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**Performance improvements of
management systems — Guideline for
Quality Assurance by Process**

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Foreword

This Japanese Industrial Standard has been established by the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal for establishment of Japanese Industrial Standard submitted by The Japanese Society for Quality Control (JSQC)/Japanese Standards Association (JSA) with the draft prepared from the association standard (JSQC-Std 21-001 : 2015) being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

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Performance improvements of management systems — Guideline for Quality Ensurance by Process

0 Introduction

0.1 General

In order to provide value to customers through products and services, it is necessary to plan and design products and services that are attractive to customers, and to produce and provide them accordingly. In planning and designing, it is essential to accurately grasp the customers' needs, including latent ones, clarify the requirements, and convert them into specifications to realize them. On the other hand, in production and provision, it is essential to establish a process that ensures the realization of the specifications and to implement it as determined. The key concept in realizing this is to “build quality by the process,” and the specific activities for this purpose is Quality Ensurance by Process. The role of Quality Ensurance by Process in quality assurance is shown in Annex A.

This Japanese Industrial Standard summarizes the guidelines for effective implementation of Quality Ensurance by Process in production and provision, with the aim of “building quality by the process.”

No corresponding International Standard has been established at this point

0.2 Consistency with other standard.

This Standard is designed with the aim of Quality Ensurance by Process and intended to be used independently; however, this Standard may be used with consistent group of such standards as

- JIS Q 9023 for policy management,
- JIS Q 9026 for data management,
- JIS Q 9024 for procedures and methodology for continual improvement
- JIS Q 9025 for quality function deployment that is utilized for Quality Ensurance by Process in planning and design stage

to complement each other. Also, this Standard is designed to be used as a supporting technique for quality management specified in JIS Q 9005.

0.3 Relation with JIS Q 9001 and JIS Q 9004

This Standard is designed to be used as a supporting technique for an organization to effectively and efficiently operate the management system on the basis of JIS Q 9001 and JIS Q 9004.

0.4 Compatibility with other management systems

This Standard has not been prepared as a specific supporting technique for such

management systems as environmental management, occupational health and safety management, and financial management, but may be used as a supporting technique to improve the performance of these management systems.

1 Scope

This Standard specifies the fundamental principles and the guidelines on Quality Assurance by Process in production and provision, which is one of the major activities of quality management. The production and provision, here, means a series of stages executed according to the process plan and design for realizing the product and service, such as preparation of production and provision, production and provision, selling, delivery, complaints handling and disposal. This Standard is applicable regardless of size and type of the organization.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this Standard. The most recent edition of the standard (including amendments) indicated below shall be applied.

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

3 Terms and definitions

For the purpose of this Standard, the terms and definitions given in JIS Q 9000, and the following apply.

3.1 quality assurance

systematic activities undertaken by organizations to ensure, verify, and demonstrate that they meet the needs of customers and society

NOTE 1 “Ensure” refers to activities of establishing a process to understand the needs of customers and society, to plan and design products and services that meet those needs, and to provide them.

NOTE 2 “Verify” refers to activities to continuously evaluate and understand whether the needs of customers and society are being met, and to take immediate remedy and/or recurrence prevention measures if they are not.

NOTE 3 “Demonstrate” refers to activities that provide a sense of trust and security by clearly stating what needs are being met as a promise to customers and society, and showing evidence that these needs are being met.

NOTE 4 The purpose part of the above definition, “meeting the needs of customers and society,” may be called quality assurance.

3.2 process

a set of interrelated or interacting activities that transform inputs into outputs

NOTE Inputs and outputs include hardware, software, services, information, and energy.