BS ISO 22514-1:2014

BSI Standards Publication

Statistical methods in process management — Capability and performance

Part 1: General principles and concepts

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National foreword

This British Standard is the UK implementation of ISO 22514-1:2014. It supersedes BS ISO 22514-1:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee SS/4, Statistical Process Management.

A list of organizations represented on this committee can be obtained on request to its secretary.

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ISBN 978 0 580 83515 5

ICS 03.120.30

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 June 2014.

Amendments issued since publication

Date	Text affected

INTERNATIONAL STANDARD

ISO 22514-1

Second edition
2014-06-01

Statistical methods in process management — Capability and performance —

Part 1: **General principles and concepts**

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

Partie 1: Principes et concepts généraux

Reference number
ISO 22514-1:2014(E)

Contents

Page

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 69, *Applications of statistical methods*, Subcommittee 4, *Applications of statistical methods in process management*.

This second edition cancels and replaces the first edition (ISO 22514-1:2009), which has been technically revised.

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 2: Process capability and performance of time-dependent process models*

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

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

— *Part 6: Process capability statistics for characteristics following a multivariate normal distribution*

— *Part 7: Capability of measurement processes*

— *Part 8: Machine performance of a multi-state production process*

An additional part, dealing with process capability statistics for attribute characteristics, is planned.

Introduction

This general introduction to capability treats the subject's capability and performance in a general way. To understand fully the concepts, it would be helpful to consult ISO 22514-2, ISO 22514-3, and ISO/TR 22514-4. These documents extend this introductory explanation to more specific uses of the procedures.

A process can be either a discrete process or a continuous process. A discrete process generates a sequence of distinguishable items and a continuous process generates a continuous product (e.g. a lane of paper).

The purpose of a process is to manufacture a product or perform a service, which satisfies a set of preset specifications. The specifications for a process under investigation are defined for one or more characteristics of the product or service. However, in process performance or capability, only one characteristic is considered at a time. The characteristic can either be measurable, countable, or it can be a property. The process is, thus, generating either a discrete or a continuous stochastic process. The discrete process can either be a process of real numbers, a process of natural numbers, or a process telling which event from a set of events has occurred for the individual items. As an example, the set of events for the individual items could be {colour acceptable; colour not acceptable}.

In general, the notation for a discrete stochastic process is $\{X_i\}$, where X_i is the outcome of element no. i in the process. In case the characteristic is a property X_i, it is a value given to each of the events in the set of events used for characterizing the process. For a discrete process, the index i is normally the number of the item in the generated sequence of items. However, sometimes it might be more convenient to use the time from a fixed point as the index. When the process is continuous, a number of possibilities exist for the index depending on the nature of the product. When the product is e.g. a lane of paper, the index could be the length from a starting point or it could be the time from a fixed point.

It should be noted that normally a serial correlation exists in a stochastic process.

A stochastic process is either stationary or non-stationary. The stringent definition of a stationary stochastic process will not be given here. However, for a stationary process a distribution exists for X_i, which is independent of i.

Stochastic processes that satisfy the specifications are either stationary processes or well-defined non-stationary processes (e.g. periodic processes).

To evaluate a process, a performance study is performed. In fact, a performance study starts as a theoretical study of all the elements in the process before the process is physically implemented. When the parameters of the various stages in the process have been analysed and redefined, the process is implemented (might be only as a test process).

Based on sampling from the implemented process, the numerical part of the performance study of the process is started. A number of questions concerning the process will, beyond any reasonable doubt, be answered correctly. The most important question to be answered is whether the process is a stationary process, which is stable or predictable for a reasonable period. For the process, it is then important to identify the probability distribution of the process and to obtain estimates of the distribution parameters with a reasonable small variance. Based on this information, the next stage in the performance study would be to map the properties of the characteristics under investigation and decide whether they are acceptable. If the properties cannot be accepted, the parameters of the process itself will be changed in order to obtain a process with acceptable properties.

Consider a well-defined and implemented process that has been accepted using a performance study. The next stage for the process would then be to ensure that the parameters of the process and thus, of the stochastic process do not change, or changes in a predicted way. This is performed by defining a suitable capability study.

These studies of performance and capability indices are today more and more used to assess production equipment, a process, or even measurement equipment relative to specification criteria. Different types of studies are used depending on the circumstances.

Statistical methods in process management — Capability and performance —

Part 1: General principles and concepts

1 Scope

This part of ISO 22514 describes the fundamental principles of capability and performance of manufacturing processes. It has been prepared to provide guidance about circumstances where a capability study is demanded or necessary to determine if the output from a manufacturing process or the production equipment (a production machine) is acceptable according to appropriate criteria. Such circumstances are common in quality control when the purpose for the study is part of some kind of production acceptance. These studies can also be used when diagnosis is required concerning a production output or as part of a problem solving effort. The methods are very versatile and have been applied for many situations.

This part of ISO 22514 is applicable to the following:

— organizations seeking confidence that their product characteristics requirements are fulfilled;

— organizations seeking confidence from their suppliers that their product specifications are and will be satisfied;

— those internal or external to the organization who audit it for conformity with the product requirements;

— those internal to the organization who deal with analysing and evaluating the existing production situation to identify areas for process improvement.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1101, *Geometrical product specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

ISO 22514-7, *Statistical methods in process management — Capability and performance — Part 7: Capability of measurement processes*

3 Terms and definitions

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

3.1 Basic terms

3.1.1
requirement
need or expectation that is stated, generally implied, or obligatory

[SOURCE: ISO 9000:2005, 3.1.2]

3.1.2
process
set of inter-related or interacting activities which transforms inputs into outputs

Note 1 to entry: Inputs to a process are generally outputs from other processes.

Note 2 to entry: Processes in an organization are generally planned and carried out under controlled conditions to add value.

[SOURCE: ISO 3534-2:2006, 2.1.1, modified]

3.1.3
system
set of interrelated or interacting elements

[SOURCE: ISO 9000:2005, 3.2.1]

3.1.4
product
result of a process

Note 1 to entry: Four generic product categories are

— services (e.g. transport),

— software (e.g. computer program),

— hardware (e.g. engine mechanical part), and

— processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. What the product is then called depends on the dominant element.

Note 2 to entry: In mathematics, the concept of product is limited to the result of multiplication.

[SOURCE: ISO 3534-2:2006, 1.2.32]

3.1.5
characteristic
distinguishing feature (of an item)

[SOURCE: ISO 9000:2005, 3.5.1, modified]

Note 1 to entry: Item is defined in ISO 3534-2:2006, definition 1.2.11.

3.1.6
quality
degree to which a set of inherent *characteristics* (3.1.5) of a *product* (3.1.4) fulfils *requirements* (3.1.1) of customers and other interested parties

Note 1 to entry: In ISO 9000:2005, 3.1.1, quality is defined without specification of who defines the requirements.

3.1.7
product characteristic
inherent *characteristic* (3.1.5) of a *product* (3.1.2)

Note 1 to entry: Product characteristics can be either quantitative or qualitative.

Note 2 to entry: The product characteristic can be multidimensional.

3.1.8
process characteristic
inherent *characteristic* (3.1.5) of a *process* (3.1.4)

Note 1 to entry: Process characteristics can be either quantitative or qualitative.

Note 2 to entry: The process characteristic can be multidimensional.

3.1.9
quality characteristic
inherent *characteristic* (3.1.5) of a *product* (3.1.4), *process* (3.1.2), or *system* (3.1.3) related to a *requirement* (3.1.1)

Note 1 to entry: Quality characteristics can be either quantitative or qualitative.

Note 2 to entry: The quality characteristic can be multidimensional.

Note 3 to entry: Often, there is a strong correlation between a process characteristic and a product characteristic, which is realized by the process. In principle, however, the individual requirement to the process characteristic and the individual requirement to the product characteristic are different. Each of these both individual requirements is the part of the quality requirement for the process and the part of the quality requirement for the product, respectively.

3.1.10
specification
document stating *requirements* (3.1.1)

Note 1 to entry: A specification can be related to activities (e.g. procedure document, process specification, and test specification), or *products* (3.1.4) (e.g. product specification, performance specification, and drawing).

[SOURCE: ISO 9000:2005, 3.7.3]

3.1.11
specification limit
limiting value stated for a *characteristic* (3.1.5)

[SOURCE: ISO 3534-2:2006, 3.1.3]

Note 1 to entry: Sometimes specification limits are called tolerance limits.

3.1.12
upper specification limit
U
specification limit (3.1.11) that defines the highest value a quality characteristic can have and still be considered conforming

Note 1 to entry: The preferred symbol for upper specification limit is *U*.

[SOURCE: ISO 3534-2:2006, 3.1.4, modified]

3.1.13
lower specification limit
L
specification limit (3.1.11) that defines the lowest value a quality characteristic might have and still be considered conforming

Note 1 to entry: The preferred symbol for lower specification limit is *L*.

[SOURCE: ISO 3534-2:2006, 3.1.5, modified]

3.1.14
specification interval
tolerance interval
tolerance zone
interval between upper and lower *specification limits* (3.1.11)

Note 1 to entry: This term is completely different from a statistical tolerance interval, which is an interval with stochastic borders.

3.1.15
target value
T
preferred or reference value of a *characteristic* (3.1.5) stated in a *specification* (3.1.10)

[SOURCE: ISO 3534-2:2006, 3.1.2]

3.1.16
nominal value
reference value of a *characteristic* (3.1.5) stated in a specification

Note 1 to entry: In ISO 3534-2, nominal value and target value are synonyms with target value as the preferred term. There is a need to distinguish the reference value in a specification and a preferred value used in production.

3.1.17
actual value
value of a quantity in a *characteristic* (3.1.5)

3.1.18
variation
difference between values of a *characteristic* (3.1.5)

Note 1 to entry: Variation is often expressed as a variance or standard deviation.

[SOURCE: ISO 3534-2:2006, 2.2.1]

3.1.19
random cause
common cause
chance cause
<process variation> source of process *variation* (3.1.18) that is inherent in a *process* (3.1.2) over time

Note 1 to entry: In a process subject only to random cause variation, the variation is predictable within statistically established limits.

Note 2 to entry: The reduction of these causes gives rise to process improvement. However, the extent of their identification, reduction and removal is the subject of cost/benefit analysis in terms of technical tractability and economics.

[SOURCE: ISO 3534-2:2006, 2.2.5]

3.1.20
product characteristic in control
product characteristic (3.1.7) parameter of the distribution of the characteristic values of which practically do not change or do change only in a known manner or within known limits

3.1.21
stable process
process in a state of statistical control
<constant mean> *process* (3.1.2) subject only to *random causes* (3.1.19)

Note 1 to entry: A production in control is a production with processes in control.

Note 2 to entry: A stable process will generally behave as though the samples from the process at any time are simple random samples from the same population.

Note 3 to entry: This state does not imply that the random variation is large or small, within or outside of specification, but rather that the variation is predictable using statistical techniques.

[SOURCE: ISO 3534-2:2006, 2.2.7, modified]

3.1.22
distribution of a product characteristic
information on the probabilistic behaviour of a *product characteristic* (3.1.7)

Note 1 to entry: The distribution contains the numerical information about the product characteristic except for the serial order in which the items have been produced.

Note 2 to entry: The distribution of product characteristic exists whether the product characteristic is being recorded or not, and it depends on technical conditions such as input batches, tools, operators, etc.

Note 3 to entry: If information about the distribution of product characteristic is desired data must be collected. The distribution that is observed depends in addition to the technical conditions (see Note 2) and the following conditions pertaining to the data collection:

— the measurement;

— the time interval over which the sampling takes place;

— the frequency of sampling.

The technical conditions (see Note 2) and the conditions of the data collection shall always be specified.

Note 4 to entry: The distribution of the product characteristic can be represented in any of the ways distributions and data from distributions are represented. The histogram is frequently used for data from a distribution whereas the density function is frequently used for a model of the distribution of the product characteristic.

Note 5 to entry: In the following clauses, the distribution of the product characteristic will be considered under different but well-defined conditions, such as performance and capability, where performance is the least restrictive.

3.1.23
class of distributions
particular family of *distributions* (3.1.22) each member of which has the same common attributes by which the family is fully specified

EXAMPLE 1 The class of normal distributions where the unknown parameters are the mean and the standard deviation. Often, the class of normal distributions is referred to simply as the normal distribution.

EXAMPLE 2 Three parameters, multi-shaped, Weibull distribution with parameters, location, shape, and scale.

EXAMPLE 3 The unimodal continuous distributions.

Note 1 to entry: The class of distributions can often be fully specified through the values of appropriate parameters.

[SOURCE: ISO 3534-2:2006, 2.5.2, modified]

3.1.24
distribution model of the product characteristic
specified *distribution* (3.1.22) or *class of distributions* (3.1.23)

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 distribution.

EXAMPLE 2 A model for the same situation 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.

[SOURCE: ISO 3534-2:2006, 2.5.3]

3.1.25
reference limits of the product characteristic

$X_{0,135\ \%}$, $X_{99,865\ \%}$

quantile of the *distribution of the product characteristic* (3.1.22)

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

Note 1 to entry: The conditions of the distribution of the product characteristic shall be specified, see Note 2 and Note 3 of 3.1.22.

Note 2 to entry: Traditionally the 0,135 % and 99,865 % quantiles have been used.

3.1.26
reference interval of a product characteristic

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

EXAMPLE 1 In a normal distribution with mean μ and standard deviation σ, the reference interval corresponding to the traditional 0,135 % and 99,865 % quantiles has limits $\mu \pm 3\sigma$, and has length 6σ.

EXAMPLE 2 For a non-normal distribution, 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 the methods described in ISO/TR 22514-4.

Note 1 to entry: The interval can be expressed by $X_{0,135\ \%}$, $X_{99,865\ \%}$, quantiles and the length of the interval is $X_{99,865\ \%}$, $- X_{0,135\ \%}$.

Note 2 to entry: This term is used only as an arbitrary, but standardized, basis for defining the process *performance index* (3.2.3) and *process capability index* (3.3.6). It is sometimes, incorrectly, referred to as a "natural" interval.

Note 3 to entry: For a normal distribution, the length of the reference interval can be expressed in terms of six standard deviations, 6σ, or $6S$, when σ is estimated from a sample.

Note 4 to entry: For a non-normal distribution, the length of the reference interval can be estimated by means of appropriate software or probability plot (e.g. log-normal) or from the sample kurtosis and sample skewness using the methods described in ISO/TR 22514-4.

Note 5 to entry: A quantile or fractile indicates a division of a distribution into equal units or fractions, e.g. percentiles.

[SOURCE: ISO 3534-2:2006, 2.5.7, modified]

3.1.27
upper fraction nonconforming of the product characteristic

p_U

fraction of the *distribution of the product characteristic* (3.1.22) that exceeds the *upper specification limitU* (3.1.12)

EXAMPLE In a normal distribution 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 Φ is the distribution function of the standard normal distribution.

[SOURCE: ISO 3534-2:2006, 2.5.4, modified]

3.1.28
lower fraction nonconforming of the product characteristic
p_L
fraction of the *distribution of the product characteristic* (3.1.22) *that is less than the lower specification limit L* (3.1.13)

EXAMPLE In a normal distribution with mean μ and standard deviation σ:

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

where Φ is the distribution function of the standard normal distribution.

[SOURCE: ISO 3534-2:2006, 2.5.5, modified]

3.1.29
fraction nonconforming of the product characteristic
p_t
sum of *upper fraction nonconforming of the product characteristic* (3.1.27) and *lower fraction nonconforming of the product characteristic* (3.1.28)

$$p_t = p_L + p_U$$

EXAMPLE In a normal distribution with mean μ and standard deviation σ:

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

where Φ is the distribution function of the standard normal distribution.

[SOURCE: ISO 3534-2:2006, 2.5.6, modified]

3.2 Performance, measures, and indices

NOTE The concepts of capability and performance have been subject to large shifts of opinion. The most fundamental shift has been to philosophically separate what is named in this part of ISO 22514 as capability conditions from performance conditions, the primary difference being whether statistical stability has been obtained (capability) or not (performance). This naturally leads to 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.

3.2.1
performance conditions
external conditions under which the process is evaluated

Note 1 to entry: The external conditions shall be specified meticulously. This includes the following:

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

— measurement process (resolution, trueness, repeatability, reproducibility, etc.);

— data collection (duration, frequency).

Note 2 to entry: Performance conditions are the least restrictive allowed.

Note 3 to entry: It is irrelevant that the process is in state of statistical control in the period considered.

3.2.2
performance measure
statistical measure of the outcome of a *characteristic* (3.1.5) from a process, which might not have been demonstrated to be in a *state of statistical control* (3.1.21)

EXAMPLE 1 The variance (ISO 3534-1:2006, 2.36) of the *distribution of the product characteristic* (3.1.22) under *performance conditions* (3.2.1).

EXAMPLE 2 The mean (ISO 3534-1:2006, 2.35) of the distribution of the product characteristic under performance conditions.

EXAMPLE 3 The *reference interval* (3.1.26) of the distribution of the product characteristic under performance conditions.

Note 1 to entry: The outcome is a distribution, the *class* (3.1.23) of which needs determination and its parameters estimated.

Note 2 to entry: Care should be exercised in using this measure as it can contain a component of variability due to special causes, the value of which is not predictable.

Note 3 to entry: Quantity that describes one or more properties of the distribution of the product characteristic under performance conditions.

3.2.3
performance index
P_p, P_m
quantity that describes *performance measure* (3.2.2) in relation to specified specifications

Note 1 to entry: Frequently, the process performance index is expressed as the value of the specified *tolerance interval* (3.1.14) divided by a measure of the length of the *reference interval* (3.1.26), namely as:

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

Note 2 to entry: For a normal distribution, the length of the reference interval is equal to $6S_t$, where the descriptor, S_t, takes into account the variation due to random (common) causes together with any special causes that can be present. S_t is used here instead of σ_t, as the standard deviation is a statistical descriptive measure.

Note 3 to entry: For a non-normal distribution, the length of the reference interval can be estimated using, for example, the method described in ISO/TR 22514-4.

Note 4 to entry: For machine performance the indicator is P_m, P_p is the indicator for process performance, and the expressions for the formula in Note 1 are the same.

[SOURCE: ISO 3534-2:2006, 2.6.2, modified]

3.2.4
upper performance index
P_{pkU}, P_{mkU}
index describing *performance measure* (3.2.2) in relation to the *upper specification limit U* (3.1.12)

Note 1 to entry: P_{pkU} is the difference between the 50 % distribution quantile, $X_{50\ \%}$, and the upper specification limit U divided by the difference between the 50 % distribution quantile, $X_{50\ \%}$, and the *upper reference limit* (3.1.25):

$$P_{pkU} = \frac{\mathrm{U} - X_{50\,\%}}{X_{99,865\,\%} - X_{50\,\%}}$$

Note 2 to entry: Occasionally one sees an upper performance index defined as

$$P_{pkU} = \frac{\mathrm{U} - X_{50\,\%}}{3S_t}$$

where $X_{50\,\%}$ denotes a measure of location, such as the mean or the median, and S_t denotes the standard deviation.

Note 3 to entry: Occasionally, and in particular if the product characteristic is qualitative, one sees an upper performance index defined as

$$P_{pkU} = \frac{z_{1-p_U}}{3}$$

where p_U is the *upper fraction nonconforming of the product characteristic* (3.1.27) under *performance conditions* (3.2.1) and z_{1-pU} is the (1-p_U), quantile in the standard normal distribution.

Note 4 to entry: For machine performance the indicator is P_{mkU}, P_{pkU} is the indicator for process performance, and the expressions for the formula in Note 1 are the same.

[SOURCE: ISO 3534-2:2006, 2.6.4, modified]

3.2.5
lower performance index

P_{pkL}, P_{pL}, P_{mkL}
index describing *performance measure* (3.2.2) in relation to the *lower specification limitL* (3.1.13)

Note 1 to entry: P_{pkL} is the difference between the 50 % distribution quantile, $X_{50\,\%}$, and the lower specification limit L divided by the difference between the 50 % distribution quantile, $X_{50\,\%}$, and the *lower reference limit* (3.1.25):

$$P_{pkL} = \frac{X_{50\,\%} - L}{X_{50\,\%} - X_{0{,}135\,\%}}$$

Note 2 to entry: Occasionally one sees a lower performance index defined as

$$P_{pkL} = \frac{X_{50\,\%} - L}{3S_t}$$

where $X_{50\,\%}$ denotes a measure of location, such as the mean or the median, and S_t denotes the standard deviation estimated from a sample size n, but only for the normal distribution this latter index equals P_{pkL}.

Note 3 to entry: Occasionally, and in particular if the product characteristic is qualitative, one sees a lower performance index defined as

$$P_{pkL} = \frac{z_{1-p_L}}{3}$$

where p_L is the *lower fraction nonconforming of the product characteristic* (3.1.28) under *performance conditions* (3.2.1) and z_{1-pL} is the (1-p_L) quantile in the standard normal distribution.

Note 4 to entry: In ISO/TR 22514-4, the symbol for the α fractile from the standard normal distribution is z_α.

Note 5 to entry: For machine performance the indicator is P_{mkL}, P_{pkL}, is the indicator for process performance, and the expressions for the formula in Note 2 are the same.

[SOURCE: ISO 3534-2:2006, 2.6.3, modified]

3.2.6
minimum performance index

P_{pk}, P_{mk}
$P_{pk} = \min\{P_{pkL}, P_{pkU}\}$
where P_{pkL} *and* P_{pkU} are the *lower performance index* (3.2.5) and *upper performance index* (3.2.4), respectively

Note 1 to entry: The term critical is sometimes used for this index.

Note 2 to entry: Sometimes a specification is given which has only one limit, e.g. a maximum (or minimum) value. In these circumstances it will only be possible to compute a P_{pk} index based on the upper (or lower) performance index.

Note 3 to entry: There will also be situations when specification limits are given and where target value is different from the specification mid-point values and the target value is the preferred (or best) value. In these circumstances it will only be possible to calculate upper process performance index and lower process performance index but not the minimum of both. The upper and lower index might then have different requirements.

[SOURCE: ISO 3534-2:2006, 2.6.5, modified]

3.2.7
position performance
statistical estimate of the two-dimensional distribution of the *product characteristic* (3.1.7) position specified under specified *performance conditions* (3.2.1)

Note 1 to entry: The process does not need to have been demonstrated to be in a state of statistical control in relation to the characteristic.

Note 2 to entry: The position performance is used in cases, where the specification is given as a positional tolerance in accordance to ISO 1101. This tolerancing method is, e.g. applied to the location of axis in a hole.

3.3 Capability, measures, and indices

3.3.1
capability conditions
external conditions under which the process is evaluated

Note 1 to entry: The external conditions shall be specified meticulously. This includes the following:

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

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

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

— data collection (duration, frequency).

Note 2 to entry: Capability conditions are the most restrictive ones among capability and performance conditions.

Note 3 to entry: The process shall be documented to be in control.

3.3.2
capability
ability of an organization, system, or process to realize a product that will fulfil the requirements for that product

[SOURCE: ISO 9000:2005, 3.1.5]

3.3.3
process capability estimate
statistical estimate of the outcome of a *characteristic* (3.1.5) from a *process* (3.1.2) which has been demonstrated to be in a *state of statistical control* (3.1.21) and which describes that ability of the process to realize a characteristic that will fulfil the requirements for that characteristic

Note 1 to entry: The outcome is a *distribution* (3.1.22), the *class* (3.1.23) of which needs determination and its parameters estimated.

3.3.4
capability distribution
distribution of the product characteristic (3.1.22) under *capability conditions* (3.3.1)

3.3.5
capability measure
quantity that describes one or more properties of the *distribution of the product characteristic* (3.1.22) under *capability conditions* (3.3.1)

EXAMPLE 1 The variance (ISO 3534-1, 2.36) of the distribution of the product characteristic under capability conditions.

EXAMPLE 2 The mean (ISO 3534-1, 2.35) of the distribution of the product characteristic under capability conditions.

EXAMPLE 3 The *reference interval* (3.1.26) of the distribution of the product characteristic under capability conditions.

3.3.6
process capability index
C_p
quantity that describes the *capability* (3.3.2) in relation to given specifications

Note 1 to entry: Frequently the process capability index is expressed as the value of the *specification interval* (3.1.14) divided by a measure of the length of the *reference interval* (3.1.26) for a *process in a state of statistical control* (3.1.24), namely as:

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

Note 2 to entry: For a normal distribution, the reference interval is equal to 6σ.

Note 3 to entry: For a non-normal distribution the reference interval can be estimated using the method described in ISO/TR 22514-4.

Note 4 to entry: The term potential process capability index is often used for this index.

[SOURCE: ISO 3534-2:2006, 2.7.2, modified]

3.3.7
upper process capability index
C_{pkU}
index describing *process capability* (3.3.3) in relation to the *upper specification limit* (3.1.12)

Note 1 to entry: Frequently, the upper process capability index is expressed as the difference between the upper specification limit and the 50 % distribution quantile, $X_{50\,\%}$, divided by a measure of the length of the upper reference interval for a *process in a state of statistical control* (3.1.21), namely as:

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

Note 2 to entry: For a normal distribution the upper reference range is equal to 3σ and $X_{50\,\%}$ represents both the mean and the median.

$$C_{\mathrm{pk}_U} = \frac{U - X_{50\,\%}}{3\sigma}$$

Note 3 to entry: For a non-normal distribution, the upper reference interval can be estimated using the method described in ISO/TR 22514-4 and $X_{50\,\%}$ represents the median.

Note 4 to entry: Occasionally, and in particular if the product characteristic is qualitative, one sees an upper performance index defined as

$$C_{\mathrm{pk}_U} = \frac{z_{1-p_U}}{3}$$

where p_u is the *upper fraction nonconforming of the product characteristic* (3.1.27) under *capability conditions* (3.3.1) and $z_{1\text{-}pU}$ is the (1-p_U), quantile in the standard normal distribution.

[SOURCE: ISO 3534-2:2006, 2.7.4, modified]

3.3.8
lower process capability index

C_{pkL}

index describing *process capability* (3.3.3) in relation to the *lower specification limit* (3.1.13)

Note 1 to entry: Frequently, the lower process capability index is expressed as the difference between the upper specification limit and the 50 % distribution quantile, $X_{50\ \%}$, divided by a measure of the length of the lower reference interval for a *process in a state of statistical control* (3.1.21), namely as:

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

Note 2 to entry: For a normal distribution, the lower reference range is equal to 3σ and $X_{50\ \%}$ represents both the mean and the median.

$$C_{\text{pk}_L} = \frac{X_{50\,\%} - L}{3\sigma}$$

Note 3 to entry: For a non-normal distribution, the lower reference interval can be estimated using the method described in ISO/TR 22514-4 and $X_{50\ \%}$ represents the median.

Note 4 to entry: Occasionally, and in particular if the product characteristic is qualitative, one sees a lower performance index defined as

$$C_{\text{pk}_L} = \frac{z_{1-p_L}}{3}$$

where p_L is the *lower fraction nonconforming of the product characteristic* (3.1.28) under *capability conditions* (3.3.1) and z_{1-pL} is the (1-p_L), quantile in the standard normal distribution.

[SOURCE: ISO 3534-2:2006, 2.7.3, modified]

3.3.9
minimum process capability index

C_{pk}

$C_{pk} = \min\{C_{pkL}, C_{pkU}\}$

smaller of *upper process capability index* (3.3.7) and *lower process capability index* (3.3.8)

[SOURCE: ISO 3534-2:2006, 2.7.5]

Note 1 to entry: Sometimes a specification is given which has only one limit, e.g. a maximum (or minimum) value. In these circumstances, it will only be possible to compute a C_{pk} index based on the upper (or lower) capability index.

Note 2 to entry: In the case of e.g. envelope requirement, when specification limits are given and where the target value is different from the specification mid-point values and the target value is the preferred (or best) value. In these circumstances, it will only be possible to calculate upper process capability index and lower capability index but not the minimum of both. The upper and lower index might then have different requirements.

3.3.10
quality capability statistic

QCS

statistic used to quantify the *capability* (3.3.2) of a *characteristic* (3.1.5)

Note 1 to entry: Quality capability statistics for processes are typically either dispersion-related or dispersion-and-location-related.

Note 2 to entry: Quality capability statistics can be used in the sense of observed, required, realizable, etc.

4 Symbols and abbreviated terms

C_{MP}	measurement process capability index
C_{MS}	measurement system capability index
C_g and C_{gk}	gauge capability indices
P_m, P_{mk}, P_{mkL}, P_{mkU}	machine performance indices
C_p, C_{pk}, C_{pkL}, C_{pkU}	process capability indices
P_p, P_{pk}, P_{pkL}, P_{pkU}	process performance indices
C_{pm}	process target capability index
L	lower specification limit
σ	population standard deviation of a characteristic of interest
S_t	standard deviation of the observations of a characteristic of interest
U	upper specification limit
μ	population mean of a characteristic of interest
$X_{99,865\ \%}$	99,865 % distribution quantile
$X_{50\ \%}$	50 % distribution quantile
$X_{0,135\ \%}$	0,135 % distribution quantile
$z_{1-\alpha}$	$(1 - \alpha)$ quantile in the standard normal distribution
Φ	distribution function of the standard normal distribution

5 Pre-conditions for application

5.1 Aspects about establishing specifications

The customers and quality management system in the companies require products consisting of one or more specifications defining quality characteristics that satisfy their needs and expectations. This means that product functions shall be defined based on these needs and expectations. All needs are translated to product specifications by the designer and often referred to as customer requirements. These product specifications shall be complete, which is met only when all intended functions of the product are described with unambiguous characteristics. In most cases however, the specifications will be found incomplete because some functions are described imperfectly. This will cause an extra uncertainty in the assessment of performance or capability.

5.2 Distribution and sample size

Capability and performance indices describe the tail behaviour of the distribution of the product characteristics. The various families of distributions have very different tail behaviour and the estimated indices will depend heavily on the chosen distribution. It is therefore essential that the appropriate distribution shall be chosen with great care.

The first step is to determine the size of samples and the sampling frequency which is necessary to use during the analysis.

The size of the total sample from which the calculations are based should be chosen depending on the desired confidence, accuracy, and the type of process under investigation, and be of an amount, which provides a sound statistical basis. This will typically be a size larger than 100 observations. In special cases, e.g. measurement analysis, the sample size might be less than 100.

In cases where it is suspected that the data are not normally distributed, it is essential to increase the sample size substantially in order to determine the appropriate distribution. This could require an increase of 50 % for data required.

5.3 Materials used in studies

All material used and products to be used in the different studies should be approved for conformance to specifications. Depending on the purpose of the study, it is not advisable for a study to be carried out with materials outside the specifications since this could lead to false conclusions. In case of machine performance calculations, the acceptability of the materials is not limited to just satisfying the tolerances.

For all studies, care shall be taken not to introduce any other sources of variation than those to be studied. In the case of measurement capability studies, refer to 7.6.

5.4 Special circumstances

In many cases, one will find situations, where the observed process is a result of several different streams. A typical example could be plastic moulding, where the process result comes from different cavities or multi-stream production.

In such cases, every single cavity should be regarded as a process of its own and analysed separately. The cavities could be put together after analysis if the customer requires only one capability index and the combined process satisfies specifications.

6 Collection of data

6.1 Traceability of data

It is important for all studies, that the collected data are traceable so that unexpected values can be investigated. This means that the prevailing conditions during the study should be written down. At least the collection sequence should be preserved so that the series of the data observed in sequence of time can be plotted. This time series plot is very useful to indicate possible unexpected variations. Such occurrences should be explained and a decision taken about the admissibility of such data. In connection to process analysis, a logbook would be suitable for recording all process settings and to monitor all events during the study, such as adjustments, temperature fluctuations, or personnel changes.

6.2 Measurement uncertainty

When reporting measurement results, it is important also to add some indications about the quality of this result. There is always a measurement uncertainty present in measuring the characteristics of interest, which should be evaluated and be in reasonable relation to the specification and process variation. This means that the employed measurement equipment should have sufficient metrological characteristics for the measurement task.

A simplified procedure to estimate the uncertainty in measurements is to calculate the measurement process capability as described in ISO 22514-7.

The requirement to the measurement process capability found by an analysis given in ISO 22514-7 is a C_{MP} value not less than 1,33. A measurement process giving under 1,33 is usually regarded as unsatisfactory and should not be used in its current condition as it is likely to disguise the process variation. For further information about measurement uncertainty, see ISO 22514-7.

6.3 Data recording

The observations should be entered in a suitable medium together with the current technical conditions such as input batches, tools, operators, etc.

6.4 Outliers

Outliers are a subset of observations in a set of data that appears to be inconsistent with the remainder of that data set. An outlier might originate from a different population, or be the result of incorrect recording or large measurement error.

It is suspected that such values do not belong to the same basic population as the other collected values, and their validity shall be investigated. If present, such values can lead to false conclusions and do not reflect the actual performance of the process.

Outliers can occur e.g. if a measurement has been read incorrectly, an instrument has been calibrated improperly, an uncontrollable event might have affected the result or a recording error might have occurred.

Time series analysis, control charts, or statistical tests can be used for detecting outliers.

7 Performance, capability, and process analysis

7.1 Six different types of performance and capability

Currently, six different kinds of performance and capability are defined:

1) machine performance (ISO 22514-3 and ISO 22514-8);

2) the “preliminary” process performance (ISO 22514-2 and ISO/TR 22514-4);

3) the “current” process capability (ISO 22514-2 and ISO/TR 22514-4);

4) the performance of the measuring equipment (ISO 22514-7);

5) position performance — performance of multivariate characteristics (ISO 22514-6);

6) attribute data — performance.

Sometimes it is necessary to calculate special capability indices, and these are covered in 7.7.

The first three capability types mentioned in the list belong to the same group. The main distinction between these types of capability examinations is the point in time forming the basis of the examinations and thus, as a basis of the calculation of the standard deviation.

7.2 Basic considerations

The method of evaluating capability and performance is divided into four steps:

Step 1: The data collected by sampling are plotted as a histogram (frequency distribution) (see Figure 1).

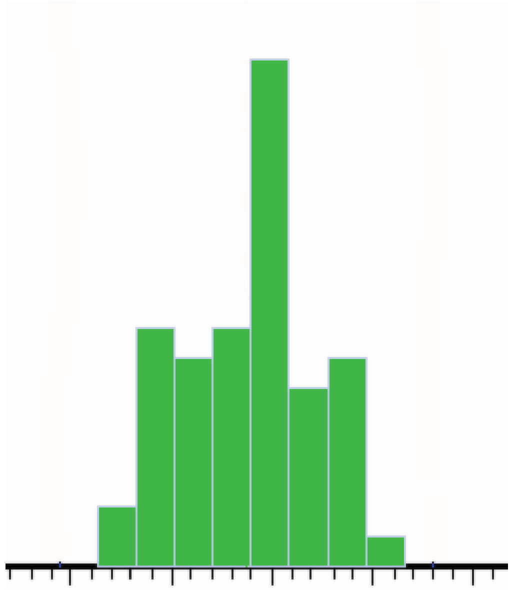

Figure 1 — Histogram

Step 2: An appropriate statistical distribution model is selected based on the actual collected data and knowledge of the process (see Figure 2).

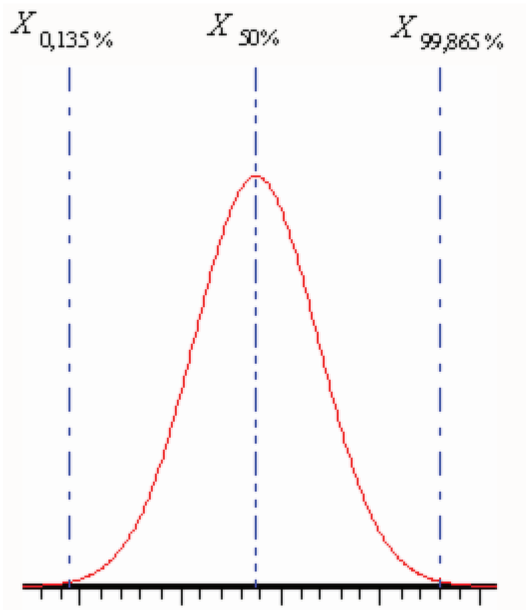

Figure 2 —Distribution

Step 3: The specification limits for the chosen characteristic are identified (see Figure 3).

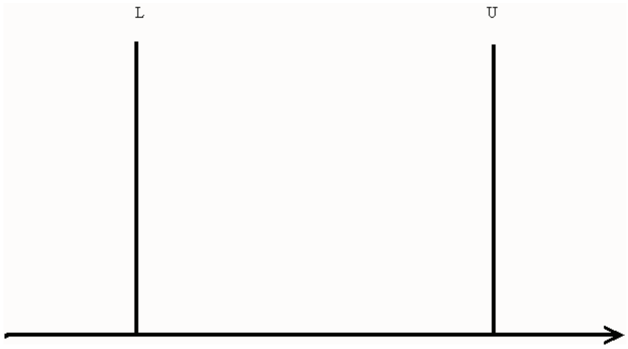

Figure 3 — Specification limits

Step 4: A comparison is made between the specification interval and the chosen distribution (see Figure 4 and 7.4).

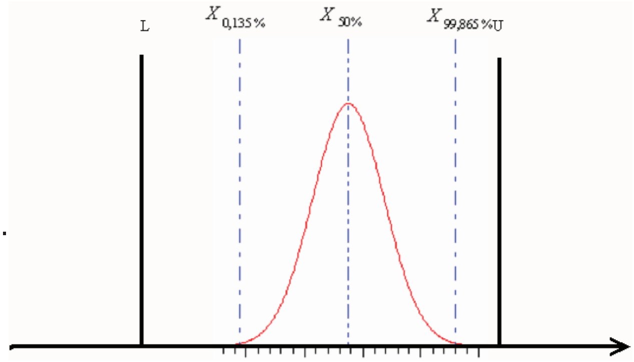

Figure 4 — Comparison

The distinction between the different types of performances and capability can be found in Figures 5 and 6.

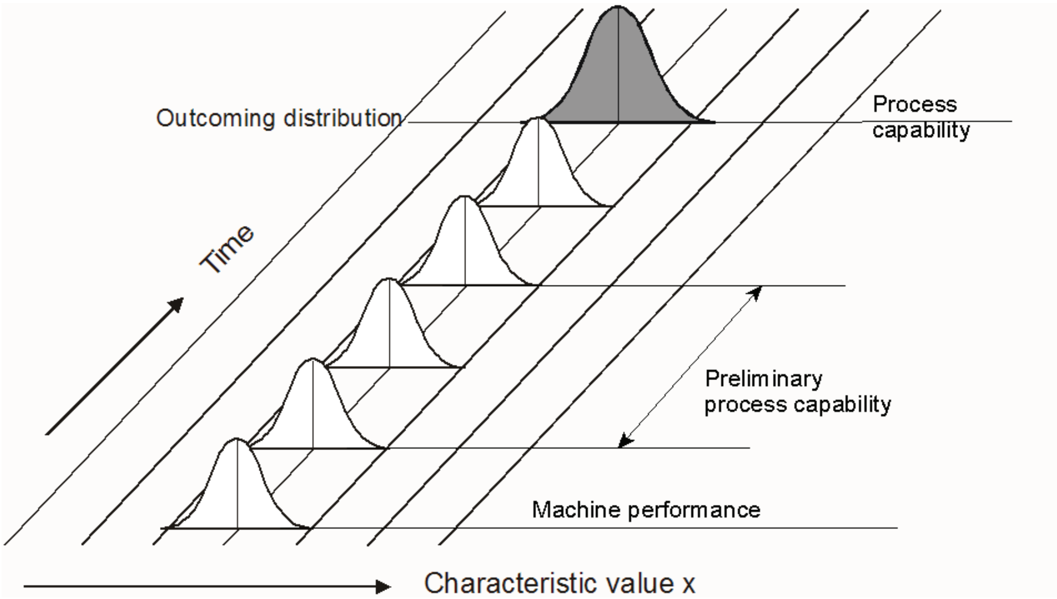

Figure 5 — Process in control and calculation of capability

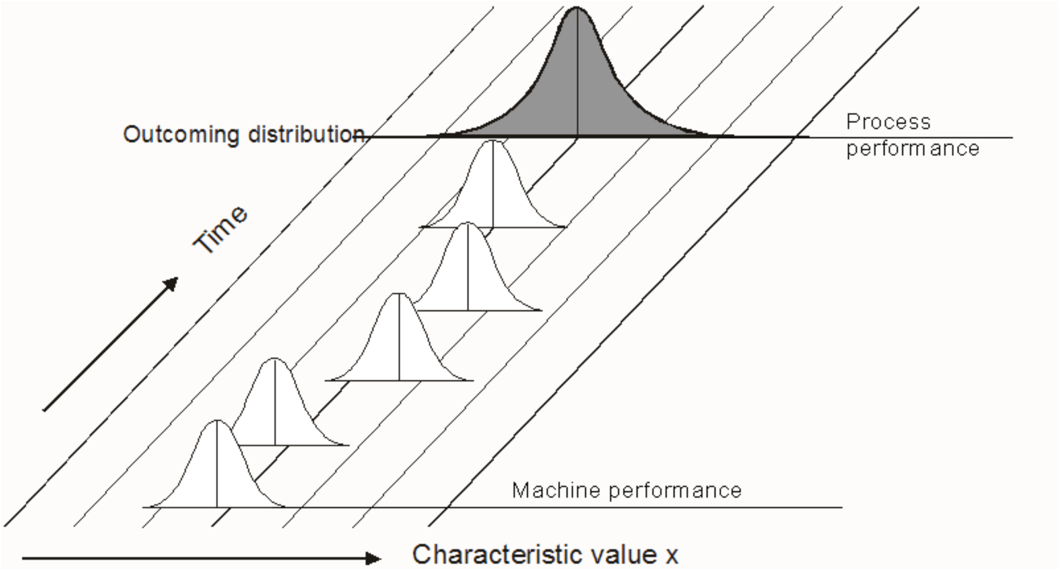

Figure 6 — Process out of control and calculation of performance

Process capability analysis as shown in Figure 5 can be made at many points in time.

If the specification is only one-sided, e.g. geometrical tolerances, only the minimum process performance/capability index is calculated. The calculations can be treated in the same manner as double-sided specification limits.

7.3 Machine performance

Analysis of the production equipment, also called machine performance, is made to get an early evaluation of a process performance seen as a "snap shot" of the process. The analysis can, at the same time, be used to determine the distribution model, according to which the process operates, and the performance. The method can also be used for comparing and evaluating the abilities of different process equipment to meet specified requirements. The analysis does not usually use a control chart because such a chart follows the process over a longer period of time. For further information about machine performance studies, see ISO 22514-3, and in case of multi-state processes (e.g. plastic moulding), see ISO 22514-8.

7.4 Process performance and process capability

Process performance and capability, which are similar analyses, are about making examinations of the natural variation pattern a process produces during a given period of time as shown in Figures 5 and 6. For a given characteristic, process performance and capability describes the distribution of the observations of a process over a time period. These enable a person to evaluate the ability to produce results in accordance with the given specifications or tolerances.

An initial process examination of a new or changed process is made (see Figure 5). This enables a person to get early information of the quality performance. Under this, a number of samples shall be plotted in a control chart used in connection with the examination before the result can be calculated.

The initial study can, in some cases, be suppliant to the machine performance analysis used up until now. Compared to this, the initial process examination also has the advantage of giving an estimation of the stability of the process in the long term.

When the data collected are measured data (for the product or for the process), it is possible to determine the natural variation pattern of the process. If the process is in a state of statistical control, the pattern of the distribution should be predictable.

If so and if the distribution is normal, it will be possible to describe its dispersion through the use of six standard deviations, which are calculated on the basis of the distribution of the process. If the observations of the process follow a normal (bell-shaped) distribution, this dispersion will cover 99,73 % of the population. If the distribution is not normal, it is necessary to use another formula to estimate the dispersion. For further information about process performance and capability analysis, see ISO/TR 22514-4.

7.5 Position performance

The traditional methods used for calculation of performance are based on one-dimensional distributions. In case of position tolerancing according to ISO 1101, where the specification defines the limits for the location of an axis in relation to two or more data, the results will form a two-dimensional distribution, which then shall be used as a model to describe the output of the process. A typical example of this is the position of a bore centre.

In general one would find that

— the analysis of a characteristic specified as a position should contain data from both axes, as a pair of data and the axes shall be perpendicular to each other, and

— usually the position tolerances are defined as a circular tolerance zone and not a rectangular one.

The analysis and the calculation of indices fundamentally use the same definitions as one-dimensional characteristics that are evaluated as a comparison between specification and process behaviour. In this case, it is a comparison between an ellipse representing the process results and an ellipse representing the tolerance zone.

The measurement data from the two axes are to be investigated with reference to stability.

A scatter diagram (figure position) is used to make decisions about the observations, if all measurements are inside the tolerance zone. The distribution of the data sets is to be investigated for segmentation or not random points.

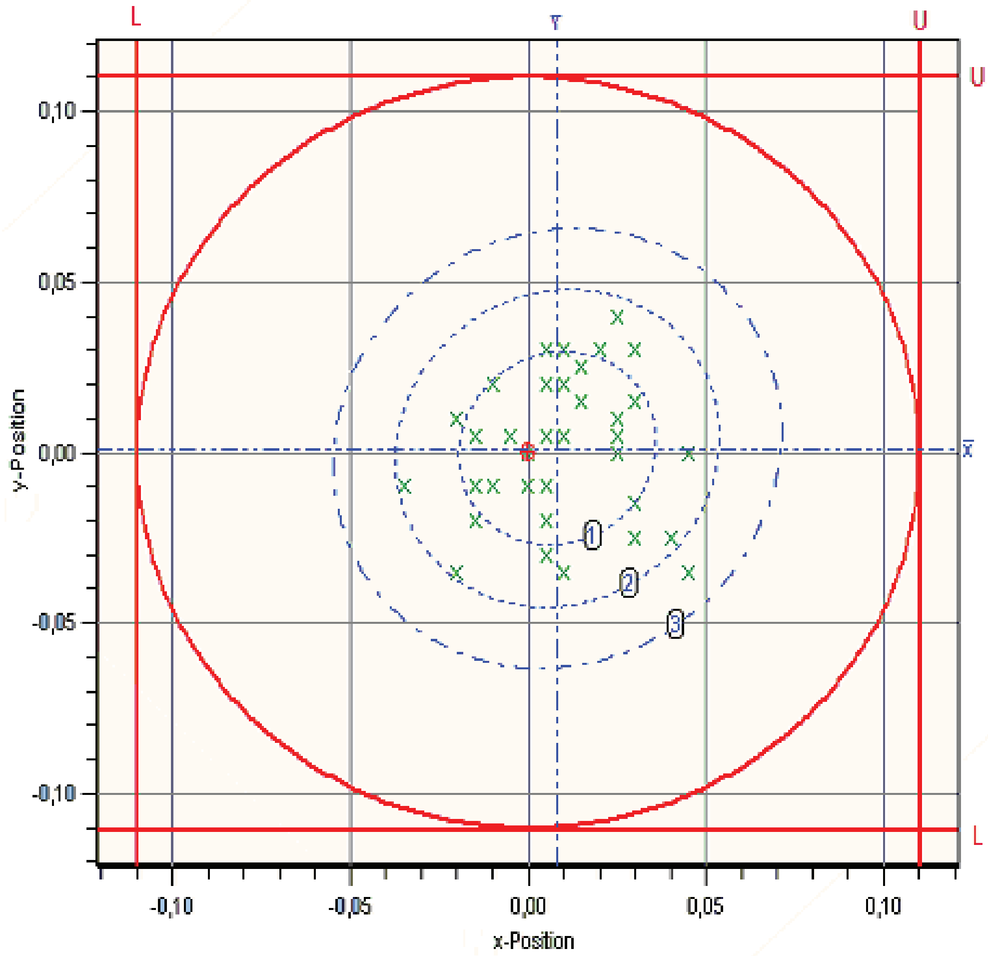

Figure 7 — Tolerance zone — position tolerance

The same principles can be used in cases where more than two dimensions influence the characteristic under investigation. For further information, see ISO 22514-6.

7.6 Measurement process capability

A set of methods used to evaluate the uncertainty of a measurement process under the range of conditions in which the process operates is known as measurement process capability. The measurement process is to be analysed using the same methods as all other processes.

Understanding the facts that variation connected to the measurements always appears and obtaining knowledge of the factors which contribute to this variation, should be a fundamental step in all process analyses. When variations in the measurement system with respect to part variation are large, it will be necessary to reduce uncertainty components that influence the measurement system before analysing the influence components on the process.

Measurement process studies (see ISO 22514-7) are often divided into different types:

— bias, linearity, and stability tests;

— GRR (Gauge Repeatability and Reproducibility) studies;

— a particular study, type III, is used to determine repeatability where no operator influence is present;

— determination of different additional influence factors on the measurement process.

Measurement analysis provides an effective way of selecting a measurement process and equipment. It also provides a basis for comparing and reconciling differences in measurements by quantifying the variation in the measurement process.

7.7 Performance and capability indices

The different types of performance and capability can be expressed by means of an index linking the current process with the tolerance zone. An often-used capability index is C_p, which measures the relation between the whole specification interval and the reference interval for the product characteristic (in the case of normal distribution this is 6σ). This range is a measure for the theoretical capability for a process whose mean is located exactly between the specification limits.

Another often-used index is C_{pk}, which describes the current capability for a process whose mean is not necessarily located on the average of the specification limits.

If a process is under control, the capability indices shall be C_p and C_{pk}; otherwise, P_p and P_{pk} shall be used. In machine studies, P_m and P_{mk} shall be used.

As a consequence of the varied ways in which process capability indices are used, indices have been developed which can have better properties in some special circumstances (e.g the presence of non-normal distributions). One of these is known as the C_{pm} index and is defined by Formula (1):

$$C_{pm} = \frac{d}{6\sqrt{\sigma^2 + (\mu - T)^2}} = \frac{d}{6\sqrt{\mathrm{E}\left[(X - T)^2\right]}} \sigma_X^2 \quad (1)$$

where

T is a “target value”;

d is the specification interval;

E [.] denotes “expected value”.

When the data from the process are attribute data (e.g. percentage of nonconforming units or number of nonconforming units), the process performance is stated as fraction of nonconforming units or the frequency of nonconforming units.

The formula is then

$$C_{pk} = \frac{z_{1-p}}{3} \quad (2)$$

8 Results of use

Performance and capability indices are used for determining the ability of a process to comply with the specification. They are also used to estimate the amount of products out of specification. (This is only possible if the distribution is correctly determined.)

Performance and capability can, in the same way, be used for estimating the degree of conformance with the requirements for every single part of a process, i.e. the individual machine. The analysis of “machine performance” can be used for evaluating equipment or evaluating its contribution to the overall process capability.

Machine performance analysis can be used for evaluating the ability of a machine to produce or function in compliance with the company’s requirements, for purchase and acceptability of a repaired condition.

Maximum permissible values of process performance and capability indices (e.g. P_p or C_p > 2) are required to achieve the desired quality and reliability performance.

Performance and capability can form the basis for setting up reasonable, well-chosen, and justifiable specifications for the manufactured products. It does so by making sure that the variations for the individual characteristics are in accordance with the permissible specifications for the entire product. However, in cases where narrow specifications are necessary, the makers of the individual components shall comply with required level and process capability.

9 Benefits of use

The process capability analysis gives the opportunity of evaluation of the natural variation pattern for a process and an estimation of the amount of nonconforming units that can be expected. It makes a company able to estimate the costs in connection with nonconforming products and can guide it in deciding what changes to make to improve the manufacturing process.

Determination of minimum requirements for process capability can guide the company in choosing processes and equipment with which it is possible to produce a satisfactory product. Such requirements can also be used in connection with agreements of purchase of components where customer and supplier can specify the quality requirements in the form of minimum requirements for capability indices. Most importantly, it develops a culture of performing right first time and promotes confidence resulting in all associated benefits including minimizing cost and, thus, maximizing return on investment.

10 Limitations of use

The actual capability concept and the corresponding indices are only valid for a process under statistical control. Thus, capability analyses can only be used in connection with methods for statistical process control to ensure an ongoing verification of the process stability.

Capability indices can be misleading if the distribution of the process deviates considerably from the normal distribution and this is not taken into consideration during the calculation.

In the same way, the indices for processes, which are under influence of systematic variation, that can be ascribed to certain causes, e.g. wear and tear of tools, can also be misleading if procedures suited for this are not used to calculate and interpret the capability.

If the calculations are based on the estimated percentage of the nonconforming products, it is usually a precondition that the normal distribution is to be used as a model. If this precondition is not fulfilled, this estimation shall be considered with caution. Furthermore, the estimation of the percentage of the nonconforming products is dependent on the current distribution assumption.

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