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Statistical methods in process management — Capability and performance —

Part 5: Process capability estimates and performance for attributive characteristics

Méthodes statistiques dans la gestion des processus — Aptitude et performance —

Partie 5: Estimations de l'aptitude du processus et performance pour les caractéristiques par attributs

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Foreword

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This document was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 4, *Applications of statistical methods in product and process management*.

A list of all parts in the ISO 22514 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Organizations need to evaluate the capability and performance of their key processes including processes where the key characteristics only can be evaluated based on attributes. The methods described in this document are intended to assist any organization in this respect.

Process capability and performance evaluations are also necessary to enable organizations to assess the capability and performance of their suppliers. Those organizations will find the indices contained within this document useful in this endeavour.

Statistical methods in process management — Capability and performance —

Part 5: Process capability estimates and performance for attributive characteristics

1 Scope

This document describes a method to calculate process capability and performance indices for attribute characteristics. This method can be used as a supplement to the commonly used capability calculations for variable characteristics.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-2 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Symbols and abbreviated terms

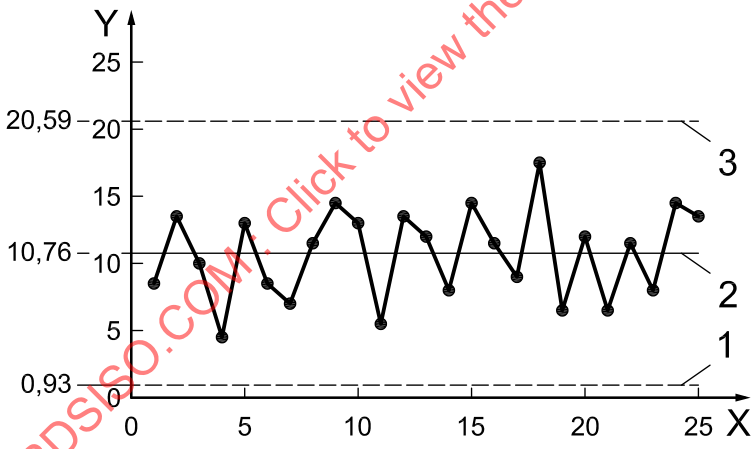
$\overline{c}$	average number of nonconformities
C_{p}^{*}, C_{pk}^{*}, $C_{\mathrm{pk}_L}^{*}$, and $C_{\mathrm{pk}_U}^{*}$	process capability indices
FRC	first run capability
n	subgroup size
NHU	nonconformities per hundred units
NMU	number of nonconformities per million
$\overline{p}$	average proportions of nonconforming units
p_U	fraction of nonconforming units over upper specification limits

p_L	fraction of nonconforming units under lower specification limits
PCI	process capability index
Q_P	process quality level
P_p^*, P_{pk}^*, $P_{pk_L}^*$, and $P_{pk_U}^*$	process performance indices
$\bar{u}$	average proportions of nonconformities
z_α	quantile of the standardized normal distribution from $-\infty$ to α

5 Pre-conditions for application

5.1 General

Attributes data represent (categorized or countable) observations obtained by noting the presence (or absence), or the frequency of occurrence of one or more characteristics or attributes in each of the items. A count is made of the number of units possessing the attribute or the frequency of occurrence of the characteristic on the item. Results are then expressed in terms of frequencies or proportions and either the binomial or the Poisson distribution is assumed. Each of these distributions has a single parameter that must be monitored for stability of the process. Because the standard deviation of the proportion or count may be estimated once the sample size is known and the proportion or count in the sample is determined, the control limits on the attributes chart can be determined (see Figure 1).



Key

X subgroup number
Y number nonconforming
1 L_{CL}
2 $n\bar{p}$
3 U_{CL}

Figure 1 — *np* Chart (see ISO 7870-2)

In case that products are manufactured at more than one location, product from each line or system of production shall be considered separately.

The percent of nonconformities can be calculated based on one of the four different charts.

5.2 Aspects about establishing specifications

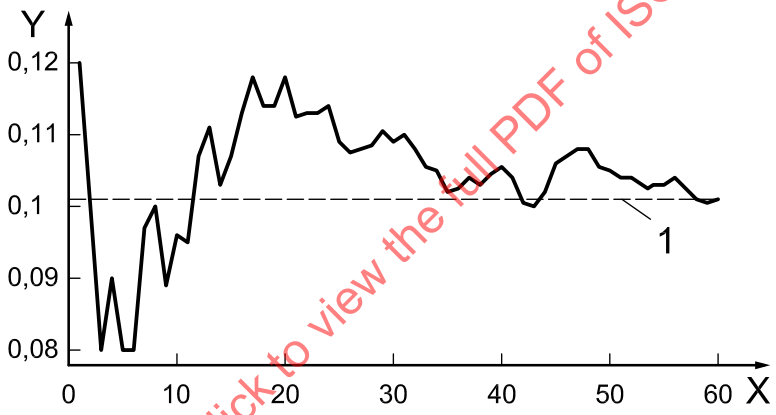
The product specifications shall be defined in a way that allows the organization to judge between parts or characteristics fulfilling the requirements, and parts or characteristics not acceptable within an acceptable measurement uncertainty (see ISO 22514-7).

5.3 Sample size

Samples are subgroups of collected items obtained from the process. Attributive data from the characteristics of these items should be computed and plotted on a control chart. It can be the number of nonconformities using a *c*-chart or a *u*-chart, or the proportion of nonconforming units using a *np* chart or a *p* chart.

No general rules can be laid down for the frequency of subgroups or the subgroup size. The frequency can depend upon the cost of taking and analysing samples and the size of the subgroup can depend upon practical considerations.

A cumulative chart can indicate when enough data has been collected to provide a stable estimate of the process quality level (NHU), see Figure 2.



Key

X number of samples

Y nonconformances per hundred units (NHU)

1 average NHU

Figure 2 — Cumulative NHU (see ISO/TR 18532)

6 Process analysis

6.1 Process variation

Process capability is a measure of inherent process variability. It represents the variation that remains after all known removable assignable causes have been eliminated. If the process is monitored using a control chart, the control chart shows an in-control state (see ISO 7870-1 for further information).

Capability of attribute characteristics is regarded as being related to the proportion of output that occurs within the product specification tolerances. Since a process in statistical control can be described by a predictable distribution, the proportion of out-of-specification outputs can be estimated. As long as the process remains in statistical control, it continues to produce the same proportion out-of-specification.

In case of calculation of capability, it is necessary to plot data on an attribute control chart and to check the chart for statistical control.

When statistical stability has not been obtained or process stability has not been demonstrated to be in a state of statistical control, the calculation results in process performance (P_{pk}) instead of process capability (C_{pk}).

6.2 Data sources

The estimation of process quality levels can be based on:

a) results from a Shewhart control chart;

b) results from audit samples that are drawn at random from the population; and/or

c) lot acceptance data.

Data from lots that fail a lot acceptance procedure, whether audit sample data or lot acceptance data, may not be excluded from the calculations.

6.3 Estimation of Q_P, the process quality level

The process quality level Q_P can be seen as equal to the centre-line of the attribute control chart of a stable process.

— When a process is monitored using a *np* chart or a *p* chart, the process quality level Q_P can be described by the average level $\bar{p}$ or $\overline{np}$ once the process is shown to be statistically stable [see Formula (1)].

$$Q_P = 100 \cdot \bar{p} \text{ or } 100 \cdot \bar{u}$$

or

$$Q_P = 100 \cdot \frac{\overline{np}}{n} \text{ or } 100 \cdot \frac{\bar{c}}{n} \quad (1)$$

The process yield, sometimes called the first run capability (FRC), can be computed as shown in Formula (2) below, i.e. FRC is the percentage of satisfactory items produced:

$$\text{FRC} = 100 \cdot (1 - \bar{p})(\%)$$

or

$$\text{FRC} = 100 \cdot \left(1 - \frac{\overline{np}}{n}\right)(\%) \quad (2)$$

— When a process is monitored using a *c*-chart or a *u*-chart, the process quality level Q_P should be expressed by recording the average level, $\bar{c}$ or $\bar{u}$, once the process is shown to be statistically stable.

Additionally, the rate of occurrence of nonconformities can be computed as the nonconformities per hundred units (NHU):

$$\text{NHU} = 100 \cdot \left(\frac{\bar{c}}{n}\right)$$

or

$$\text{NHU} = 100 \cdot \bar{u} \quad (3)$$

where *n* is the subgroup size taken.

If the occurrence of nonconformities per hundred is so low that the NHU is very much less than the value 1, consider the number of nonconformities per million instead, i.e. NMU. When processing discrete items this measure is often given as parts per million (ppm).

— No control chart used. When sample results from only a single lot from which d nonconforming items have been found in a sample of size n, Q_P is estimated using the formula where n is the subgroup size taken.

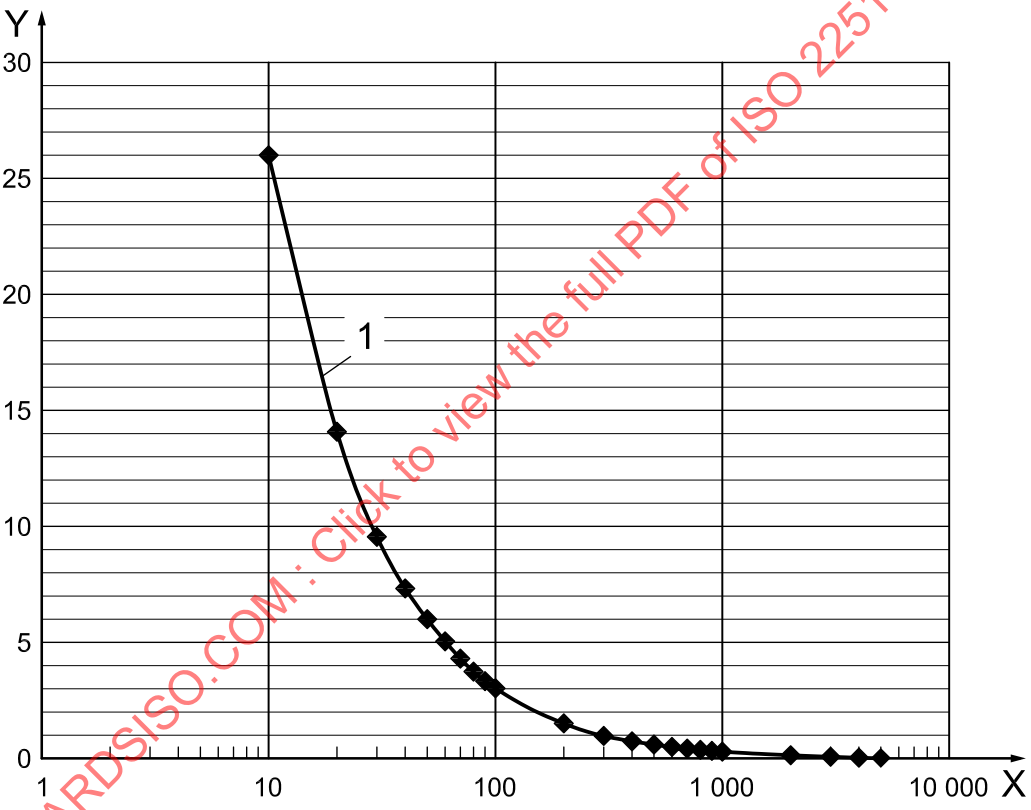
$$Q_P = 100 \cdot \frac{d}{n} (\%) \tag{4}$$

— No nonconformities or nonconforming parts have been found.

If there are no nonconformities in the sample(s), the confidence limits shall be used as Q_P while the average is zero.

NOTE If the process is not documented as in a state of statistical control, it can be difficult to identify the population and therefore difficult to calculate indices.

Figure 3 can be used to find the value of the upper confidence interval of Q_P.



Key

X number of samples
Y lower confidence limit
1 curve of confidence interval

Figure 3 — One-sided confidence limit — No nonconforming parts — Different sample size *n*

Figure 3 is the upper one-sided confidence limit for the binomial distribution calculated for different sample size n, and $1-\alpha = 95\ \%$ can be found from the Formula (5)[1]:

$$Q_P = 1 - \sqrt[n]{\alpha} \tag{5}$$

If $n > 50$ and $p = 0$, the approximation:

$$Q_P \approx 3/n \quad (6)$$

can be used instead of Formula (5).

EXAMPLE A sample size n = 200 is taken. No nonconformities are found. The confidence limit found from Figure 3 is 1,5 %. Then Q_P is 1,5 %.

7 Process performance

7.1 General

Process performance for a characteristic or a part is the achieved distribution of results. The single important difference between capability and performance is that, for performance, there is no requirement for the process to be in a state of statistical control nor for the process to be controlled using a control chart. The following are the conditions that apply for performance:

— all technical conditions, e.g. temperature and humidity, shall be clearly stated;

— the duration over which the data has been gathered shall be recorded;

— the frequency of sampling shall be specified, as well as the start and finish dates of data collection;

— the process needs not be controlled with a control chart; and

— the process needs not be in a state of statistical control, in particular, historical data where the sequence is unknown can be used to evaluate process performance.

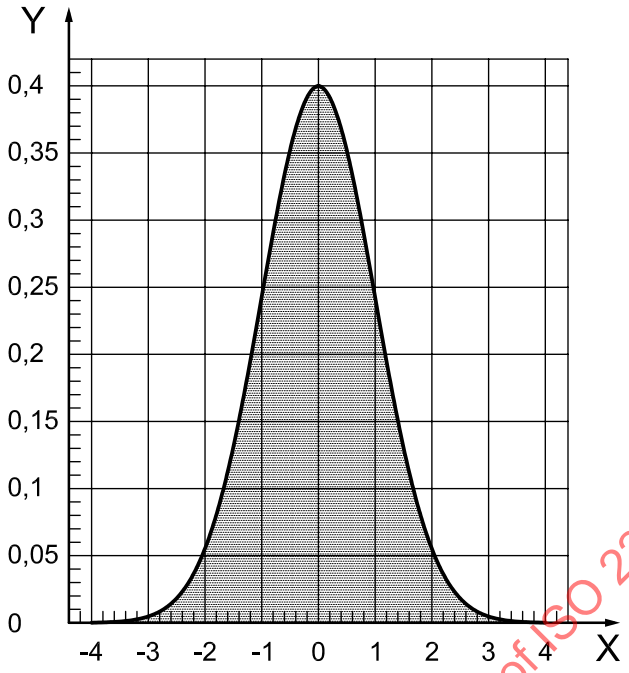
Indices are given below to express process performance, and they are named P_p^*, $P_{pk_L}^*$ and $P_{pk_U}^*$ respectively. In most cases, P_{pk}^* is calculated based only on $P_{pk_U}^*$, while lower performance index is not relevant.

The P_{pk}^* can be calculated based on the average number of nonconformities or on the average number of nonconforming units $\bar{Q}_P$.

$$\hat{P}_{pk} = \frac{z_{1-\bar{Q}_P}}{3} \quad (7)$$

where

$z_{1-\bar{Q}_P}$ in a standard normal distribution is shown in Figure 4.



Key

X $z_{1-\bar{Q}_P}$

Y probability

Figure 4 — $z_{1-\bar{Q}_P}$ in a standardised normal distribution

7.2 Confidence interval in case of nonconforming parts

The Q_P value is calculated by using the following formulaes:

$$\bar{Q}_P - 1{,}96\sqrt{\frac{\bar{Q}_P(1-\bar{p})}{n}} \le \bar{Q}_P < \bar{Q}_P + 1{,}96\sqrt{\frac{\bar{Q}_P(1-\bar{p})}{n}} \qquad (1-\alpha = 95\%) \tag{8}$$

EXAMPLE 1 A sample size n = 200 is taken from production of shafts. No nonconformities are found. The confidence limit found in Figure 3 is 1,5 %.

Then Q_P is 1,5 %.

The performance index P^*_{pk} is calculated based on the following formula:

$$\hat{P}^*_{pk} = \frac{z_{1-Q_P}}{3} \quad \text{where} \quad \hat{P}^*_{pk} = \frac{z_{0{,}985}}{3} = \frac{2{,}17}{3} = 0{,}72 \tag{9}$$

EXAMPLE 2 A sample size n = 200 is taken from production of shafts and one nonconforming part is found.

Q_P = 0,5 %

Then the confidence interval is found as follows:

$$\bar{Q}_P - 1{,}96\sqrt{\frac{\bar{Q}_P\left(1-\bar{Q}_P\right)}{n}} \le \bar{Q}_P \le \bar{Q}_P + 1{,}96\sqrt{\frac{\bar{Q}_P\left(1-\bar{\bar{Q}}_P\right)}{n}} \rightarrow 0 \le \bar{Q}_P \le 1{,}478\% \tag{10}$$

$0 \leq Q_{\mathrm{p}} \leq 1,478\,\%$ results in a $z_{1\text{-}p} = 2{,}438$, and the confidence interval:

$$\frac{2,438}{3} \leq \hat{P}^{*}_{\mathrm{pk}} \leq \frac{0}{3} \rightarrow 0,81 \leq \hat{P}^{*}_{\mathrm{pk}} < \infty \tag{11}$$

EXAMPLE 3 An example where 3 PCI indices can be calculated is the diameter of a hole, where a fixed gauge is used as measurement equipment (percent of parts with a diameter below minimum and percent of parts with a diameter over maximum).

Found results in a production:

$n = 250$

1 part above the upper tolerance limit.

2 parts below the lower tolerance limit.

Indices are given below to express process performance, and they are named P^{*}_{p}, $P^{*}_{\mathrm{pk}_L}$ and $P^{*}_{\mathrm{pk}_U}$ respectively.

Index	Estimate
$P^{*}_{\mathrm{p}} = \frac{P^{*}_{\mathrm{pk}_U} + P^{*}_{\mathrm{pk}_L}}{2}$	$\hat{P}^{*}_{\mathrm{p}} = \frac{\hat{P}^{*}_{\mathrm{pk}_U} + \hat{P}^{*}_{\mathrm{pk}_L}}{2}$
$P^{*}_{\mathrm{pk}_U} = \frac{z_{1-p_U}}{3}$	$\hat{P}^{*}_{\mathrm{pk}_U} = \frac{z_{1-\hat{p}_U}}{3}$
$P^{*}_{\mathrm{pk}_L} = \frac{z_{1-p_L}}{3}$	$\hat{P}^{*}_{\mathrm{pk}_L} = \frac{z_{1-\hat{p}_L}}{3}$

Calculations:

$$Q_{\mathrm{p}_U} = 0,4\% \rightarrow z_{1-p_{\mathrm{U}}} = 2,65 \tag{12}$$

$$Q_{\mathrm{p}_L} = 0,8\% \rightarrow z_{1-p_{\mathrm{L}}} = 2,41 \tag{13}$$

and

$$\hat{P}^{*}_{\mathrm{p}} = \frac{\hat{P}^{*}_{\mathrm{pk}_U} + \hat{P}^{*}_{\mathrm{pk}_L}}{2} = \frac{0,88 + 0,80}{2} = 0,84$$

$$\hat{P}^{*}_{\mathrm{pk}_U} = \frac{z_{1-\hat{p}_U}}{3} = \frac{2,65}{3} = 0,88 \tag{14}$$

$$\hat{P}^{*}_{\mathrm{pk}_L} = \frac{z_{1-\hat{p}_L}}{3} = \frac{2,41}{3} = 0,80$$

The confidence interval on the PCI's can be found using Formula (10).

8 Process capability

Process capability is defined as a statistical measure of the process variability for a given characteristic or a product. Data shall be taken from a control chart. Capable processes are the processes where the process has been in control in the actual period. The result from the control chart shall be linked to the fraction of actual values conforming or nonconforming. In particular, the same fraction conforming or

