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Quality management and quality assurance standards -- Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003

Normes pour le management de la qualité et l'assurance de la qualité -- Partie 2: Lignes directrices pour l'application de l'ISO 9001, l'ISO 9002 et l'ISO 9003

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INTERNATIONAL STANDARD

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Quality management and quality assurance standards —

Part 2:
Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003

Normes pour la gestion de la qualité et l'assurance de la qualité — Partie 2: Lignes directrices pour l'application de l'ISO 9001, l'ISO 9002 et l'ISO 9003

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Contents

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Annex

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 9000-2 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Sub-Committee SC 2, *Quality systems*.

ISO 9000 consists of the following parts, under the general title *Quality management and quality assurance standards*:

— *Part 1: Guidelines for selection and use*

— *Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*

— *Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*

— *Part 4: Guide to dependability programme management*

Part 1 is a revision of ISO 9000:1987.

Annex A of this part of ISO 9000 is for information only.

Introduction

This part of ISO 9000 gives guidelines for application of ISO 9001, ISO 9002 and ISO 9003. To facilitate cross-reference to those standards, this part of ISO 9000 has the same clause structure as ISO 9001 and contains clause-by-clause cross-references to ISO 9001, ISO 9002 and ISO 9003.

In general, the number and scope of the quality system elements and procedures contractually required for quality assurance are greatest in ISO 9001 and least in ISO 9003. For all clauses, the guidelines of this part of ISO 9000 should be applied in a manner consistent with the scope and requirements of the corresponding clause, if present, in the standard involved (i.e. ISO 9001, ISO 9002 or ISO 9003). Reference should be made to sub-clause 8.3 of ISO 9000 for guidance on the extent and degree of demonstration that may be appropriate.

ISO 9000 provides an overview of the ISO 9000 series of International Standards, and is a "road map" for use of the entire series. ISO 9004 provides extensive quality management guidance to the supplier organization, for designing and installing a quality system appropriate to its needs, without regard to contractual requirements of quality assurance.

This part of ISO 9000 does not duplicate the guidance to users that is provided in other ISO guidance standards such as ISO 9000, ISO 9000-3, ISO 9004 and ISO 9004-2.

Quality management and quality assurance standards —

Part 2:
Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003

1 Scope

This part of ISO 9000 gives guidance to enable its users to have improved consistency, precision, clarity and understanding when applying the requirements of the quality systems standards ISO 9001, ISO 9002 and ISO 9003. This part of ISO 9000 is phrased in terms of guidance to the supplier in order to reflect the requirements of ISO 9001, ISO 9002 or ISO 9003. However, this part of ISO 9000 does not add to, or otherwise change, the requirements of ISO 9001, ISO 9002 and ISO 9003. In a case of conflicting interpretation of ISO 9001, ISO 9002 or ISO 9003 on the one hand, and ISO 9000-2 on the other, the interpretation of the text in ISO 9001, ISO 9002 or ISO 9003 takes precedence.

This part of ISO 9000 is equally applicable to both manufacturing and service industries seeking to implement quality assurance into organizations.

In particular, this part of ISO 9000 gives guidance for the following users:

a) **suppliers** and **purchasers** involved directly in contractual applications of ISO 9001, ISO 9002 and ISO 9003;

b) **sub-contractors** who provide to the supplier raw materials, intermediate processing, equipment, services, etc., and who are affected by the application of ISO 9001, ISO 9002 or ISO 9003;

c) **auditors** who need to assess and communicate the adequacy of implementation of the requirements of ISO 9001, ISO 9002 or ISO 9003 in a specific situation.

The field of application of this part of ISO 9000 corresponds to the field of application of ISO 9001, ISO 9002 or ISO 9003.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9000. 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 9000 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 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002:1987, *Quality systems — Model for quality assurance in production and installation.*

ISO 9003:1987, *Quality systems — Model for quality assurance in final inspection and test.*

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

3 Definitions

For the purposes of this part of ISO 9000, the definitions given in ISO 8402 apply.

In order to clarify the meaning of the terms "supplier", "purchaser" and "sub-contractor", the following usages apply in this part of ISO 9000.

3.1 supplier: Organization to which the requirements of ISO 9001, ISO 9002 or ISO 9003 apply.

3.2 purchaser: Recipient of products (including services) delivered by the supplier.

3.3 sub-contractor: Organization which provides products (including services) to the supplier.

NOTE 1 For any one situation, an organization can, in addition to being *the* supplier, also be *a* purchaser and/or *a* sub-contractor at the same time.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

Guidance for ISO 9001 (4.1.1), ISO 9002 (4.1.1) and ISO 9003 (4.1.1)

When defining and documenting its quality policy, quality objectives and commitment to quality, supplier management should consider the following points.

a) The quality policy should be expressed in language which is easy to understand.

b) The quality policy should be relevant to the organization, its other policies, the products or services provided, and the organization's personnel.

c) The objectives should be achievable.

Management should demonstrate commitment visibly and actively on a continuing basis.

Commitment can be demonstrated by activities such as the following:

— ensuring that the organization's personnel understand and implement the quality policy;

— initiating, managing and following up on the implementation of the quality policy, including implementation of the quality system;

— not accepting deviations from quality policy or wasted resources in any part or aspect of the organization;

— providing adequate resources and training to support quality system development and implementation.

4.1.2 Organization

4.1.2.1 Responsibility and authority

Guidance for ISO 9001 (4.1.2.1), ISO 9002 (4.1.2.1) and ISO 9003 (4.1.2.1)

Individuals in the supplier organization should be aware of the scope, responsibility and authority of their functions and their impact on product or service quality.

Adequate authority should be delegated to individuals to allow them to carry out their designated responsibilities. They should have a clear understanding of their defined authority, and freedom and designated channels to take action. Everyone in the organization should be made aware of, and feel responsibility for, achieving the quality objectives and for fulfilling the requirements for the quality of its products.

It is usual to designate one or more individuals to monitor and to report the quality achieved. It is important that those so designated have access to the highest levels of management in the organization.

4.1.2.2 Verification resources and personnel

Guidance for ISO 9001 (4.1.2.2), ISO 9002 (4.1.2.2) and ISO 9003 (4.1.2.2)

Supplier management should recognize that adequate verification resources and personnel can involve the following:

— people doing the verification;

— awareness of the standards and verification arrangements which exist;

— training (see 4.18);

— sufficient time to do the work;

— production schedules which allow time for activities such as inspection, test and verification;

— equipment;

— documented procedures;

— means to access quality records.

4.1.2.3 Management representative

Guidance for ISO 9001 (4.1.2.3), ISO 9002 (4.1.2.3) and ISO 9003 (4.1.2.3)

The management representative may have other functions. Where this is the case, the responsibilities and authorities for both the quality system and the other functions should be clearly defined. Potential conflicts of interest should be examined to ensure that the effectiveness of the quality system is not degraded.

4.1.2.4 Management review

Guidance for ISO 9001 (4.1.3), ISO 9002 (4.1.3) and ISO 9003 (4.1.3)

The quality system review process and the reasons behind it should be known and understood by the organization. Reviews should include the following:

— the organizational structure, including the adequacy of staffing and resources;

— the structure and degree of implementation of the quality system;

— the achieved quality of the end product or service in relation to the requirements for quality;

— information based on purchaser feedback, internal feedback (such as results of internal audits), process performance and product (including services) performance.

The management should review periodically the appropriateness of the review frequency. The frequency depends on individual circumstances. Many organizations have found that annual management reviews are appropriate, but this interval is not mandatory.

Activities and results may be evaluated on a systematic and/or random basis. Chronic problem areas should receive special attention. Results should be documented and analysed for trends that may indicate systematic problems. These results should be discussed with the individuals concerned.

Required changes to the quality system determined during a management review should be implemented in a timely manner. The effectiveness of any changes should be evaluated.

4.2 Quality system

Guidance for ISO 9001 (4.2), ISO 9002 (4.2) and ISO 9003 (4.2)

The implementation of a quality system by the supplier is most effective when those in the organization understand its intention and how it functions, in particular in the area of their responsibility and its interface with other parts of the system.

The note to sub-clause 4.2 in ISO 9001 and in ISO 9002 provides guidance. As in all International Standards, the notes given in ISO 9001 and ISO 9002 are not mandatory requirements. The following guidance expands upon item a) in the notes to sub-clause 4.2 in ISO 9001 and in ISO 9002.

The quality system is often documented by means of a quality manual. The quality manual could be one document supported by several tiers of documents, each tier becoming progressively more detailed. For example, there may be an overall system manual and one or more specific procedural manuals. Together these documents define the quality system.

Quality plans may be used to define how the quality system requirements will be met in a specific contract, or for a specific class of products. Most of them will have a sequence of activities in relation to a time-frame. Here again, the plans can be in several tiers, becoming progressively more detailed. An example could include a detailed sequence of inspections, together with the type of inspection equipment and quality record requirements for a particular contract.

4.3 Contract review

Guidance for ISO 9001 (4.3) and ISO 9002 (4.3)

The importance of a thorough understanding of the purchaser's needs during the tendering stage, at the formulation of the contract and in all subsequent stages cannot be overstated. Often dialogue will be necessary to achieve this understanding, that should clearly establish the purchaser's requirements as to the product, delivery and other critical factors. The contract review can be viewed by the supplier as a process of three steps.

The existence of a draft quality plan is sometimes useful to support a contract review.

The process steps include the following.

a) Review of the contract; this may be appropriate at the tendering stage and at subsequent stages.

b) Achievement of agreements within the supplier's organization that

— the requirements have been completely defined;

— the requirements are understood;

— the supplier has the capability to meet contractual requirements.