002 and ISO 9003). This may include periodic assessment of supplier quality system assurance by the purchaser.

9.5 Agreement on verification methods

A clear agreement should be developed with the supplier on the methods by which conformance to purchaser's 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 quality disputes

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

A very important aspect of these systems and procedures is the provision of effective communication channels between the purchaser and the supplier on matters affecting quality.

9.7 Receiving inspection planning and controls

Appropriate measures should be established to ensure that supplies which have been received are properly controlled. These procedures should include segregation or other appropriate methods to prevent unqualified supplies from being inadvertently used. (See 14.4.)

The extent to which receiving inspection will be performed should be carefully planned. The level of inspection, when inspection is deemed necessary, should be selected with overall cost being borne in mind.

In addition, when the decision has been made to perform an inspection, it is necessary to select with care the characteristics to be inspected.

It is also necessary to ensure, before the supplies arrive, that all the necessary sampling tools and vessels for samples and reagents for chemical analysis, meters, instruments and equipment are available and properly calibrated, together with adequately trained personnel.

In some cases, long-distance or long-time transportation is needed for the delivery of purchased products from supplier to purchaser. It is recommended that the supplier submit samples of the will-be-shipped material to the purchaser prior to shipment.

9.8 Receiving quality records

Appropriate receiving quality records should be maintained to ensure the availability of historical data to assess supplier performance and quality trends.

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

Retention of samples from each lot for a defined period of time may be found to be advisable.

10 Quality in production

10.1 Planning for controlled production

10.1.1 Planning of production operations should ensure that these proceed under controlled conditions in the specified manner and sequence. Controlled conditions include appropriate controls for materials, production equipment, processes and procedures, measurements, computer software, personnel, and associated supplies, utilities and environments.

At the start of production, an early-warning system should be established to identify obstacles to stable production.

Production operations 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). Care should be taken to consider the effects of auto-correlation[2] which may be present in these processes.

Provisions for common practice that apply throughout the production facility should be similarly documented and referenced in individual work instructions. These instructions should describe the criteria for determining satisfactory work completion and conformity to specifications and standards of good workmanship. Workmanship standards should be defined to the necessary extent by written standards, photographs and/or physical samples.

10.1.2 Verification of the quality status of a product, process, software, material or environment should be considered at important points in the production sequence to minimize effects of errors and to maximize yields. By their nature, processed (bulk) materials manufactured by continuous processes may be difficult to sample. This situation increases the importance of the use of statistical sampling and evaluation procedures with processed materials. The use of control charts and statistical sampling procedures and plans are examples of techniques employed to facilitate production/process control (see also 12.2).

10.1.3 Verifications at each stage should relate directly to finished product specifications or to an internal requirement, as appropriate. If verification of characteristics of the process itself is not physically or economically practical or feasible, then verification of the product should be utilized. In all cases, relationships between in-process controls, their specifications and final product specifications should be developed, communicated to production and inspection personnel, and documented.

10.1.4 All in-process and final inspections should be planned and specified. Documented test and inspection procedures should be maintained, including the specific equipment to perform such checks and tests, as well as the specified requirement(s) and/or workmanship standard(s) for each quality characteristic to be checked.

10.1.5 Efforts to develop new methods for improving production quality and process capability should be encouraged.

10.2 Process capability

Production processes should be verified as being capable of producing in accordance with product 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 specification or that appropriate modifications or changes are made.

Verification of production processes should include material, equipment, measurement of product and process characteristics, computer system and software, procedures and personnel.

10.3 Supplies, utilities and environments

Where they are important to quality characteristics, auxiliary materials and utilities (such as water, compressed air, electric power, fuels and chemicals used for processing) should be controlled and verified periodically to ensure uniformity of effect on the process. These types of supplies may be important when they can infiltrate the product. Where a production environment (such as temperature, humidity and cleanliness) is important to product quality, appropriate limits should be specified, controlled and verified. Environmental and process conditions that can materially affect the product quality during processing should be recorded at regular intervals and produced as evidence of product quality assurance.

11 Control of production

11.1 General

The quality loop (figure 1) involves the control of quality in a manufacturing cycle. (See also 5.1 in which the interaction of various quality system functions is outlined.)

11.2 Material control and traceability

All materials should conform to appropriate specifications and quality standards before being introduced into production. However, in determining the amount of test and/or inspection necessary, consideration should be given to cost impact and the effect that substandard material quality will have on production flow (see clause 9). Materials should be appropriately stored, segregated, handled and protected during production to maintain their suitability. Special consideration should be given to shelf-life and deterioration control. Where in-plant traceability of material is important to quality, appropriate identification should be maintained throughout the production process to ensure traceability to original material identification and quality status (see 11.7 and 16.1.3). Material control and traceability may present specific problems where continuous processes are involved. It is common to depend on real-time analysis for such processes.

2) The internal correlation between members of a series of observations ordered in time or space.

11.3 Equipment control and maintenance

All production equipment and process instrumentation should be tested for bias and precision 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 its bias and precision.

A programme of preventive maintenance should be established to ensure continuing process capability. Special attention should be given to process characteristics that contribute to key product quality characteristics.

11.4 Special processes

Special consideration should be given to process stages at which control is particularly important to product quality. More frequent verifications should be made at such stages. When verification indicates that there is a failure to conform to specified or expected product or process parameters, action needs to be taken to correct the process. This may involve a temporary suspension of the process until the causes are identified and process controls are modified. Changes of unit settings, adjustments to inputs or similar, may be required, according to a predetermined procedure. More frequent verification of special processes should be made to keep check on

a) the accuracy and variability of equipment used to make or measure the product, including settings and adjustments;

b) the skill, capability and knowledge of operators to meet quality requirements;

c) verification techniques, including pressure, time, temperature, flow, environment and level of measurements made to evaluate physical and chemical characteristics;

d) certification records maintained for personnel, processes and equipment, as appropriate.

11.5 Documentation

Work instructions, specifications and drawings should be controlled as specified by the quality system (see 5.3 and 17.2).

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 equipment, materials or processes should be documented. The implementation should be covered by defined procedures.

Change control is vital, since a change may alter an unmeasured or unmeasurable characteristic that impacts the customer.

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 relationships between process and product characteristics resulting from the change should be documented and appropriately communicated.

11.7 Control of verification status

For continuous processes the verification status of material needs special attention. Computerized recording of verification status is frequently necessary.

11.8 Control of nonconforming materials

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

12 Product verification

12.1 Incoming materials

The method used to ensure the quality of purchased materials 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 supplier and the impact on costs (see clause 9, in particular subclauses 9.7 and 9.8).

Both bulk and packaged materials should be segregated and/or marked to avoid consumption before being accepted and to avoid inadvertent mixing.

Introduction of new bulk materials into the inventory of existing materials raises the potential of cross-contamination (intermixing of materials). In some cases (e.g. pipeline shipments), raw materials proceed directly from the supplier's process, without going into inventory, and are immediately consumed in the customer's process. In such cases, mutual confidence to the level discussed in 9.4 a) may be needed.

12.2 In-process monitoring and control

Inspection or test 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 at the stage of production. In general, verification should be made as

close as possible to the point of production of the feature or characteristic.

Many processed-material industries are heavily dependent on real-time automatic controllers. In addition, many internal recycle loops are under real-time control. The general aim is to control important process parameters to target values and/or within approved ranges.

Monitoring and control may include the following:

a) the use of sensors, control equipment and operators for feedback/feedforward loops (e.g. flow control);

b) automatic analysis or inspection (e.g. on-line gas chromatographs and infrared scanners);

c) off-line chemical and physical analyses (e.g. composition of sample);

d) the use of instrument observations by process operators (e.g. temperature reading);

e) the use of designated physical inspection stations within the process (e.g. visual inspection of colour).

Outputs from these activities may be used to make manual or automatic process adjustments. Statistical process control tools can be useful with data from in-process testing.

In-process testing has assumed a high level of importance in the process industries. Process knowledge is used extensively to predict conformance to required finished product parameters. Nonetheless, finished-product verification retains important roles

— to confirm predictions based on process parameters;

— to guide longer-term process adjustments;

— to provide the basis for product acceptance or rejection;

— to provide data for statistical analysis of process and product performance.

12.3 Completed-product verification

To augment inspections and tests made during production, two forms of final verification of completed 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 materials or lots produced have met performance and other quality requirements. Reference may be made to the purchase order to verify that product to be shipped agrees in type and quantity. Examples include screening (100 % of materials), lot sampling and continuous sampling.

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

It is often difficult to designate or identify precise lots or batches from a continuous process. Even in the case of a batch process, the batch identity is often difficult to maintain due to downstream blending. The producer needs to address these issues carefully, using process knowledge, to develop appropriate sampling plans that provide assurance of quality. It is also desirable to be able to relate product test results to the appropriate upstream process test results (e.g. log records and knowledge of process time lags). The following should be considered when selecting the sampling plan:

a) cost of the test;

b) whether the test is meaningful in relation to customer requirements;

c) whether the test is destructive;

d) process stability;

e) measurement error in proportion to total variability;

f) time to complete the test;

g) customer or statutory requirements.

Acceptance inspection and product quality auditing may be used to provide rapid feedback for corrective action on a product or process. Nonconformities should be reported and appropriate action taken (see clauses 14 and 15).

13 Control of measuring and test equipment

13.1 Measurement control

Sufficient control should be maintained over all measurement systems used in the development, manufacture, installation and servicing of a 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 computer software. In addition, process instrumentation that can affect the specified characteristics of a product or process should be suitably controlled (see 11.3). Procedures should be established to monitor and maintain the measurement process itself under statistical control, including equipment, procedures and operator skills. Measurement error should be compared with requirements

and appropriate action taken when precision and/or bias requirements are not achieved.

Measurement systems are important processes in themselves. Measurement control is vital since so much of the available information on raw materials, process and product is derived from measurements. Sources of these measurements include instruments located on or near process equipment, as well as test equipment in laboratories. (See ISO 10012 for guidance.)

Components of both within- and between-laboratory variation must be well understood and estimated in evaluating processed materials.

13.2 Elements of control

Most process-industry tests involve complex equipment and procedures. Statistical process control (SPC) tools may be used to maintain the processes in statistical control. Records are recommended as documentary evidence of control.

The control of measuring and test equipment and test methods should include the following factors, as appropriate:

a) correct specification and acquisition, including range, bias, precision, robustness and durability under specified environmental conditions for the intended service;

b) initial calibration prior to first use in order to validate the required accuracy; 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, the method and extent of use, to maintain the required accuracy in use;

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

e) traceability to reference standards of known accuracy and stability, preferably to national or international standards or, in industries or products where such do not exist, to specially developed criteria; traceability to national and international primary reference standards is often difficult due to the nature of the materials involved; industry often uses secondary reference materials and statistical methods to validate part of a given measurement process.

13.3 Supplier measurement controls

The control of measuring and test equipment and test methods should extend to all furnishing products and services.

The application of statistical methods to keep measurement processes in control should be encouraged.

13.4 Corrective action

Where measuring processes are found to be out of control or where measuring and test equipment is found to be outside the required calibration limits, corrective action is necessary. Evaluation should be made to determine the effects on completed processed material and to what extent reprocessing, retesting, recalibration, or complete rejection may be necessary.

Review of statistical control records is often a useful step in identifying the corrective actions needed. If the statistical records show the measurement process to be out of control, the user should look for a root cause, rather than recalibrating.

13.5 Outside testing

Processed-materials testing is generally integrated into the process. Where outside testing organizations are needed to avoid costly duplication or additional investment, the recommendations given in 13.2 and 13.4 should still be followed.

14 Nonconformity

14.1 General

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 meet the specified requirements.

14.2 Identification

Products suspected of being nonconforming should be immediately identified and the occurrence(s) recorded. Whenever possible, provision should be made as necessary to examine previous productions lots.

Circumstances may arise when, due to the complexity of the required storage conditions (e.g. extremes of temperature or pressure or corrosive nature of the product), it is not possible directly to mark the nonconforming product. In such cases, documented or computer-based control systems are acceptable for identification purposes, provided the system is designed for the prevention of inadvertent use or shipment (i.e. a low-customer-risk segregation system).

14.3 Segregation

Wherever possible, the nonconforming products should be segregated from the conforming product and adequately identified to prevent further use of them until the appropriate disposition is decided.

In the case of materials or products that have immediate delivery (e.g. electricity, drinkable water, gas, etc.) where it is not possible to prevent the delivery of nonconforming product to the customer, the supplier should establish emergency plans in order to reduce problems incurred by the customer. The plans should identify the personnel to perform the requested activities.

14.4 Review

Nonconforming products should be subjected to review by designated persons to determine whether they can be used as they are or whether they should be reworked, reclassified or scrapped. Persons carrying out the review should be competent to evaluate the effects of nonconformity on interchangeability, further processing, performance, reliability, safety and aesthetics. (See 9.7 and 11.8.)

14.5 Disposition

Disposal of nonconforming products should be taken as soon as practicable in accordance with decisions made following the recommendations given in 14.4. Decisions to accept nonconforming materials or products should be accompanied by authorized concessions/waivers, with appropriate precautions, but such practices should be minimized by prevention. (See 15.8.)

Some nonconforming products may be blended with conforming product, under controlled procedures which ensure that the resulting mixture is in full compliance with specified requirements.

The acceptance of nonconforming finished product by concession, where one or more parameters are outside agreed specification, should involve the agreement of the customer.

14.6 Documentation

The steps for dealing with nonconforming products should be set out in documented procedures with examples of the format of markers, forms and reports (see 17.2).

Abnormal operation of the production process should be recorded even if it is not expected to affect the final quality of the product.

14.7 Prevention of recurrence

Appropriate steps should be taken to prevent the recurrence of nonconformity (see 15.5 and 15.6). Measures necessary for the early warning of out-of-control operating conditions of the production process should be identified and implemented in order to prevent the delivery of nonconforming products. Consideration should be given to establishing a file listing nonconformities to help identify those problems having a common source, in contrast to those that are unique occurrences.

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 a problem. Corrective action also includes the reworking, recall or scrapping of unsatisfactory products, and revision of the quality system.

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 organization or a particular product should be assigned to a particular function within the organization. Responsibility and authority for the implementation of emergency plans should be identified in those cases where products for immediate delivery are concerned.

However, the analysis and execution may involve a variety of functions, such as sales, design/development, purchasing, production engineering, production 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 production costs, quality costs, performance, reliability, safety and customer satisfaction.

15.4 Investigation of possible causes

The relationship between cause and effect should be determined, with all potential causes considered. Important variables affecting the capability of the process to meet required standards should be identified.