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Requirements**

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14. Consequently **JIS Q 9001:2000** is replaced with this Standard.

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Quality management systems— Requirements

Introduction

0.1 General

This Japanese Industrial Standard has been prepared based on the fourth edition of **ISO 9001** published in 2008 without modifying the technical contents.

This Standard is revised to clarify points in the text of **JIS Q 9001** and to enhance compatibility with **JIS Q 14001** : 2004.

NOTE : The first and second editions of **ISO 9001** were published as **JIS Z 9901** and further the third edition was published as the first edition of **JIS Q 9001**.

The portions underlined with dots are the matters not stated in the original International Standard.

Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

The details of changes in this Standard among changes between the third edition (**ISO 9001** : 2000) and the fourth edition (**ISO 9001** : 2008) of the corresponding International Standard are shown in Annex B.

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization’s quality management system is influenced by

- a) its organizational environment, changes in that environment, and the risks associated with that environment,
- b) its varying needs,
- c) its particular objectives,
- d) the products it provides,
- e) the processes it employs,
- f) its size and organizational structure.

It is not the intent of this Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this Standard are complementary to requirements for products.

This Standard can be used by internal and external parties, including certification bodies, to assess the organization’s ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization’s own requirements.

The quality management principles stated in **JIS Q 9000** and **JIS Q 9004** have been taken into consideration during the development of this Standard.

0.2 Process approach

This Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and meeting requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in figure 1 covers all the requirements of this Standard, but does not show processes at a detailed level.

NOTE : In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization’s policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

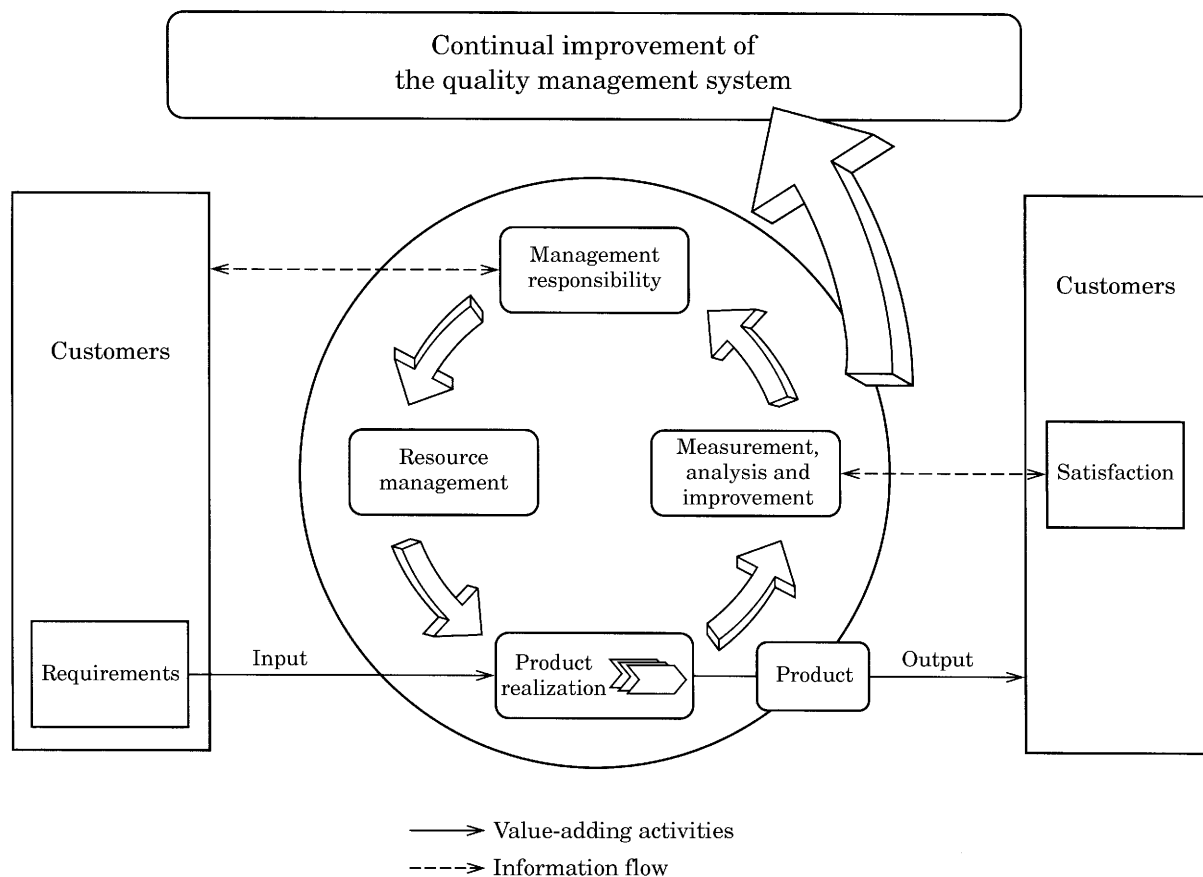


Figure 1 Model of a process-based quality management system

0.3 Relationship with JIS Q 9004

JIS Q 9001 and **JIS Q 9004** are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

At the time of publication of this Standard, **ISO 9004** is under revision. The revised edition of **ISO 9004** will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. **ISO 9004** provides a wider focus on quality management than **ISO 9001**; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

NOTE : **JIS Q 9004:2000** will be also revised according to the revision of **ISO 9004**.

0.4 Compatibility with other management systems

During the development of this Standard, due consideration was given to the provisions of **JIS Q 14001:2004** to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between **JIS Q 9001:2008** and **JIS Q 14001:2004**.

This Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this Standard.

1 Scope

1.1 General

This Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this Standard, the term “product” only applies to

- a) product intended for, or required by, a customer,
- b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

NOTE 3 The International Standard corresponding to this Standard is as follows.
ISO 9001:2008 *Quality management systems—Requirements* (IDT)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21**.

1.2 Application

All requirements of this Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization’s ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

2 Normative references

The following standard contains provisions which, through reference in this text, constitute provisions of this Standard. For the normative standard with the year

indication, only the edition of the indicated year shall apply but the revision (including amendments) made thereafter shall not apply.

JIS Q 9000 : 2006 *Quality management systems—Fundamentals and vocabulary*

NOTE : Corresponding International Standard: ISO 9000 : 2005 *Quality management systems—Fundamentals and vocabulary* (IDT)

3 Terms and definitions

For the purposes of this document, the terms and definitions given in **JIS Q 9000** apply.

Throughout the text of this Standard, wherever the term “product” occurs, it can also mean “service”.

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this Standard.

The organization shall

- a) determine the processes needed for the quality management system and their application throughout the organization (see **1.2**),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure where applicable, and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this Standard.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2 An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and

regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
- b) the degree to which the control for the process is shared,
- c) the capability of achieving the necessary control through the application of **7.4**.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures and records required by this Standard, and
- d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term “documented procedure” appears within this Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions (see **1.2**),
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in **4.2.4**.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see **7.2.1** and **8.2.1**).

5.3 Quality policy

Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see **7.1 a)**], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

- a) the planning of the quality management system is carried out in order to meet the requirements given in **4.1**, as well as the quality objectives, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) reporting to top management on the performance of the quality management system and any need for improvement, and
- c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE 1 The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

NOTE 2 There may be more than one management representatives as far as having the above responsibility and authority.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see **4.2.4**).

5.6.2 Review input

The input to management review shall include information on

- a) results of audits,
- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system, and
- g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of product related to customer requirements, and
- c) resource needs.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

- a) to implement and maintain the quality management system and continually improve its effectiveness, and
- b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE : Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 Competence, training and awareness

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) where applicable (unless they achieve the necessary competence), provide training or take other actions to achieve the necessary competence,
- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience (see **4.2.4**).

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

- a) buildings, workspace and associated utilities (such as electricity, gas or water),
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport, communication or information systems).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE : The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see **4.1**).

In planning product realization, the organization shall determine the following, as appropriate: