JSQC STANDARD

Guideline for Quality Assurance by Process

JSQC-Std 21-001 (E) : 2015

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Preference

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Guideline for Quality Assurance by Process

（Note: This doccument is an official English translation of JSQC-Std 21-001:2015 written in Japanese.）

Introduction

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. These activities are called new product and service development management, which also include the designing of software, construction etc. that are basically undertaken one at a time independently. 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."

This standard summarizes the guidelines for effective implementation of Quality Assurance by Process in production and provision, with the aim of "building quality by the process." In Clause 4, the role and elements of Quality Assurance by Process are described as the fundamentals of Quality Assurance by Process. Clause 5 explains how to proceed with each element of Quality Assurance by Process such as standardization, study and improvement of process capability, trouble prediction and prevention, inspection and verification, and action on process abnormalities. Clause 6 describes the Process Capability Index, Process FMEA, and the Quality Assurance Network (QA Network), which are effective tools for Quality Assurance by Process.

This standard uses terms that are common to a wide range of fields so that it can be applied to a wide range of products and services.

Note In this standard, term "quality assurance" is used in a broader sense (see 3.1) than the ISO 9000's definition that is "part of quality management focused on providing confidence that quality requirements will be fulfilled" because of the typical usage in Japan.

1. Scope

This standard provides recommendations by the Japanese Society for Quality Control (JSQC) regarding Quality Assurance by Process in production and provision, which is one of the major activities of quality management.

2. Normative references

The following standards constitute a part of the provisions of this standard, as they are cited here. Only the version of the stated year is applicable, and no revised versions or amendments are applicable.

JSQC-Std 00-001: 2011 Quality management terms

JSQC-Std 32-001: 2013 Guidelines for daily management

JIS Q 9024: 2003 Performance improvement of management systems－Guidelines for procedures and methodology for continual improvement

JIS Q 9025: 2003 Performance improvement of management systems -- Guidelines for quality function deployment

3. Terms and definitions

The terms and definitions specified in JSQC-Std 00-001 and the following terms and definitions apply to this standard. The following terms and definitions include those quoted and reprinted from other standards.

3.1 Quality assurance

A set of 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.

(Same as JSQC-Std 00-001)

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.

(Same as JSQC-Std 00-001)

3.3 Quality Assurance by Process

A set of activities to ensure, verify and demonstrate that the outputs of the process meet the required criteria.

(Same as JSQC-Std 00-001)

Note Quality Assurance by Process is intended to build quality by the process, and consists of a series of activities to realize this, so that the final output of the process will be in accordance with the purpose and criteria if it is carried out in accordance with the established procedures and methods.

3.4 Standard

(1) Agreement for unification and simplification to equally benefit related organizations or people.

Note 1 Subject of standard includes physical object, performance, capacity, layout, condition, movement, procedure, method, formality, responsibility, duty, authority, point of view, concept and so on.

Note 2 A standard written in a documented form is called “documented standard.”

Note 3 In general, among standards, the agreement that specifies technical aspects directly or indirectly related to a product, service, process or system is called “specification.” The agreement on contents, formalities and methods mainly related to an organization or work is called “procedure.”

(2) Normative method or physical object that denotes the size of the quantity used as a criterion established to give universality to measurements.

Note For example, prototype kilogram as the standard measure of mass, fixed point of temperature and the standard platinum resistance thermometer to realize the International Practical Temperature Scale as the standard for temperature scale, standard substances as the measure of density, standard hardness tester and standard indenter as the measure of hardness, color chart for color sensory test, and so on.

(Same as JSQC-Std 00-001)

3.5 Standardization

Activities to establish and utilize agreements for common and repeated use for the purpose of effective and efficient organizational management.

(Same as JSQC-Std 00-001)

3.6 Process capability

The extent to which the process is capable of providing products and services with small variation with respect to requirements.

(Same as JSQC-Std 00-001)

Note. The index that quantitatively expresses the process capability is called the Process Capability Index.

3.7 Prevention/preventive action

Activities to identify problems that are expected to occur during the implementation of tasks at the planning stage and to take countermeasures against them in advance.

Note For prevention, it is effective to collect and streamline problems that have occurred in the past, to clarify the commonalities behind them, and to use these commonalities to predict the occurrence of similar problems.

(Same as JSQC-Std 00-001)

3.8 Inspection

The act of determining whether one or more characteristic values of a product or service conform to the

specified requirements by measuring, testing, gauge alignment or comparing with a sample.

Note 1 There are two types of inspections: one for each product, and one for a group of products (lot).

Note 2 Specified requirements are the requirements that are explicitly stated, for example, in a document.

(Same as JSQC-Std 00-001)

Note 3 The term inspection may be used to refer only to activities performed by third parties. In this standard, the term "inspection and verification" is used to clearly indicate that it includes inspections performed by the person in charge within their own process and inspections performed automatically using equipment, etc.

3.9 Nonconformity

Failure of product, service, process, or system to meet the specified requirements.

(Same as JSQC-Std 00-001)

3.10 Process abnormality

A state where the process is not under the controlled condition.

Note The controlled condition is defined as the stable condition at the technically and economically desirable level.

(Same as JSQC-Std 00-001)

4. Fundamentals of Quality Assurance by Process

4.1 Role of Quality Assurance by Process in quality assurance

4.1.1 What is quality assurance?

Quality assurance is "a set of systematic activities undertaken by an organization to ensure, verify, and demonstrate that it meets the needs of its customers and society" (JSQC-Std 00-001). Here, (1) "ensure" means to understand the needs of customers and society, to plan and design products and services that meet those needs, and to establish a process to provide those products and services, and (2) "verify" means to continuously evaluate and understand whether the needs of customers and society are being met, and to take prompt emergency and recurrence prevention measures if they are not being met. In addition, (3) "Demonstrate" means to clearly state what needs are being met as a promise to customers and society, and to show evidence that the promise is being kept, thereby providing a sense of trust and security. Hereafter, (1), (2), and (3) are collectively referred to as "assurance."

The "needs" to be met in quality assurance include those explicitly or implicitly indicated by customers and society, as well as those latent needs that are not clearly recognized by customers and society itself.

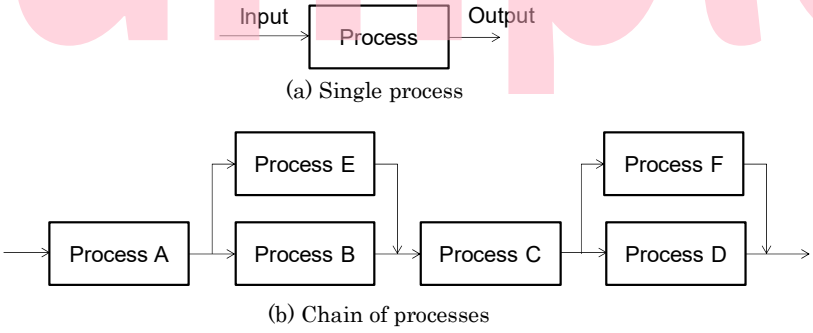
4.1.2 What is Quality Assurance by Process?

Products and services are realized through a number of processes, as shown in Fig. 1. A process in this context

is “a series of interrelated or interacting activities that converts inputs into outputs” (JSQC-std 00-001). It is not possible to assure (ensure, verify, and demonstrate) that the needs will be met by inspection and verification of the final product or service alone. It can only assure that the measured point meets the need, not what peripheral results are without information about the process. However, proper control of the process can assure that the product or service will meet the needs not only at the measured point but also in the peripheral results.

Quality Assurance by Process is a series of activities to ensure that the final output of a process is in accordance with the purpose and criteria if it is performed in accordance with the established procedures and methods. This includes a series of activities in which the conditions for input such as parts, materials and information, resources such as man, machine and technical know-how, and conditions concerning work procedures are specified for the process, education and training are carried out so as to implement the process accordingly, and the output obtained is inspected and verified, and actions are taken as necessary.

In order to make Quality Assurance by Process work effectively, it is necessary to break down the process into smaller parts and apply these activities to each process to realize a chain of Quality Assurance by Process.



(a) Single process

(b) Chain of processes

Fig. 1 Concept of process

4.1.3 Quality assurance system

In order to provide products and services that meet the needs of customers and society, it is necessary to: a) accurately understand the needs of customers and society and reflect these needs in the planning and design of products and services, and b) produce and provide products and services as designed. For this purpose, it is important to ensure that Quality Assurance by Process is practiced for a series of activities from market research and planning to production, provision, sales, after-sales service, collection, reuse, and disposal.

In order to carry out consistent Quality Assurance by Process across multiple activities, it is necessary to clarify the roles to be played by each department in the organization and to ensure that activities are carried out accordingly. To clarify what each department should do, it is recommended to summarize all the processes involved in the provision of products and services in a quality assurance system chart. In a quality assurance system chart, the chronological stages are plotted on the vertical axis and the departments on the horizontal axis, and which departments are involved in which stages, activities and decisions are shown by rectangles, and the flow of information and materials is shown by arrow lines. A simplified example of a quality assurance system

chart is shown in Fig. 2. The quality assurance system chart shows the activities and decisions to be made and the departments involved in them from a chronological perspective, and provides a bird's eye view of what should be done as an organization and the connections between them.

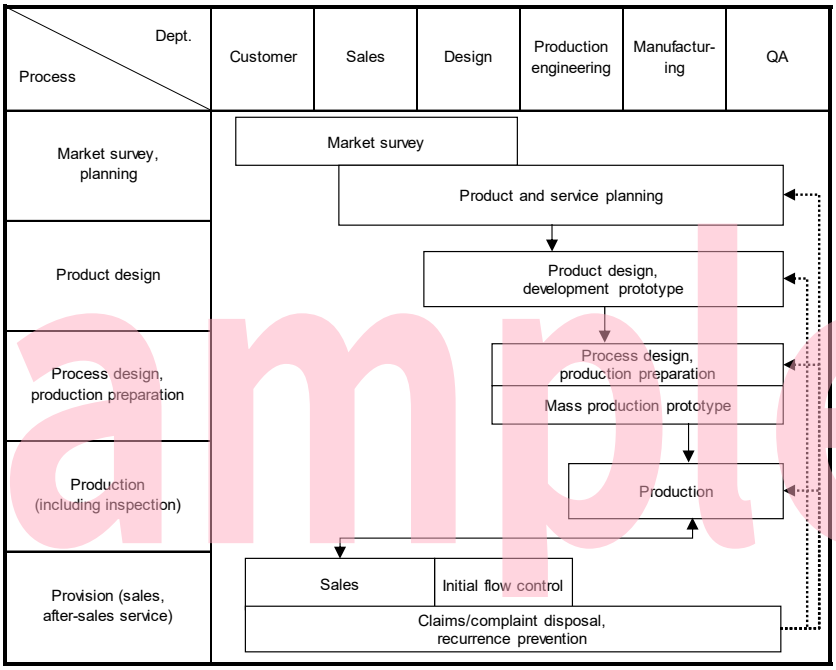


Fig. 2 Example of quality assurance system chart

（Source: Created based on Japan Society for Quality Control Ed., *New Edition Quality Assurance Guidebook*, JUSE Press, p.27, 2009.）

4.2 Elements of Quality Assurance by Process for production and provision

In production and provision, the purpose is to realize products and services as designed. Production and provision here refer to procurement, production, sales, provision, after-sales service, collection, reuse, and disposal based on the design and planning of processes to realize products and services. There are five main elements to realize Quality Assurance by Process in production and provision.

(1) Standardization: Define the process, and identify and standardize the critical factors. This will ensure the stability of the process.

(2) Study and improvement of process capability: Evaluate the qualitative aspects of the process, i.e., how well the process is capable of meeting the requirements. Improve process capability based on assessment results, as needed.

(3) Trouble prediction and prevention: Predict what kinds of troubles will occur during the implementation phase of the process. Prioritize predicted troubles and take countermeasures to prevent them from occurring, starting with those that are considered critical.

(4) Inspection and verification: Inspection and verification shall be carried out for nonconformities that are

expected to occur despite the results of (1) through (3). In addition to the detection of nonconformity, inspection and verification may also be carried out to confirm that nonconformities have not occurred.

(5) Action on process abnormalities: Detect process abnormalities and take action in consideration of the stable condition of the process.

A summary of these is shown in Fig. 3. As the Quality Assurance by Process advances, unnecessary inspections and verifications will be reduced, ensuring that products and services are delivered as designed. This is the goal of Quality Assurance by Process in production and provision.

In addition, to ensure effective and efficient Quality Assurance by Process in production and provision, it is necessary to implement (1) through (5) from the design stage of product/service and the design/planning stage of production and provision processes.

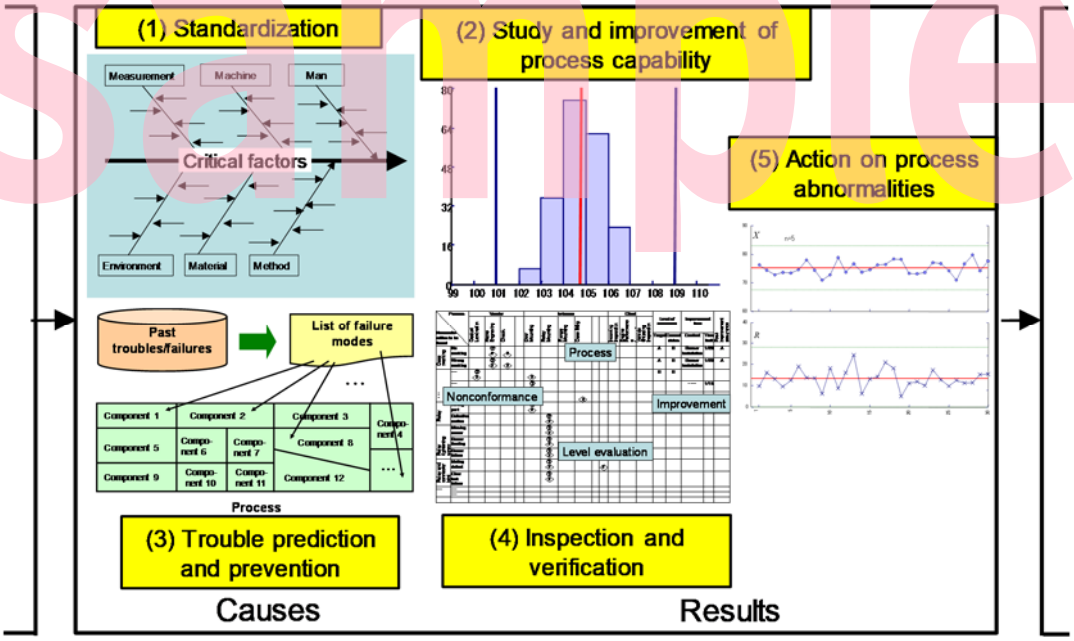


Fig. 3 Elements of Quality Assurance by Process

4.3 Standardization

4.3.1 What is standardization?

Standardization refers to “the activity of establishing and utilizing agreements for common and repeated use for the purpose of effective and efficient organizational management” (JSQC-Std 00-001). In Quality Assurance by Process, standardization has a role to play in ensuring that the process operates as specified in the standard and that the output is stable. Standardization targets those factors that affect the stability of output among a wide range of factors such as the 5M1E (Man, Machine, Material, Method, Measurement, Environment) of the process. Standardization not only produces stable output, but also clarifies the tasks to be performed, improves mutual understanding among processes, and increases productivity by eliminating unnecessary search.

It is not enough to create a standard, but it is important to educate and train people so that they can maintain it,

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