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Statistične metode za obvladovanje procesov - Zmogljivost in delovanje - 4. del: Ocene zmogljivosti procesov in mere delovanja

Statistical methods in process management - Capability and performance - Part 4: Process capability estimates and performance measures

Méthodes statistiques dans la gestion de processus - Aptitude et performance - Partie 4: Estimations de l'aptitude de processus et mesures de performance

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Statistical methods in process management — Capability and performance —

Part 4: Process capability estimates and performance measures

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

Partie 4: Estimations de l'aptitude de processus et mesures de performance

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 22514-4 has been prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 4, *Applications of statistical methods in process management*.

ISO 22514 consists of the following parts, under the general title *Statistical methods in process management — Capability and performance*:

— *Part 1: General principles and concepts*

— *Part 3: Machine performance studies for measured data on discrete parts*

— *Part 4: Process capability estimates and performance measures* [Technical Report]

In the future, it is planned to revise ISO 21747:2006 (*Statistical methods — Process performance and capability statistics for measured quality characteristics*) as Part 2.

NOTE ISO/TR 22514-4 was initially prepared as ISO/DTR 12783. It was renumbered before publication to include it in the ISO 22514 series.

Introduction

Many organizations have embarked upon a continuous improvement strategy. To comply with such a strategy, any organization will need to evaluate the capability and performance of its key processes. The methods described in this part of ISO 22514 are intended to assist any management in this respect. These evaluations need to be constantly reviewed by management so that actions compatible with continuous improvement can be taken when required.

The content of this part of ISO 22514 has been subject to large shifts of opinion during recent times and this report attempts to reflect the current position. The most fundamental shift has been to philosophically separate what is named in this document as capability conditions from performance conditions, the primary difference being whether statistical stability has been obtained (capability) or not (performance). This naturally leads onto the two sets of indices that are to be found in their relevant clauses. It has become necessary to draw a firm distinction between these since it has been observed in industry that companies have been deceived about their true capability position due to inappropriate indices being calculated and published.

The progression of this part of ISO 22514 is from the general condition to the specific and this approach leads to general formulae being presented before their more usual but specific manifestations.

There exist numerous references that describe the importance of understanding the processes at work within any organization, be it a manufacturing process or an information handling process. As organizations compete for sales with each other, it has become increasingly apparent that it is not only the price paid for a product or service that matters so much, but also what costs will be incurred by the purchaser from using such a product or service. The objective for any supplier is to continually reduce variability and not to just satisfy specification.

Continual improvement leads to reductions in the costs of failure and assists in the drive for survival in an increasingly more competitive world. There will also be savings in appraisal costs for as variation is reduced the need to inspect product might disappear or the frequency of sampling might be reduced.

Process capability and performance evaluations are necessary to enable organizations to assess the capability and performance of their suppliers. Those organizations will find the indices contained within this part of ISO 22514 useful in this endeavour.

Quantifying the variation present within a process enables judgement of its suitability and ability to meet some given requirement. The following paragraphs and clauses provide an outline of the philosophy required to be understood to determine the capability or performance of any process.

All processes will be subject to certain inherent variability. This part of ISO 22514 does not attempt to explain what is meant by inherent variation, why it exists, where it comes from nor how it affects a process. This part of ISO 22514 starts from the premise that it exists and is stable.

Process owners should endeavour to understand the sources of variation in their processes. Methods such as flowcharting the process and identifying the inputs and outputs from a process assist in identification of these variations together with the appropriate use of cause and effect (fishbone) diagrams.

It is important for the user of this part of ISO 22514 to appreciate that variations exist that will be of a short-term nature as well as those that will be of a long-term nature and that capability determinations using only the short-term variation might be greatly different to those which have used the long-term variability.

When considering short-term variation, a study that uses only the shortest-term variation, sometimes known as a machine study, might be carried out. The method required to carry out such a study will be outside the scope of this part of ISO 22514; however, it should be noted that such studies are important and useful.

It should be noted that where the capability indices given in this part of ISO 22514 are computed, they only form point estimates of their true values. It is therefore recommended that, wherever possible, the indices' confidence intervals are computed and reported. This part of ISO 22514 describes methods by which these can be computed.

Statistical methods in process management — Capability and performance —

Part 4:
Process capability estimates and performance measures

1 Scope

This part of ISO 22514 describes process capability and performance measures that are commonly used.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1 Basic terms

2.1.1
product
result of a process

NOTE Process is defined in ISO 12207:1995, 3.17 and in ISO 9000:2005, 3.4.1.

2.1.2
characteristic
distinguishing feature

NOTE 1 A characteristic can be inherent or assigned.

NOTE 2 A characteristic can be qualitative or quantitative.

NOTE 3 There are various classes of characteristics, such as the following:

— physical (e.g. mechanical, electrical, chemical or biological characteristics);

— sensory (e.g. relating to smell, touch, taste, sight, hearing);

— behavioural (e.g. courtesy, honesty, veracity);

— temporal (e.g. punctuality, reliability, availability);

— ergonomic (e.g. physiological characteristic, or related to human safety);

— functional (e.g. maximum speed of an aircraft).

[ISO 9000:2005, 3.5.1]

2.1.3
quality characteristic
inherent **characteristic** (2.1.2) of a **product** (2.1.1), process or system related to a requirement

NOTE 1 Inherent means existing in something, especially as a permanent characteristic.

NOTE 2 A characteristic assigned to a product, process or system (e.g. the price of a product, the owner of a product) is not a quality characteristic of that product, process or system.

[ISO 9000:2005, 3.5.2]

2.1.4
specification limit
limiting value stated for a **characteristic** (2.1.2)

[ISO 3534-2:2006, 3.1.3]

2.1.5
specified tolerance
difference between the upper specification limits and lower **specification limits** (2.1.4)

[ISO 3534-2:2006, 3.1.6]

2.1.6
target value
T
preferred or reference value of a **characteristic** (2.1.2) stated in a specification

[ISO 3534-2:2006, 3.1.2]

2.1.7
distribution
⟨of a characteristic⟩ information on the probabilistic behaviour of a **characteristic** (2.1.2)

NOTE 1 The distribution of a **characteristic** (2.1.2) can be represented, for example, by ranking of the values of the **characteristic** (2.1.2) and showing the resulting pattern of measures or scores in the form of a tally chart or histogram. Such a pattern provides all of the numerical value information of the **characteristic** (2.1.2) except for the serial order in which the data arises.

NOTE 2 The distribution of a **characteristic** (2.1.2) is dependent on prevailing conditions. Thus, if meaningful information about the distribution of a **characteristic** (2.1.2) is desired the conditions under which the data are collected should be specified.

NOTE 3 It is important to know the **class of distributions** (2.1.8), for instance, normal or log-normal, before predicting or estimating process capability or performance measures and indices or fraction nonconforming.

[ISO 3534-2:2006, 2.5.1]

2.1.8
class of distributions
particular family of **distributions** (2.1.7) each member of which has the same common attributes by which the family is fully specified

EXAMPLE 1 The two-parameter, symmetrical bell-shaped, normal distribution with parameters mean and standard deviation.

EXAMPLE 2 The three-parameter Weibull distribution with parameters location, shape and scale.

EXAMPLE 3 The unimodal continuous distributions.

NOTE 1 The class of distributions can often be fully specified through the values of the appropriate parameters.

NOTE 2 Tests for the normality of data can be found in ISO 5479.

NOTE 3 Adapted from ISO 3534-2:2006, 2.5.2.

2.1.9
distribution model
specified **distribution** (2.1.7) or **class of distributions** (2.1.8)

EXAMPLE 1 A model for the distribution of a product characteristic, such as the diameter of a bolt, might be the normal distribution with mean 15 mm and standard deviation 0,05 mm. Here the model is a fully specified one.

EXAMPLE 2 A model for the diameter of bolts as in Example 1 could be the class of normal distributions without attempting to specify a particular distribution. Here the model is the class of normal distributions.

[ISO 3534-2:2006, 2.5.3]

2.1.10
reference limits
nominated quantiles of the **distribution** (2.1.7) of the product characteristic

NOTE 1 The conditions of the **distribution** (2.1.7) of the product characteristic must be specified, see Notes 2 and 3 of 2.1.7.

NOTE 2 Traditionally the 0,135 % and 99,865 % quantiles have been used.

EXAMPLE If the **distribution** (2.1.7) of the product characteristic is normal with mean μ and standard deviation σ, the limits are $\mu \pm 3\sigma$ when the traditional 0,135 % and 99,865 % quantiles are used.

2.1.11
reference interval
interval bounded by the 99,865 % distribution quantile, $X_{99,865\,\%}$, and the 0,135 % distribution quantile, $X_{0,135\,\%}$

NOTE 1 The interval can be expressed by $\left(X_{99,865\,\%}, X_{0,135\,\%}\right)$ and the length of the interval is $\left(X_{99,865\,\%} - X_{0,135\,\%}\right)$.

NOTE 2 This term is used only as an arbitrary, but standardized, basis for defining the **process performance index** (2.3.3) and **process capability index** (2.2.3).

NOTE 3 For a normal **distribution** (2.1.7), the reference interval may be expressed in terms of six standard deviations, 6σ, or $6S$, when estimated from a sample.

NOTE 4 For a non-normal distribution, the length of the reference interval can be estimated by means of appropriate probability papers (e.g. log-normal) or from the sample kurtosis and sample skewness using, for example, Pearson curves.

NOTE 5 A quantile or fractile indicates division of a distribution into equal units or fractions, e.g. percentiles. Quantile is defined in ISO 3534-1.

[ISO 3534-2:2006, 2.5.7]

2.1.12
upper fraction nonconforming
p_U
fraction of the **distribution** (2.1.7) of a **characteristic** (2.1.2) that is greater than the upper **specification limit** (2.1.4), U

EXAMPLE In a normal **distribution** (2.1.7), with mean, μ, and standard deviation σ:

$$p_U = 1 - \Phi\left(\frac{U-\mu}{\sigma}\right) = \Phi\left(\frac{\mu-U}{\sigma}\right)$$

where

p_U is the upper fraction nonconforming;

Φ is the distribution function of the standard normal distribution;

U is the upper specification limit.

NOTE 1 Tables (or functions in statistical computer packages) of the standard normal distribution are readily available which give the proportion of process output expected beyond a particular value of interest, such as a **specification limit** (2.1.4), in terms of standard deviations away from the process mean. This obviates the need to work out the statistical distribution function given in the example.

NOTE 2 The function relates to a theoretical distribution. In practice, with empirical distributions, the parameters are replaced by estimates.

[ISO 3534-2:2006, 2.5.4]

2.1.13
lower fraction nonconforming
p_L
fraction of the **distribution** (2.1.7) of a **characteristic** (2.1.2) that is less than the lower **specification limit** (2.1.4), L

EXAMPLE In a normal **distribution** (2.1.7), with mean, μ, and standard deviation, σ:

$$p_L = \Phi\left(\frac{L-\mu}{\sigma}\right)$$

where

p_L is the lower fraction nonconforming;

Φ is the distribution function of the standard normal distribution;

L is the lower specification limit.

NOTE 1 Tables (or functions in statistical computer packages) of the standard normal distribution are readily available which give the proportion of process output expected beyond a particular value of interest, such as a **specification limit** (2.1.4), in terms of standard deviations away from the process mean. This obviates the need to work out the statistical distribution function given in the example.

NOTE 2 The function relates to a theoretical distribution. In practice, with empirical distributions, the parameters are replaced by estimates.

[ISO 3534-2:2006, 2.5.5]

2.1.14
total fraction nonconforming
p_t
sum of **upper fraction nonconforming** (2.1.12) and **lower fraction nonconforming** (2.1.13)

EXAMPLE In a normal **distribution** (2.1.7), with mean, μ, and standard deviation, σ:

$$p_t = \Phi\left(\frac{\mu - U}{\sigma}\right) + \Phi\left(\frac{L - \mu}{\sigma}\right)$$

where

p_t is the total fraction nonconforming;

Φ is the distribution function of the standard normal distribution;

U is the upper specification limit;

L is the lower specification limit.

[ISO 3534-2:2006, 2.5.6]

2.2 Process capability, estimates and indices

2.2.1
process capability
⟨estimate⟩ statistical estimate of the outcome of a characteristic from a process which has been demonstrated to be in a state of statistical control and which describes that process's ability to realize a characteristic that will fulfil the requirements for that characteristic

NOTE 1 The characteristic from the process needs to be documented to have been in statistical control.

NOTE 2 The outcome is a **distribution** (2.1.7), the class of which needs determination and its parameters estimated.

NOTE 3 In certain circumstances, the standard deviation, S_w, that represents only within subgroup variation can be used as an estimator for S_t:

$$S_w \approx \frac{\bar{R}}{d_2} \quad \text{or} \quad \frac{\sum_{j=1}^{m} S_j}{m c_4} \quad \text{or} \quad \sqrt{\frac{\sum_{j=1}^{m} S_j{}^2}{m}}$$

where

$\bar{R}$ is the average range calculated from a set of m subgroup ranges;

S_j is the sample standard deviation of the jth subgroup;

m is the number of subgroups of the same size, n;

d_2, c_4 are constants based on subgroup size, n.

Alternatively, for a normal distribution, the process overall standard deviation σ_t, can be estimated using the formula for S_t.

The value of the estimators S_t and S_w converge for a process in a state of statistical control. A comparison of the two gives an indication of the degree of stability of the process. For an out-of-control process about a constant mean, or for a process that is subject to systematic changes in the mean, the value of S_w is likely to significantly underestimate the process standard deviation. Hence S_w should be used with extreme caution. Sometimes, too, the estimator S_t is preferred to S_w because it has more tractable statistical properties (e.g. facilitating the calculation of confidence limits).

NOTE 4 For a normal distribution, process capability can be assessed from the expression:

$$\bar{\bar{X}} \pm z S_t$$

where

$$\bar{\bar{X}} = \frac{1}{m}\sum_{j=1}^{m} \bar{X}_j$$

and $\bar{X}_j$ is the observed mean of the jth subgroup.

The choice of z depends on the particular parts per million capability standard used. Typically z takes the value of 3, 4 or 5. If the process capability meets the specified requirements, a z value of 3 indicates an expected 2 700 parts per million outside of specification. Similarly, a z of 4 indicates an expected 64 parts per million and a z of 5 an expected 0,6 parts per million outside of specification.

NOTE 5 For a non-normal distribution, process capability can be assessed using, for example, an appropriate probability paper or from the parameters of the distribution fitted to the data. The expression for process capability takes the asymmetric form:

$$\bar{\bar{X}}{}^{+a}_{-b}$$

The notation ${}^{+a}_{-b}$ is in the same style as standard drawing office practice for expressing specified tolerances about a nominal, or preferred, value for a characteristic when the preferred value is not equidistant from each limit. The equivalent notation for limits symmetrical about the preferred value is $\pm$. This enables a direct comparison to be made between the dimensional performance of a characteristic and its specified requirements in terms of both location and dispersion.

NOTE 6 When $S_w = \dfrac{\bar{R}}{d_2}$ is used, it needs to be appreciated that this estimator:

— becomes progressively less efficient as the subgroup size increases;

— is very sensitive to the distribution of individual values;

— makes it difficult to estimate confidence limits.

NOTE 7 Capability conditions are very restrictive and include:

— the methods applied to demonstrate that the process is in control;

— technical conditions (input batches, operators, tools, etc.);

— the measurement process (discrimination, accuracy, repeatability, reproducibility, etc.); and

— data collection (duration, frequency).

NOTE 8 Adapted from ISO 3534-2:2006, 2.7.1.

2.2.2
process capability estimate

quantity that describes one or more properties of the **distribution** (2.1.7) of the product characteristic under capability conditions

EXAMPLE 1 The standard deviation (ISO 3534-1:2006, 2.37) of the **distribution** (2.1.7) of the product characteristic under capability conditions (see 2.2.1, Notes 1 and 7).

EXAMPLE 2 The mean (ISO 3534-1:2006, 2.35.1) of the **distribution** (2.1.7) of the product characteristic under capability conditions (see 2.2.1, Notes 1 and 7).

EXAMPLE 3 The **reference interval** (2.1.11) of the **distribution** (2.1.7) of the product characteristic under capability conditions (see 2.2.1, Notes 1 and 7).

2.2.3
process capability index

C_{p}

index describing **process capability** (2.2.1) in relation to **specified tolerance** (2.1.5)

NOTE 1 Frequently, the process capability index is expressed as the value of the **specified tolerance** (2.1.5) divided by a measure of the length of the **reference interval** (2.1.11) for a process in a state of statistical control, namely as:

$$C_{\mathrm{p}} = \frac{U - L}{X_{99{,}865\,\%} - X_{0{,}135\,\%}}$$

NOTE 2 For a normal **distribution** (2.1.7), the **reference interval** (2.1.11) is equal to $6S_{\mathrm{w}}$ (see 2.2.1, Notes).

NOTE 3 For a non-normal **distribution** (2.1.7), the **reference interval** (2.1.11) can be estimated, for example, using the probability paper method or the Pearson curves method.

NOTE 4 Adapted from ISO 3534-2:2006, 2.7.2.

2.2.4
upper process capability index

$C_{\mathrm{pk}U}$

index describing **process capability** (2.2.1) in relation to the upper **specification limit** (2.1.4), U

NOTE 1 Frequently, the upper process capability index is expressed as the difference between the upper **specification limit** (2.1.4) and the 50 % distribution quantile, $X_{50\,\%}$ divided by a measure of the length of the upper **reference interval** (2.1.11) for a process in a state of statistical control, namely as:

$$C_{\mathrm{pk}U} = \frac{U - X_{50\,\%}}{X_{99{,}865\,\%} - X_{50\,\%}}$$

NOTE 2 For a normal **distribution** (2.1.7), the upper **reference interval** (2.1.11) is equal to $3S_{\mathrm{w}}$ (see 2.2.1, Notes) and $X_{50\,\%}$ represents both the mean and the median.

NOTE 3 For a non-normal **distribution** (2.1.7), the upper **reference interval** (2.1.11) can be estimated, for example, using the probability paper method or the Pearson curves method and $X_{50\,\%}$ represents the median.

NOTE 4 Adapted from ISO 3534-2:2006, 2.7.4.

2.2.5
lower process capability index

$C_{\mathrm{pk}L}$

index describing **process capability** (2.2.1) in relation to the lower **specification limit** (2.1.4)

NOTE 1 Frequently, the lower process capability index is expressed as the difference between the 50 % distribution quantile, $X_{50\,\%}$, and the lower **specification limit** (2.1.4) divided by a measure of the length of the lower **reference interval** (2.1.11) for a process in a state of statistical control, namely as:

$$C_{\mathrm{pk}L} = \frac{X_{50\,\%} - L}{X_{50\,\%} - X_{0{,}135\,\%}}$$

NOTE 2 For a normal **distribution** (2.1.7) the lower **reference interval** (2.1.11) is equal to $3S_{\mathrm{w}}$ (see 2.2.1, Notes) and $X_{50\,\%}$ represents both the mean and the median.

