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

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Contents

	Page
0 Introduction	1
0.1 General	1
0.2 Consistency with other standards	1
0.3 Relation with JIS Q 9001 and JIS Q 9004	1
0.4 Compatibility with other management systems	1
1 Scope	2
2 Normative reference	2
3 Terms and definitions	2
4 How to proceed with Quality Ensurance by Process	4
4.1 Elements of Quality Ensurance by Process for production and provision	4
4.2 How to proceed with standardization	5
4.3 How to proceed with study and improvement of process capability	7
4.4 How to proceed with trouble prediction and prevention	13
4.5 How to proceed with inspection and verification	20
4.6 How to proceed with action to process abnormalities	25
5 Tools for Quality Ensurance by Process	29
5.1 Process Capability Index	29
5.2 Process FMEA	33
5.3 Quality Assurance Network (QA Network)	39
Annex A (informative) The roles of Quality Ensurance by Process in quality assurance	43
Annex B (informative) Standardization	45
Annex C (informative) Study and improvement of process capability	46
Annex D (informative) Trouble prediction and prevention	47
Annex E (informative) Inspection and verification	49
Annex F (informative) Action to process abnormalities	51

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 standards

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 daily 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 Ensurance 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.

3.3 Quality Ensurance by Process

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

NOTE Quality Ensurance 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

<object, method, philosophy and so forth> 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 and concept.

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 “standard.” The agreement on contents, procedure, formalities and methods mainly related to an organization or work is called “specification.”

3.5 standard

<measurement> 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 reference for measurement 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, colour chart for colour sensory test.

3.6 standardization

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

3.7 process capability

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

NOTE The index that quantitatively expresses the process capability is called the process capability index.

3.8 prevention

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.

3.9 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.

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.

3.10 nonconformity

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

3.11 process abnormality

a state where the process is not under the controlled condition

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

4 How to proceed with Quality Ensurance by Process

4.1 Elements of Quality Ensurance by Process for production and provision

In production and provision, the purpose is to realize products and services as designed. It is recommended to implement the following five elements to achieve the purpose effectively and efficiently as Quality Ensurance by Process in production and provision.

- a) **Standardization** : Define the process, and identify and standardize the critical factors. This will ensure the stability of the process. The outline and the role of standardization in Quality Ensurance by Process is shown in Annex B for reference.
- b) **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. The outline and the role of study and improvement of process capability in Quality Ensurance by Process is shown in Annex C for reference.
- c) **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. The outline and the role of trouble prediction and prevention in

Quality Ensurance by Process is shown in Annex D for reference.

- d) Inspection and verification : Inspection and verification shall be carried out for nonconformities that are expected to occur despite the results of **a)** through **c)**.

In addition to the detection of nonconformity, inspection and verification may also be carried out to confirm that nonconformities have not occurred. The outline and the role of inspection and verification in Quality Ensurance by Process is shown in Annex E for reference.

- e) Action to process abnormalities : Detect process abnormalities and take action in consideration of the stable condition of the process. The outline and the role of action to process abnormalities in Quality Ensurance by Process is shown in Annex F for reference.

A summary of these is shown in Figure 1. As the Quality Ensurance 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 Ensurance by Process in production and provision.

In addition, to ensure effective and efficient Quality Ensurance by Process in production and provision, it is necessary to implement **a)** through **e)** from the design stage of product/service and the design/planning stage of production and provision processes.

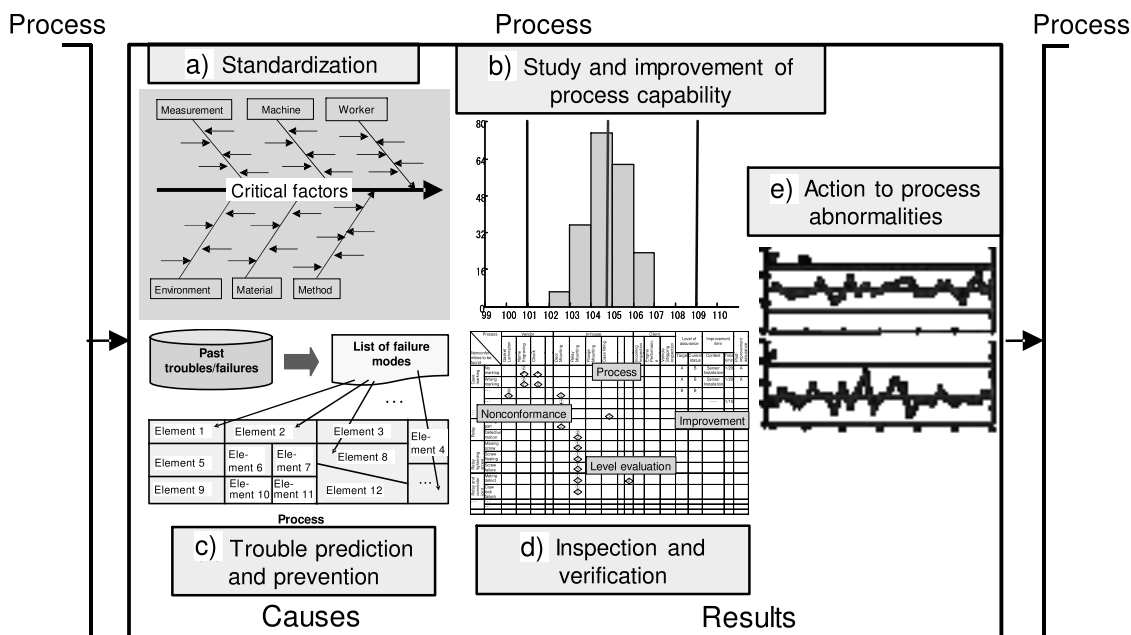


Figure 1 Elements of Quality Ensurance by Process

4.2 How to proceed with standardization

4.2.1 Essentials of standardization

The first step in standardization is to define what the process is and to identify the factors that should be kept constant. If the process is broadly defined, it will be difficult

to identify the factors that should be kept constant to obtain the desired results. Therefore, in order to ensure Quality Ensurance by Process, it is necessary to define the process in detail and identify the factors that should be controlled for each process. In order to evaluate the impact of each factor on the output, the interrelationship and chain (connection between input and output) between the final output to be assured and the subdivided process should be clarified. For each of the identified factors, it is recommended to determine the level and control method so that the output will be desirable.

In addition, in order to check whether a process is stable or not, it is recommended to clarify the output that should be assured for each process. In addition, it is recommended to clarify the judgment method and criteria for each output.

4.2.2 Procedure of standardization

Standardization should ideally be pursued according to the following a) and b) :

a) Clarification of processes (see 4.2.3)

- 1) Clarify the process flow that represents the flow and sequence of processes in the targeted work.
- 2) Clarify the output, criteria, and input for each process in the process flow.
- 3) For each process, clarify the methods for converting the input into output, and the necessary resources such as people, equipment, and technical know-how.

b) Process standardization

- 1) Specify the critical factors for the output of the process and set conditions for the factors so that the output meets the corresponding criteria.
- 2) Examine the methods to realize the conditions for the previously determined factors, and summarize the work procedures in an easy-to-understand standard.
- 3) Disseminate the standard among relevant persons and provide education and training necessary to follow the standard.
- 4) Ensure compliance with standards and implement error proofing to prevent unintended errors.
- 5) Revise standards based on periodic review and analysis of problems as they arise.
- 6) Clarify the change points in persons, parts/materials, machine, etc., and prevent process abnormalities from occurring, as well as take immediate remedies against process abnormalities that have occurred and prevent recurrence.

For details of b) above, refer to **JIS Q 9026**.

4.2.3 Clarification of processes

The following procedure is recommended for clarifying the processes :

- a) Organize the requirements for the final output and clarify the criteria (characteristic values, standard values, etc.) that it should meet.

- b) Break down the process into smaller sub-processes. When breaking down, it is advisable to consider the commonality of the workers, equipment, parts/materials, methods, and environment involved, as well as the scope of application of the standard. For each broken down sub-process, clarify the inputs and outputs. It is recommended to use methods such as IE (Industrial Engineering) and WBS (Work Breakdown Structure). The results of the break down should be represented using diagrams such as process diagram, work flow diagram, process mapping, and arrow diagram.
- c) Organize the relationship between the final output and the output of each sub-process, and clarify the criteria that should be met by the output of each sub-process based on the criteria for the final output. For this purpose, it is recommended to use QFD (Quality Function Deployment). For more information on QFD, refer to **JIS Q 9025**.

If the broken down sub-processes are too large, Quality Ensurance by Process cannot be effectively promoted. In such a case, apply steps **b)** and **c)** to the sub-process in question, and break it down into smaller sub-processes. Repeat this recursively, and finish when it has been broken down to the required size (see Figure 2). This will enable clarification of all activities, corresponding requirements, and necessary controls to ensure that the final output meets the criteria.

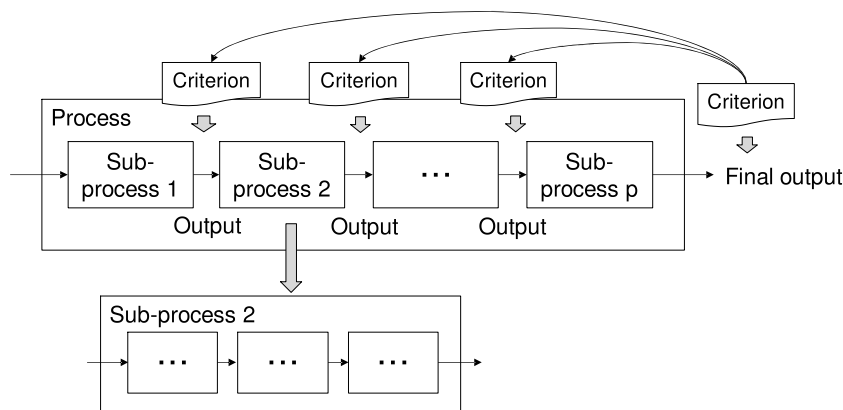


Figure 2 Outline of process break down

4.3 How to proceed with study and improvement of process capability

4.3.1 Essentials of study and improvement of process capability

In a process capability study, the first step is to collect the appropriate data to assess the variation. There are two types of variation: variation when the standard is followed and variation when it is not followed. What should be assessed in a process capability study is the variation when standards are being followed. To be able to assess the variation, appropriately grouped data should be collected for an appropriate length of time, and analyzed.

Whether the variation of the output is sufficiently small and whether the output is at a desirable level can be checked by comparing the distribution of the output with the specification. For this purpose, indexation is useful.

For Quality Ensurance by Process, it is important to ensure process capability in process design. For this purpose, it is recommended to use the results of the past process capability studies as well as the results of the process capability studies of the process under consideration in the process design.

If the process capability is insufficient, the process design should be reviewed. If the relationship between the process conditions and the process capability is unclear, the optimum conditions should be obtained by experiments, etc., with technical studies at the core.

4.3.2 Procedure of process capability study

The study of the process capability when the quality characteristic is continuous variables, generally it proceeds as follows :

a) Collect data.

Operate under the current operating conditions and obtain data on the quality characteristic. The number of data should be as large as possible, but at least 50 is necessary to understand the distribution pattern. Preferably the number should be not less than 100.

The sampling interval should be determined appropriately depending on what factors of variation are needed. For example, if it is necessary to know the variation among workers, collect data including multiple workers. If it is necessary to know the difference in setup changes, determine the sampling interval to include setup changes. The important thing is to be able to see which factors are included in the variation by the sampling method.

If the study is conducted over a long period of time, there is a possibility that variations caused by deviations from the standards and criteria, and variations caused by changes in conditions beyond the normal range that are not specified in the standards and criteria may creep in. Therefore, it is better to conduct the study in a short period of time so that these factors of variation that cannot be ignored do not creep in.

b) Prepare the $\bar{X} - R$ Control Chart.

Grouping is performed to check whether the process is in a stable state (i.e., there is no deviation from the standard or criteria, or no change beyond the normal range of conditions not specified in the standard or criteria). The number of groups should preferably be not less than 25.

If the process is not in a stable state, it does not mean that process capability should not be sought. However, when the process is not in a stable state, it is in a state where each group has a different distribution, and it is not appropriate to obtain 6σ from a distribution that is not uniform distribution. In that case, improve

the process to a stable state first.

- c) Draw the histogram and calculate the process capability.

Draw a histogram, and if it shows an anomaly like a twin-peaks type and outliers, the cause of the anomaly needs to be determined first. If there is no particular anomaly in the distribution pattern, calculate the estimated value of μ , i.e. $\bar{x}$, and the estimated value of σ using the following formula.

$$\hat{\sigma} = s$$

Here, s is the standard deviation obtained from all the data. The value obtained from the control chart using the following formula can also be used as the estimated value of σ .

$$\hat{\sigma} = \frac{\bar{R}}{d_2}$$

Here, d_2 is the coefficient used in the control chart and it satisfies $E\left(\frac{R}{d_2}\right) = \sigma$. This shows the variation due to unavoidable causes, which can be regarded as the variation when the process is thoroughly controlled and variation between groups is eliminated. This value becomes the yardstick for achievable process capability. On the other hand, when $\hat{\sigma} = s$ is used as an estimated value for σ , it represents the process capability that can be achieved under the current conditions.

In the production preparation stage, since the data is collected in a relatively short period of time and in compliance with the standard, there is little need to consider time-series variation, and the process capability index is calculated using s .

4.3.3 Outline of Process Capability Index (PCI)

Process capability is recommended to be evaluated by comparing the variation of quality characteristic with the specification limits or the range of specification. In general, when the quality characteristic values follow a normal distribution, the usage of Process Capability Index shown in Table 1 is recommended.

The upper and lower specification limits are expressed with S_U and S_L respectively.

Table 1 Basic Process Capability Indexes

Specification	Bias	Definition of Process Capability Index	Estimation from data
Lower limit S_L only		$C_{pL} = \frac{\mu - S_L}{3\sigma}$	$\hat{C}_{pL} = \frac{\bar{x} - S_L}{3\hat{\sigma}}$
Upper limit S_U only		$C_{pU} = \frac{S_U - \mu}{3\sigma}$	$\hat{C}_{pU} = \frac{S_U - \bar{x}}{3\hat{\sigma}}$
Both sides S_L, S_U	Not taken into account	$C_p = \frac{S_U - S_L}{6\sigma}$	$\hat{C}_p = \frac{S_U - S_L}{6\hat{\sigma}}$
Both sides S_L, S_U	Taken into account	$C_{pk} = \min(C_{pU}, C_{pL})$ $= (1 - k)C_p$	$\hat{C}_{pk} = \min(\hat{C}_{pU}, \hat{C}_{pL})$ $= (1 - k)\hat{C}_p$
	Here, $k = \mu - M /d$, $\hat{k} = \bar{x} - M /d$, $M = (S_U + S_L)/2$, $d = (S_U - S_L)/2$		

Process Capability Index is closely related to the defective rate. For instance, in the case of a both-sided specification, if the quality characteristic values follow a normal distribution $N(\mu, \sigma^2)$ and the mean and the centre of the specification are the same, then 99.7% of the products and services fall within $\pm 3\sigma$ when $C_p = 1$, and the defective rate is 0.27 %. Similarly, when the value of C_p is 1.33 and 1.67, the defective rate is 63 ppm and 0.57 ppm, respectively.

Table 2 is often recommended as evaluation criteria for process capability. If the *PCI* (Process Capability Index) is greater than 1.33, the process capability is sufficient, and below that it should be regarded as insufficient.

As a general symbol for Process Capability Index, *PCI* is sometimes used in the same way as in **JIS**.

Table 2 Evaluation criterion for process capability

$PCI \geq 1.33$	Process capability is sufficient
$1.00 \leq PCI < 1.33$	Process capability is somewhat insufficient
$PCI < 1.00$	Process capability is insufficient
NOTE 1	Process capability index : $PCI = 1.33$ means that the process capability is 6σ against that the range of upper and lower specification limits is 8σ , therefore there is 1σ margin for both sides of specification.
NOTE 2	The criteria $10/6=1.67$ is sometimes used as sufficient by adding to 1σ margin more when lower defective rate is required such as part industries.
NOTE 3	The criteria shown in the above are not universal; the criteria such as 1.33 should be modified based on the required defective rate.

In the case of a both-sided specification, it is recommended to calculate both $\hat{C}_p$ and $\hat{C}_{pk}$. As shown in Figure 3, the values of $\hat{C}_p$ and $\hat{C}_{pk}$, and the difference between them indicate whether there is a problem with the mean, with the variation, or with both.

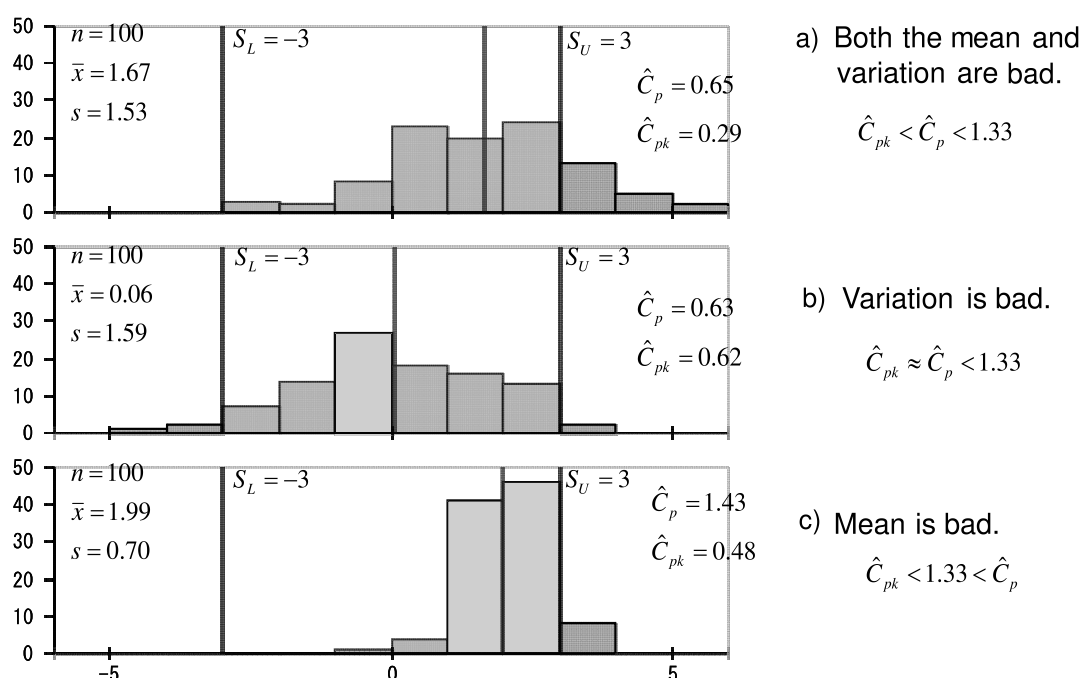


Figure 3 $\hat{C}_p, \hat{C}_{pk}$ values and the corresponding problems (in case of both-sided specification)

In the case of quality characteristics that can only be expressed by attributes, such as incorrect assembly or the number of flaws, the defective rate or the number of defects itself indicates the process capability. Since the defective rate is the result of comparison with the specification, the average defective rate is equivalent to the Process Capability Index in the case of continuous variables. In the case of the number of defects, the process capability is expressed by the average number of defects, and if there are specified values or target values, the presence or absence of process capability is judged based on comparison with these values.

4.3.4 Utilization of process capability information

The utilization of process capability information includes the following :

- a) **Process capability table** A table of the results of the process capability study is called a process capability table which should include the following information to provide a bird's eye view and help visualize the process capability.
 - Process name
 - Methods/conditions for production and provision
 - Product/service name,
 - Quality characteristic,
 - Study period

- Study method, conditions (method of measurement, sampling method, materials, workers, etc.)
- Number of samples
- Estimated value of σ
- Process Capability Index

An example of process capability table is shown in Table 3. The top row of Table 3 shows the machining conditions, and the middle row shows the measurement conditions. The process capability under these conditions is summarized in the bottom row.

Table 3 An example of process capability table

Machining conditions					
Process	Tools	RPM	Machining margin		
Process 1	Cutting tool SKH-51	1 000 rpm	0.88 ± 0.02		
Process 2	Grinding stone WA 120H	3 300 rpm	0.03		
Process 3	Grinding stone WA 60K	3 300 rpm	0.02		

Measuring conditions					
No.	Measurement item	Standard	Measuring instrument	Measurement unit	Remarks
1	Notch thickness	2.28 + 0 − 0.08	Micrometer	0.005	$n = 120$
2	Notch size	51.5 ± 0.1	Dial gauge	0.01	$n = 120$
3	Central runout	≤ 0.04	Dial gauge	0.001	$n = 33$ Measure 1 dressing interval

Process capability						
No.	Measurement item	Standard	$\bar{x}$	$\hat{\sigma}$	$6\hat{\sigma}, (3\hat{\sigma})$	$\hat{C}_p, \hat{C}_{pk}$
1	Notch thickness	2.28 + 0 − 0.08	2.255	0.007	0.044	1.70
2	Notch dimension	51.5 ± 0.1	51.550	0.019	0.114	1.76
3	Central runout	≤ 0.04	0.007 2	0.002 3	(0.006 9)	4.75

NOTE Source : Created based on Takeshi Nakajo and Shu Yamada Ed., *Fundamentals of TQM*, JUSE Press, p. 83, 2006.

- b) **Utilization in product and service design** Process capability represents the level that can be achieved by bringing the process to a stable state, and provides information on whether or not the specification to be set can be achieved at the current technical and economic level when designing products and services. Therefore, when setting specifications and tolerances in product/service design, it is advisable to consider not only the function and performance aspects of the product/service, but also to utilize information on process capability. If the process capability cannot

be ensured with the specified values that are to be set, but the functional and performance requirements are so strong that the specification cannot be expanded, the process is considered to be a bottleneck process, and the realization method is examined at an early stage. On the other hand, it is also necessary to consider whether it is possible to widen the specification range. In this case, the range of levels is determined in consideration of the process capability, and it is recommended to confirm whether there are any problems in terms of function and performance based on experiments.

When using FMEA (Failure Mode and Effects Analysis) to predict troubles in design, it is advisable to consider process capability in evaluating the frequency of occurrence in the priority scoring. If the process capability of the characteristic for the process related to the trouble is low, the frequency of occurrence of the trouble is likely to be high. It is also important to include check items for process capability in the checklist for Design Review.

In the case of confirmation by experiment in prototyping and evaluation of products and services, the range of levels is determined based on the process capability. In order to detect problems at an early stage, it is advisable to set a level slightly wider than the current process capability and check whether the functional and performance requirements are satisfied.

- c) **Utilization in process planning and design** At the process planning and design stage, when examining the realization method and selecting equipment and jigs/tools, it is recommended to secure process capability by referring to the previous process capability table. For processes for which it is estimated that process capacity will be insufficient, consider how to realize or improve it at an early stage.

It is recommended to conduct process capability studies and confirm the process capability in prototyping and evaluation before production and provision of products and services. For processes with insufficient process capability, take actions such as improving process capability through process improvement, reflecting the insufficient process capability in inspection and verification plans, and reviewing the specifications.

4.3.5 Improvement in process capability

In the production/provision stage, the process capability should be periodically monitored using data collected in daily management, and inspection and verification, or data collected for the purpose of studying process capability, and processes with a Process Capability Index below 1.33 should be improved. For this purpose, it is recommended to use improvement procedures like QC Stories, the Seven QC Tools, etc. For more information on improvement procedures and the Seven QC Tools, refer to JIS Q 9024.

4.4 How to proceed with trouble prediction and prevention

4.4.1 Essentials of trouble prediction and prevention

A cross-cases view of various troubles shows that “similar troubles are often caused

elsewhere.” For this reason, a large number of examples of troubles that have occurred in the past should be collected and common types (patterns) of troubles can be extracted and streamlined from them. By applying these types to the process under consideration, possible troubles can be systematically identified and omissions in trouble prediction can be reduced. The common type of trouble is called “failure mode” (depending on the nature of the trouble, it may be called error mode, fault mode, etc.). Furthermore, when applying failure modes to a process, it is important to divide the process into smaller elements. This is because the larger the process, the rougher the view and more omissions can occur. In addition, it is not practical to take countermeasures against all the troubles identified. Therefore, it is recommended to evaluate the impact on QCDES (Quality, Cost, Delivery, Environment, Safety), etc., and determine whether countermeasures are necessary or not.

FMEA is a typical method for doing these things. Figure 4 shows the basic method of trouble prediction.

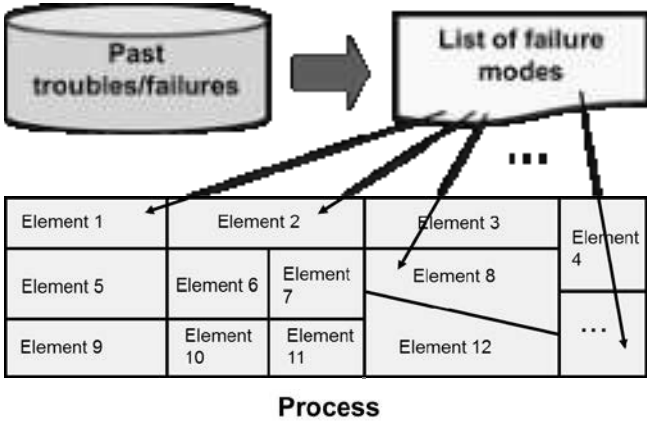


Figure 4 Basic method of trouble prediction

Among the predicted troubles, it is necessary to develop and implement specific countermeasures for those that are judged to require countermeasures. Many of the predicted troubles have been experienced in similar processes, and effective countermeasures often already exist. For this reason, when formulating countermeasures, it is advisable to organize the past effective countermeasures as an idea checklist (a list of hints for considering countermeasure ideas) or countermeasure database (a collection of case studies), and utilize them. Figure 5 shows the basic method for formulating countermeasures in prevention.