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Quality management system— Guidelines for sustainable growth

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Foreword

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Quality management system – Guidelines for sustainable growth

0 Introduction

0.1 General For an organization to fulfill its mission, maintain competitiveness and achieve sustainable growth, it is essential for the organization to upgrade its reason for existence by winning satisfaction of customers and other interested parties in the value of the products supplied by the organization. For this reason, the organization shall adapt to changes in the environment swiftly, upgrade general performance of the organization effectively and efficiently and respond to the needs and expectations of customers and other interested parties in order to create outstanding customer value.

The management guidelines presented in this Technical Report is founded on the following 12 Quality Management Principles identified in view of the changes in thinking in organizational management, as well as changes in the environment surrounding many organizations.

- a) **Creating customer value** The organization should provide products (or services) in which customers recognize value.
- b) **Focus on social value** The organization should fulfill towards society its responsibility in public service, such as ethics, safety and protection of the environment.
- c) **Visionary leadership** The leader should establish vision, clear-cut policy to achieve division, guide and motivate people, and lead the organization in the appropriate direction.
- d) **Understanding core competence** The organization should be aware of its core competence, consisting of technologies, capabilities, and organizational climate that the organization possesses (and/or should possess).
- e) **Involvement of people** The organization should utilize the knowledge, skills, creativity, etc., of people in its activities.
- f) **Collaboration with partners** The organization should collaborate with partners to create value and win customer satisfaction.
- g) **Total optimization** The organization should build systems for total optimization, with attention to the ideals in each process.
- h) **Process approach** The organization should define the processes for creating values, assess their interrelationship, and administer and manage them, together with of applying these processes as a system.
- i) **Factual approach** The organization should make decisions based on facts.
- j) **Organizational and personal learning** The organization should encourage personal learning and utilize personal knowledge as organizational knowledge.
- k) **Agility** The organization should make decisions and act with agility in response to changes in the environment.

- 1) **Autonomy** The organization should make decisions and taking action based on its own values standards.

The technical report has been written for the purpose of providing the following benefits.

- Improvement in the people's awareness, knowledge and attitude toward learning.
- Assessment of capabilities of the organization
- Improvement and innovation of businesses and processes
- Adaptation to environmental changes

0.2 Elements and creation of knowledge The elements of knowledge are “tacit knowledge” and “explicit knowledge”. “Tacit knowledge” is personal knowledge related to specific conditions that cannot be easily expressed in language and difficult to communicate to others. On the other hand, “explicit knowledge” is knowledge that can be communicated through media such as language and illustrations and can be regarded “organization of knowledge”.

Interaction between tacit knowledge and explicit knowledge, which are in complementary relations with each other, leads to creation of personal knowledge and, through learning and activity, to greater stimulation of creation of knowledge by people in the organization and to improvement of organizational knowledge. Through shared experience of tacit knowledge of an individual with tacit knowledge of others, knowledge is created and, by emerging to the surface, becomes clear as explicit knowledge. Furthermore, such knowledge combines with existing explicit knowledge to create a new explicit knowledge. Acquisition of such explicit knowledge into oneself is internalization of knowledge.

0.3 Learning Continual improvement/innovation executed to adapt to rapid environmental changes is dependent on organizational knowledge. Of accumulation of organizational knowledge is the foundation of creating customer value and achieving sustainable growth for the organization. Knowledge is acquired through analysis of information and personal experience and evolves into wisdom when this knowledge combines with action. Consolidation and sharing of such knowledge and wisdom builds organizational knowledge.

The objective of learning is to gather and share personal knowledge and consolidate and crystallize it into organizational knowledge. Moreover, organizational knowledge promotes improvements/innovation and therefore enriches the substance of organizational knowledge through further learning of such experiences to achieve greater sophistication. Learning is founded on voluntary action, autonomy and mutual trust, regardless of the methodology, and this is consolidation and sharing of knowledge conducted through relations among colleagues in a dynamic manner. Education and training themselves can be learning.

0.4 Innovation By nature, an organization does not have life span like a living organism. However, the rationale of its existence is lost when it no longer is able to adapt to environmental changes, leading to termination. In case of rapid environmental changes or aggregate of changes exceeding the threshold value for the organization's flexibility, innovation becomes essential. The objective of innovation is to adapt to rapid changes in the environment of the organization and to aggregate of changes. In addition, it means change in the environment of the organization itself.

Innovation means destroying all or part of an existing framework to build a new one. Improvement is based on the existing framework and has its limits in creative destruction. Innovation is not gradual improvement of performance through modifications but is aimed at dramatic leap, in which singular thinking of an individual or learning organization brings their ability to the full.

In contrast to innovation that destroys the existing framework, building of a totally new framework where none existed is called creation. In other words, it means creation of a new paradigm with paradigm shift or creative development on one's own. It points to totally new change. Because of this, this is heavily dependent on the exceptional individual or potential capabilities of the leader. The term "innovation" used in this Technical Report should be used to suggest "creation" as well.

For an organization not to lose its rationale of existence, it is necessary to make innovation not a transient event but making it to repeat itself after a suitable interval. At the same time, however, uninterrupted change and continuing innovation to address it may cause wear in the organization. To prevent wear in the organization caused by innovation, attention should be paid toward extensive selection of target of the innovation, selection of suitable method of innovation, preservation of invariables (such as values), and control of innovation speed.

0.5 Understanding of the organizational profile To achieve sustainable growth of the organization, the organization shall have appropriate understanding of the characteristics of the business activities that it engages in constantly.

In the application of this Technical Report that provides comprehensive guidelines on Quality Management Systems founded on sustainable growth as its basic approach, each organization needs not apply everything in the guidelines with equal level of importance. Especially when sustainable growth of an organization is the objective, it is not necessary to apply everything in the guidelines with equal level of importance. The reason is that the elements of quality management system that should be prioritized in an organization for sustainable growth varies by the products the organization supplies, the industry to which it belongs and the management environment of the organization.

Therefore, the Technical Report introduces the concept of the organizational profile. By clarifying the profile of the organization based on the various characteristics that underlie the organization, from the perspective of the environment surrounding the organization and the capabilities and resources found inside the organization, the areas and elements that should be prioritized in the quality management system of the

organization can be established. In addition, viewpoints, benchmarks, and weights are to vary in self-assessment, depending on the ideal profile of the organization, as basis for appropriate evaluation of the organization.

0.6 Consistency with TR Q 0005 family of standards This Technical Report had been written for the purpose of use separate from TR Q 0006 *Quality management system – Guidelines for self-assessment*. However, it may be used as complementary material that is in consistency with this Technical Report. Moreover, this Technical Report may be used together with JIS Q 9023 *Performance improvement of management systems – Guidelines for management by policy*, JIS Q 9024 *Performance improvement of management systems – Guidelines for procedures and methodology for continual improvement* and JIS Q 9025 *Performance improvement of management systems – Guidelines for quality function deployment to contribute to sustainable growth*.

0.7 Relationship with JIS Q 9001 JIS Q 9001 defines the requirements for quality management systems and focuses on the effectiveness of quality management systems in satisfying product requirements.

On the other hand, this Technical Report focuses on the effectiveness, efficiency and innovation in quality management system when satisfying the needs and expectations, including requirements, of customers, people in the organization, and other interested parties. Vis-à-vis JIS Q 9001, the Technical Report establishes the guidelines in quality management systems by adding items related to creating customer values, creating social values, creating knowledge, learning and innovation. It is recommended as guidelines when an organization aspires to achieve sustainable growth beyond the scope of requirements defined in JIS Q 9001.

0.8 Coexistence with other management systems This Technical Report does not include guidelines specific to other management systems, such as environmental management, occupational health and safety management, financial management, and risk management. However, the Technical Report has been written with attention to possible combination or integration of quality management system with other related management systems. When an organization takes action to build a quality management system based on these guidelines, these may be adapted to existing management systems.

In addition, it can also be combined with the model of performance excellence on the highest level in an organization.

1 Scope

1.1 General This Technical Report provides guidelines to support effectiveness, efficiency, and innovation in quality management system, beyond the requirements established in JIS Q 9001. The focus of this report is on the following.

- Support in improvement of performance and competitiveness of an organization
- Support in sustainable growth of an organization that is powerful and resistant in all environments
- Support in providing benefits to interested parties through creation of customer values

1.2 Application This technical report applies to all organizations that aspire to achieve sustainable growth, regardless of industry, type of business, business scale or products provided.

By identifying clearly the organization and its organizational profile, including product characteristics, the report can be applied to the organization in the best suited manner, by focusing on a number of provisions in the reports or excluding those that are inappropriate.

2 Normative reference The following normative document contains provisions which, through reference in this text, constitute provisions of this Technical Report. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply.

JIS Q 9000:2000 *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions For the purpose of this Technical Report, the terms and definitions given in **JIS Q 9000 :2000**, and the following terms and definitions apply.

A term in definition or note that is defined elsewhere in clause 3. is indicated by boldface. Terms given in **JIS Q 9000** are indicated in boldface, followed by **JIS Q 9000** shown in parentheses. Such a boldface term may be replaced in the definition by its complete definition.

The term “products” wherever used throughout this Technical Report also means “services”.

3.1 organizational profile summary of the business environment surrounding the **organization (JIS Q 9000)** conducting business and **organizational structure (JIS Q 9000)** .

EXAMPLE Form, members and scale of the **organization (JIS Q 9000)** .
technologies and knowledge, facilities and financial resources the organization owns.
competition surroundings in the industry and market information

3.2 mission objective of the existence and business objective of the **organization(JIS Q 9000)**.

3.3 values document written for the purpose of defining the mission of the **organization (JIS Q 9000)** and justifying its existence.

Reference: This may at times be called corporate philosophy or company principles.

3.4 vision the future profile of the organization that the **organization (JIS Q 9000)** aspires to achieve and which has been officially announced by **top management (JIS Q 9000)**.

3.5 strategy measures for realizing the **vision (3.4)** of the organization, based on analysis of its business environment and internal resources.

3.6 business strategy measures for realizing the **vision (3.4)** of the organization in a certain business area.

NOTE: This includes decision-making on the basic goals of the organization, based on the business environment and its changes, selection of means and methodology most appropriate in gaining a competitive nest for executing these goals, and allocating resources for this purpose.

3.7 quality policy general purpose and policy of the **organization (JIS Q 9000)** related to quality, announced officially by **top management (JIS Q 9000)**.

- Reference
- 1 Generally speaking, **quality policy** is harmonized with **vision (3.4)** of the organization and provides a framework for establishing the **objectives**.
 - 2 The quality policy is positioned at the top of the quality management system.

3.8 enabler factors that promote action in a **process (JIS Q 9000)**.

EXAMPLE Tone of the organization, education and training, resources, and methodology.

3.9 best practice **system (JIS Q 9000)**, **process (JIS Q 9000)** and **enabler (3.8)** that are regarded as outstanding in view of the **quality policy (3.7)** of the **organization (JIS Q 9000)**.

3.10 benchmarking systematic method of searching for **best practices (3.9)** inside and outside the organization regarding **process (JIS Q 9000)** and **system (JIS Q 9000)** to be improved, conducting comparative analysis with the one's own organization and introducing **best practice (3.9)** suited to the organization for improvement and innovation of existing quality management system.

3.11 business model system (JIS Q 9000) that links values to be provided to customers (JIS Q 9000) with the **mission (3.2)** of the organization.

Reference: A business model generally consists of the following.

- Customers targeted by the organization
- Products to be provided
- Combination of the organization's strengths with management resources
- Procurement of management resources, including collaboration with partners
- Communication with customers
- Distribution for delivering products

4 Quality management system

4.1 Business strategy and quality management system An organization should plan business strategy as part of business planning in order to achieve the vision of the organization, based on analysis of the organization's business environment and internal resources. Business strategy is commonly planned in the following three levels.

- a) **General strategy** Measures that pertain to the general direction for a number of businesses. Examples are planning management resources allocation, business rationalization, and mergers and buyouts in an organization engaged in diversified business management.
- b) **Business strategy** Measures for realizing vision in a single business area (see 4.2). Examples are products structure, product value to be added, basic policies pertaining to dealing with customers and other interested parties, measures pertaining to preservation and acquisition of core technologies, and management resources that the organization should possess.
- c) **Product strategy** Measures pertaining to product value from the customer perspective, such as quality, pricing, timing in provision, and the volume, regarding products with a single concept, as well as product characteristics viewed from the standpoint of other interested parties (see 8.3 and 8.4).

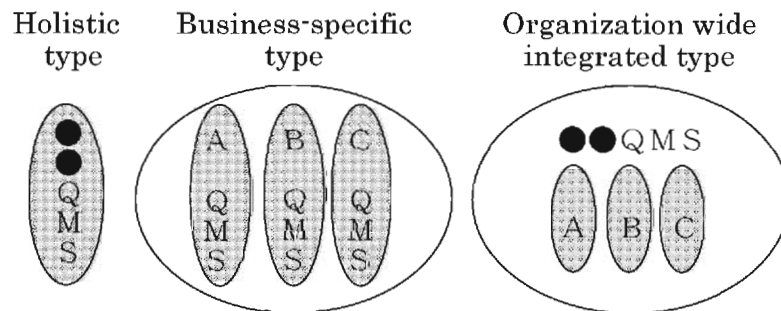
An organization should plan business strategy to achieve the vision in a single business area in a way that harmonizes with the general strategy (if any). If an organization has only one business area in which it operates, the general strategy and its business strategy may be one and the same.

An organization should develop a quality management systems suited to the business area. For this purpose, the organizational profile should be identified clearly with analysis of the business environment and internal organizational structure conducted in development of the business strategy (see 4.2) and therefore identify clearly the capabilities and characteristics that the organization's quality management system should have in order to realize its business strategy (see 4.3).

The form of quality management system suited to the organization's management systems should be selected. The quality management system may take the following

forms.

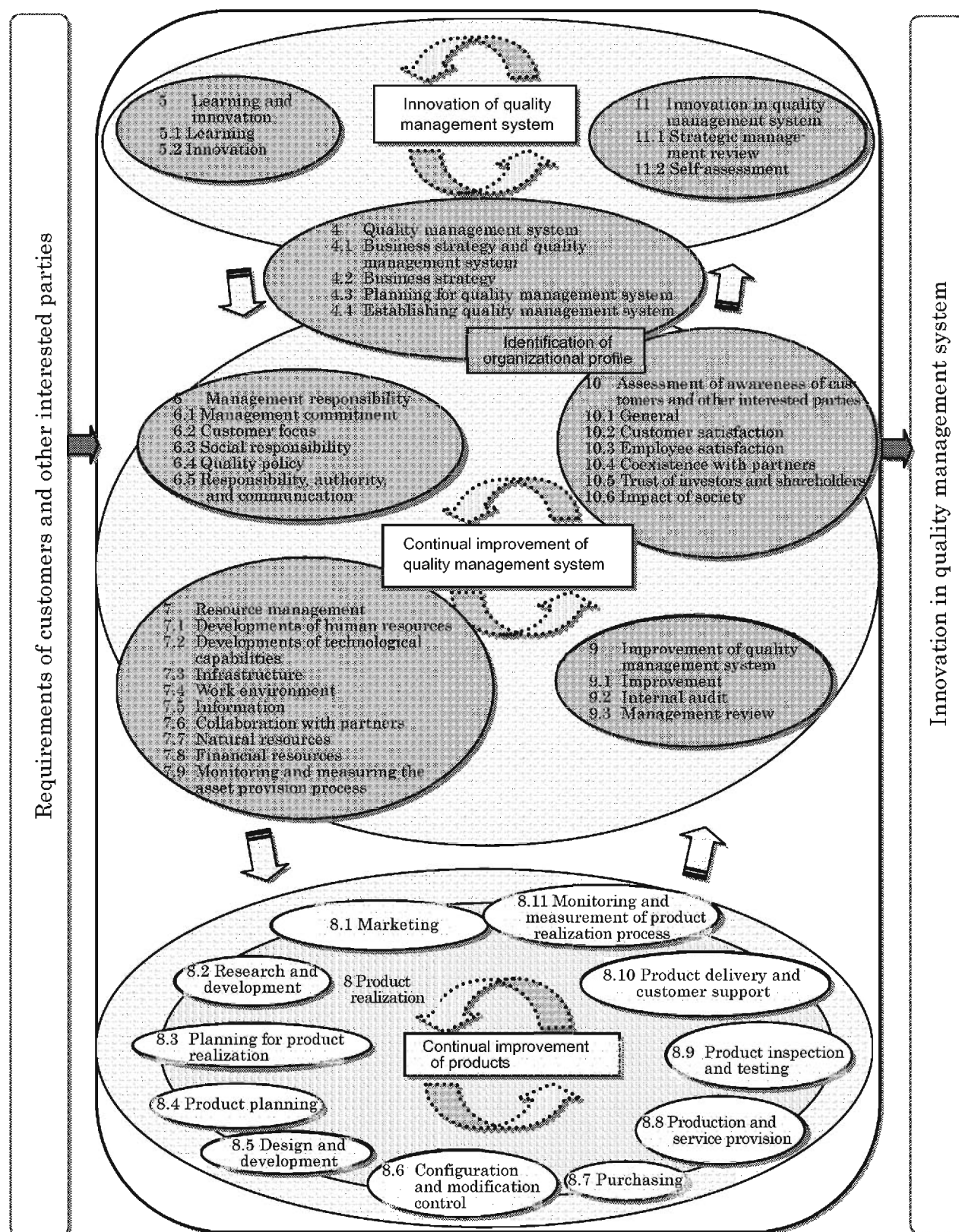
- Holistic type (single quality management system)
- Business-specific type (quality management system for each business area)
- Organization wide integrated type (quality management system in which a number of business areas exist)



The following items should be taken into consideration in determining the form of quality management system.

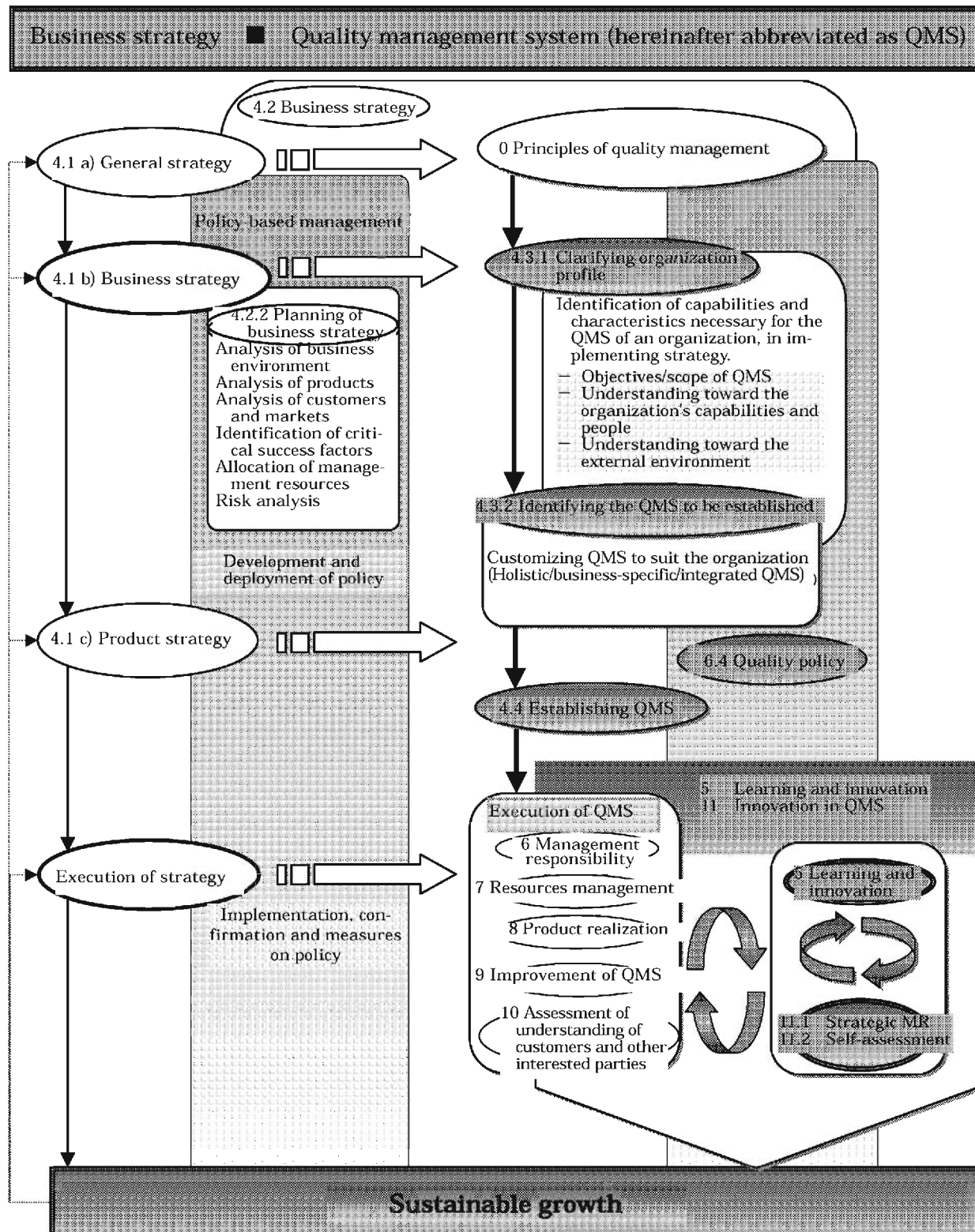
- Customer requirements regarding quality management systems
- General strategy (group management policy)
- Understanding toward top management policy
- Organizational profile

The relationships among elements in a quality management system are shown in Figure 1. The position of elements in a quality management system from this perspective of business strategy deployment is shown in Figure 2.



NOTE: Numbers indicate section and clause numbers in the Technical Report

Figure 1 Model of a quality management system



NOTE: Numbers indicate chapter and section numbers in the Technical Report

Figure 2 Activities related to establishing quality management system

4.2 Business strategy

4.2.1 Management principles and vision The top management of an organization should plan the vision of the organization as the direction that the organization should take, as well as its ideal profile, with the following items in consideration. These principles and vision should be disseminated throughout the organization, reaching to all people, to ensure development of business strategy.

- Harmonization with management principles.
- Clear strategic goals and clear date of achievement.

4.2.2 Planning of business strategy The business strategy should be developed as measure for achieving the management principles and relevant business vision of the organization.

The top management should develop business strategy consisting of the following, in order to define the framework for optimal allocation of the organization's management resources that assures total competence that are to become success factors in the relevant business area and conforms to the needs and expectations of the customers and other interested parties.

- a) Target markets and customers
- b) Products to be provided
- c) Critical success factors in order to ensure competitive advantage
- d) Allocation of management resources
- e) Action items necessary to realize the above a) through d)

Examples of items referred to in business strategy are the following.

- a) Development of new products and new technologies
- b) Creation of new business models and new markets
- c) Development of new processes, including outsourcing
- d) Collaboration with new partners and technology transfer
- e) Organization restructuring and human-resources development

4.2.3 Analysis for business strategy planning The top management should take the following items into consideration in planning business strategy.

a) Analysis of the business environment

- 1) Analysis of macroeconomic, political and social developments and identification of the business environment surrounding the entire industry.
- 2) Analysis of the competitive environment consisting of the following, to identify opportunities and threats.
 - Threat from new entries

EXAMPLE An industry that is easy to enter is an industry in which anyone can start business and competition is intense.

– Threat from alternative products

EXAMPLE In a period of rapid environmental changes, the emergence of alternative products can threaten the existence of industry itself.

Power balance with customers

EXAMPLE Customers have strong power within the industry, such as general consumer products, in which customer have the discretion of choice.

– Power balance with suppliers

EXAMPLE Power balance can change, depending on whether or not the business is a dominant supplier.

– Competition within the industry

EXAMPLE An industry that is growing and easy to enter is susceptible to intense competition and to cutthroat pricing.

- b) **Product analysis** Benchmarking should be conducted from the discriminatory features of the product in the marketplace (such as functions, performance, reliability, delivery and service) and pricing (such as procurement cost and operating cost) in order to identify weaknesses and strengths.
- c) **Customer and market analysis** All decisions made by an organization should contribute to the benefit of the customers in some way. Assessment of the needs and expectations of customers is fundamental to organizational decision-making. In conducting research on customer needs and expectations, questionnaires, interviews, and field surveys are recommended. For analysis, tools such as quality function deployment should be utilized.

NOTE: See JIS Q 9025 *Performance improvement of management systems – Guidelines for quality function deployment*

d) **Analysis of organizational capabilities**

- 1) Knowledge-based capabilities that an organization should possess
- 2) Personal capabilities that an individual should possess
- 3) Management capabilities that should exist on each level of the organization

- e) **Identifying critical success factors** Factors that lead business to success should be identified for development of business model. Such a factor is closely linked to the core competence of an organization and is an element in management and that is both objective and concrete, such as quality, cost, and time (e.g., development time, delivery and service time).

- f) **Allocation of management resources** Management resources including manpower and budget should be allocated according to strategy determined by identifying critical success factors.

- g) **Risk analysis** Risks in the business environment should be analyzed, and important risks should be addressed.
- 1) The scale of the impact of a risk, the probability of its occurrence, and vulnerability to such a risk should be listed up in identifying risks
 - 2) The risks should be selected, based on standards identified as important for the organization.
 - 3) Review countermeasures against key risks.

4.3 Planning for quality management system

4.3.1 Clarifying organizational profile In order to plan quality management system suited in realizing sustainable growth, an organization should identify its organizational profile and customize the quality management system suited to itself by identifying its own strengths and weaknesses. An organizational profile is a description of the analytic findings in business strategy and others view from the perspective of quality management systems. The following items should be taken into consideration.

a) **Scope of quality management system**

- 1) Principal products and their characteristics
- 2) Scale of the organization (total sales, number of employees, and capital)
- 3) Location of the organization

b) **Understanding toward organizational capabilities**

- 1) Management principles, vision, and mission
- 2) Technologies and knowledge the organization possess and their level
- 3) Level of management
- 4) Level of capability for various management functions (planning, design and development, production and realization, marketing and sales, and partners)
- 5) Facilities and equipment ownership
- 6) Financial resources
- 7) Strength of principal products and their reason
- 8) Maturity level of the organization (see **TR Q 0006** *Quality Management System – Guidelines for Self-Assessment*)

NOTE: b) and c) may have two aspects, level necessary for business and level found in the organization.

c) **Understanding toward people**

- 1) Organizational culture
- 2) Level of freedom in authority and decision-making
- 3) Level of leadership

- 4) Education and knowledge levels of employees
- 5) Type of employees
- 6) How knowledge is shared
- d) **Understanding toward the external environment**
 - 1) **Market and customers**

Principal requirements for key customers and market segments
 - 2) **Interested parties**
 - Key partners and their requirements
 - Requirements of key investors and shareholders
 - 3) **Requirements from society**
 - Requirements under laws and regulations
 - Environmental issues
 - 4) **Competitive environment**
 - Threat from new entries
 - Threat from alternative products
 - Power balance with customers
 - Power balance with suppliers
 - Competition within the industry

The organization should determine priorities in elements of quality management system by comparing the requirements for implementing business strategy and realizing sustainable growth with the realities on what is possible.

4.3.2 Identifying the quality management system to be established In order to identify the quality management system best suited to the organization for effective and efficient delivery of products to customers, the organization should weigh the provisions described in clause 5, based on 4.2.1.

In order to identify the quality management system best suited to the organization, the following items should be taken into consideration.

- a) Decide on the scope of quality management system [see 4.1 and 4.3.1a)].
- b) Review management strategy (see 4.2).
- c) Within the organizational profile pertaining to organizational capabilities and people [see 4.3.1b) & c)] identify items on which the organization should focus from the perspective of implementing business strategy.
- d) Observe what should be done regarding the above c).
- e) The organizational profile pertaining to the external environment [see 4.3.1 d)], should identify items on which the organization shall focus from the perspective of

implementing business strategy.

- f) Regarding the above c), observe what action should be taken with attention to understanding pertaining to organizational capabilities and people.
- g) Combine the above d) and f) to identify important items in the processes and aspects of the quality management system.
- h) Weigh the elements in the quality management system based on the above g) and on analysis of important items, strengths, and weaknesses.

4.4 Establishing quality management system

4.4.1 General An organization should establish, implement and maintain of quality management system based on its business strategy. Moreover, the effectiveness and efficiency of the quality management system should be improved continually and at the same time maintained and innovated in response to environmental changes.

In order to optimize the entire quality management system by prioritizing processes necessary for the system, the organization should execute the following.

- a) Identify the processes necessary in building the quality management system and their application on the organization (see 1.2).
- b) Identify the order and correlations among the processes.
- c) Identify the goals and establish evaluation indicators for process and performance in order to ensure efficiency and effectiveness in process operation and management.
- d) Monitor, measure, and analyze the process and performance indicators to identify opportunities for improvement.
- e) Improve the process to gain satisfaction of customers and other interested parties.
- f) Innovate quality management system creatively through learning in order to adapt to environmental changes.
- g) Review into operation of quality management system that has been innovated and into achievement of performance goals.

4.4.2 Documentation In order to implement and maintain quality management system, as well as to manage processes in the organization effectively and efficiently, the organization should establish rules regarding necessary documents, including relevant records.

Documentation should be planned for people in the organization to offer and share knowledge, contribute to recording the establishment and implementation of standards, and help gain clearer understanding of the organizational profile. For this purpose, following items should be taken into consideration.

- a) Documents should be available for reading by people in the organization for communication.
- b) People in the organization should be able to share knowledge.

- c) People in the organization should be able to learn and respond to environmental changes with agility.
- d) Documents should be made available as evidence at appropriate time and at appropriate location.

4.4.3 Document management The organization should manage documents required for quality management system in order to ensure effective and efficient use of such documents.

The organization should establish procedures for management necessary for the following activities.

- a) Confirm document suitability, document issue, update when necessary, screening of revised and terminated documents, and ensure that documents are in usable state whenever and wherever necessary.
- b) Verify whether actual procedure conforms to procedure documentation.
- c) Ensure that content of corrective measure and preventive measure is reflected in the documentation.
- d) Ensure that document revision is executed with agility.
- e) The volume of document under management should be kept at the least minimum necessary, considering efficiency.
- f) Use media suited to the purpose, with attention to advances in information technology.
- g) Make continual improvements on documentation management procedures.

5 Learning and innovation

5.1 Learning

5.1.1 General Improvements/innovations aimed at adapting to changes depend on organizational knowledge. Learning is defined as gathering and sharing of personal knowledge, transformation of such knowledge in to organizational knowledge, and further enrichment and sophistication in substance. (See 0.3)

5.1.2 Individual learning and organizational learning The organization should execute the following items related to learning.

- Provide appropriate opportunities and resources for individual learning.
- Create mechanism for individual learning to be utilized in the organization.

EXAMPLE Creation of venue for transmission of knowledge to others and inter-divisional exchange of knowledge; development of knowledge database

5.1.3 Mission of top management The top management should execute the following to promote learning.

- The top management itself should take opportunities for learning such as taking private lessons and case study and undertaking the job of instructing.
- Provide foundation for the learning process.
- Support learning in education and training programs.
- Develop learning environment.
- Build organizational culture that encourages learning.
- Provoke vacillation or chaos in the organization for the organization to shed its existing frameworks.

NOTE: Message from the top management containing ambiguities regarding manner of delegation of authority, given within the scope of a clearly established direction in business, can cause vacillation or chaos, which in turn nurtures the seeds of creativity and development. Also, top management decision essential in innovation can very often be based on tacit understanding, such as insight, inspiration and intuition. The method for learning these systematically are case studies and direct instructions under conditions that require decision-making.

5.1.4 Learning process In the learning process, the organization should take into consideration the individual differences of human capability, suitability, emotion, standpoint, and relations that are most fundamental to learning in order to share the knowledge creation process with the organization and that beyond the organization.

The following items should be taken into consideration for promotion of systematic learning.

a) Provision of venue

- Provide venue with attention to individual differences.
- Provoke vacillation.

b) Creation of knowledge

- Makes people realize the importance of learning and motivate them to learn.
- Build the knowledge creation process. (EXAMPLE Respect for dialogue and conversation; communication; etc.)
- Built a network that links people in the organization organically.

c) Utilization of knowledge

- Train “knowledge workers” who act based on knowledge.

NOTE: Knowledge workers are people who create and use knowledge and can be any person in the organization.

- Plan, manage and reform business processes effectively and efficiently.
- Evaluate activity results.