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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

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Contents

Page

Foreword

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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.

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 22514-1 was 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]

The following parts are planned:

— *Part 5: Process capability statistics for attribute characteristics*

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

— *Part 7: Capability of measurement processes*

It is planned to reissue ISO 21747, *Statistical methods — Process performance and capability statistics for measured quality characteristics*, as part 2 of ISO 22514 in the future.

Introduction

0.1 This introduction to capability treats the subjects “capability” and “performance” in a general way. To fully understand the concepts, it would be helpful to consult ISO 22514-3, ISO/TR 22514-4 and ISO 21747. These documents extend this introductory explanation to more specific uses of the procedures.

A process can either be 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 be measurable, countable or a property. The process thus generates either a discrete or a continuous stochastic process.

— The discrete process can 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 i in the process. In the case where 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 may 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.

To obtain a process which satisfies the specifications, the stochastic process should be a stationary process or a well-defined non-stationary process (e.g. a periodic process).

To evaluate a process, a performance study is performed. A performance study should, in fact, start 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 (this may 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 must, 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 within a reasonable small variance. Based on this information, the next stage in the performance study is 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 must 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 change in a predicted way. This is performed by defining a suitable capability study.

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

0.2 The concepts of performance and capability have been subject to large shifts of opinion. The most fundamental shift has been to philosophically separate what is called “capability conditions” in this part of ISO 22514-1 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 2.2 and 2.3. It has become necessary to draw a firm distinction between these sets, since it has been observed in industry that companies have been misled about their true capability position due to inappropriate indices being calculated and published.

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 requested or is 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 may 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 Terms and definitions

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

2.1 Basic terms

2.1.1
requirement
need or expectation that is stated, generally implied or obligatory

[ISO 9000:2005, definition 3.1.2]

2.1.2
process
set of inter-related or interacting activities which transforms inputs into outputs

NOTE 1 Inputs to a process are generally outputs from other processes.

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

NOTE 3 Adapted from ISO 3534-2:2006, definition 2.1.1.

2.1.3
system
set of interrelated or interacting elements

[ISO 9000:2005, definition 3.1.3]

2.1.4
product
result of a process

NOTE 1 Four generic product categories are:

- services (e.g. transport);
- software (e.g. computer program);
- hardware (e.g. engine mechanical part);
- 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 In mathematics, the concept of product is limited to the result of multiplication.

[ISO 3534-2:2006, definition 1.2.32]

2.1.5
characteristic
distinguishing feature (of an item)

NOTE 1 Adapted from ISO 9000:2005, definition 3.5.1

NOTE 2 Item is defined in ISO 3534-2:2006, definition 1.2.11.

2.1.6
quality
degree to which a set of inherent **characteristics** (2.1.5) of a **product** (2.1.4) fulfils **requirements** (2.1.1) of customers and other interested parties

NOTE In ISO 9000:2005 (3.1.1), quality is defined without specification of who defines the requirements.

2.1.7
product characteristic
inherent **characteristic** (2.1.5) of a **product** (2.1.4)

NOTE 1 Product characteristics can be either quantitative or qualitative.

NOTE 2 The product characteristic may be multidimensional.

2.1.8
process characteristic
inherent **characteristic** (2.1.5) of a **process** (2.1.2)

NOTE 1 Process characteristics can be either quantitative or qualitative.

NOTE 2 The process characteristic may be multidimensional.

2.1.9
quality characteristic
inherent **characteristic** (2.1.5) of a **product** (2.1.4), **process** (2.1.2) or **system** (2.1.3) related to a **requirement** (2.1.1)

NOTE 1 Quality characteristics can be either quantitative or qualitative.

NOTE 2 The quality characteristic may be multidimensional.

NOTE 3 Often, there is a strong correlation between a process characteristic and a product characteristic realized by a process. However, the individual requirements differ. For a process characteristic, the individual requirement is part of the quality requirement for the process; for a product characteristic realized by the process, the individual requirement is part of the quality requirement for a product.

2.1.10
specification
document stating **requirements** (2.1.1)

NOTE A specification can be related to activities (e.g. procedure document, process specification and test specification), or products (e.g. product specification, performance specification and drawing).

[ISO 9000:2005, definition 3.7.3]

2.1.11
specification limit
limiting value stated for a **characteristic** (2.1.5)

[ISO 3534-2:2006, definition 3.1.3]

NOTE Sometimes specification limits are called “tolerance limits”.

2.1.12
upper specification limit
U
specification limit (2.1.11) that defines the highest value a quality characteristic may have and still be considered conforming

NOTE 1 The preferred symbol for upper specification limit is U.

NOTE 2 Adapted from ISO 3534-2:2006, definition 3.1.4.

2.1.13
lower specification limit
L
specification limit (2.1.11) that defines the lowest value a quality characteristic may have and still be considered conforming

NOTE 1 The preferred symbol for lower specification limit is L.

NOTE 2 Adapted from ISO 3534-2:2006, definition 3.1.5.

2.1.14
specification interval
tolerance interval
interval between upper and lower **specification limits** (2.1.11)

NOTE This term is completely different from a statistical tolerance interval, which is an interval with stochastic borders.

2.1.15
tolerance zone
space limited by one or several geometrically perfect lines or surfaces, and characterized by a linear dimension, called a tolerance

[ISO 1101:2004, definition 3.1]

2.1.16
target value
T
preferred or reference value of a **characteristic** (2.1.5) stated in a **specification** (2.1.10)

[ISO 3534-2:2006, definition 3.1.2]

2.1.17
nominal value
reference value of a **characteristic** (2.1.5) stated in a specification

NOTE In ISO 3534-2:2006, 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 the preferred value used in production.

2.1.18
actual value
value of a quantity in a **characteristic** (2.1.5)

2.1.19
variation
difference between values of a **characteristic** (2.1.5)

NOTE Variation is often expressed as a variance or standard deviation.

[ISO 3534-2:2006, definition 2.2.1]

2.1.20
random cause
common cause
chance cause
⟨process variation⟩ source of process **variation** (2.1.19) that is inherent in a **process** (2.1.2) over time

NOTE In a process subject only to random cause variation, the variation is predictable within statistically established limits.

2.1.21
product characteristic in control
product characteristic (2.1.7) parameter of the distribution of the characteristic values, which practically do not change or do change only in a known manner or within known limits

2.1.22
stable process
process in a state of statistical control
⟨constant mean⟩ **process** (2.1.2) subject only to **random causes** (2.1.20)

NOTE 1 A production in control is a production with processes in control.

NOTE 2 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 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.

NOTE 4 Adapted from ISO 3534-2:2006, definition 2.2.7.

2.1.23
distribution of a product characteristic
information on the probabilistic behaviour of a **product characteristic** (2.1.7)

NOTE 1 The distribution contains the numerical information about the product characteristic, except for the serial order in which the items have been produced.

NOTE 2 The distribution of a 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 If information about the distribution of a product characteristic is desired, data must be collected. The distribution that is observed depends on the technical conditions (see Note 2) and on the following data collection conditions:

— 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 must always be specified.

NOTE 4 The distribution of the product characteristic may 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 In this part of ISO 22514, 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.

2.1.24
class of distributions
particular family of **distributions** (2.1.23), 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 parameter, multi-shaped, 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 appropriate parameters.

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

2.1.25
distribution model of the product characteristic
specified **distribution** (2.1.23) or **class of distributions** (2.1.24)

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.

[ISO 3534-2:2006, definition 2.5.3]

2.1.26
reference limits of the product characteristic
$X_{0,135\ \%}$, $X_{99,865\ \%}$
quantile of the **distribution of the product characteristic** (2.1.23)

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 The conditions of the distribution of the product characteristic must be specified, see Notes 2 and 3 of 2.1.23 distribution of the product characteristic.

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

2.1.27
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 may 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 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 This term is used only as an arbitrary, but standardized, basis for defining the process performance index, (see 2.2.3, Notes 1, 2 and 3), and process capability index (see 2.3.6, Notes 1, 2 and 3). It is sometimes incorrectly referred to as a “natural” interval.

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

NOTE 4 For a non-normal distribution, the length of the reference interval may 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 A quantile or fractile indicates a division of a distribution into equal units or fractions, e.g. percentiles.

NOTE 6 Adapted from ISO 3534-2:2006, definition 2.5.7.

2.1.28
upper fraction nonconforming of the product characteristic
p_U
fraction of the **distribution of the product characteristic** (2.1.23) that exceeds the **upper specification limit**, U (2.1.12)

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

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

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

NOTE Adapted from ISO 3534-2:2006, definition 2.5.4.

2.1.29
lower fraction nonconforming of the product characteristic
p_L
fraction of the **distribution of the product characteristic** (2.1.23) that is less than the **lower specification limit** L (2.1.13)

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

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

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

NOTE Adapted from ISO 3534-2:2006, definition 2.5.5.

2.1.30
fraction nonconforming of the product characteristic
p_t
sum of **upper fraction nonconforming of the product characteristic** (2.1.28) and **lower fraction nonconforming of the product characteristic** (2.1.29)

$$p_\mathrm{t} = p_L + p_U$$

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

$$p_\mathrm{t} = \Phi(\frac{\mu-U}{\sigma}) + \Phi(\frac{L-\mu}{\sigma})$$

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

NOTE Adapted from ISO 3534-2:2006, definition 2.5.6.

2.2 Performance — Measures and indices

2.2.1
performance conditions
precisely defined external conditions under which the process is evaluated, and where statistical stability has not been obtained

NOTE 1 Examples of external conditions include:

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

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

— data collection (duration, frequency).

NOTE 2 Performance conditions are the least restrictive allowed.

NOTE 3 It is irrelevant that the process is in state of statistical control in the period considered.

NOTE 4 See the Introduction, 0.2.

2.2.2
performance measure
statistical measure of the outcome of a **characteristic** (2.1.5) from a process which may not have been demonstrated to be in a **state of statistical control** (2.1.22)

EXAMPLE 1 The variance (ISO 3534-1:2006, 4.38) of the **distribution of the product characteristic** (2.1.23) under **performance conditions** (2.2.1).

EXAMPLE 2 The mean (ISO 3534-1:2006, 4.37) of the distribution of the product characteristic under performance conditions.

EXAMPLE 3 The **reference interval** (2.1.27) of the distribution of the product characteristic under performance conditions.

NOTE 1 The outcome is a **distribution** (2.1.23), the **class** (2.1.24) of which needs determination and its parameters estimated.

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

NOTE 3 Quantity that describes one or more properties of the **distribution of the product characteristic** (2.1.23) under **performance conditions** (2.2.1).

2.2.3
performance index
P
quantity that describes **performance measure** (2.2.2) in relation to specified specifications

EXAMPLE The process performance index, P_p, and the machine performance index, P_m.

NOTE 1 Frequently, the process performance index, P_p, is expressed as the value of the specified **specification interval** (2.1.14) divided by a measure of the length of the **reference interval** (2.1.27), namely as:

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

NOTE 2 For a normal distribution, the length of the reference interval is equal to $6S_\mathrm{t}$, where the descriptor, S_t, takes into account the variation due to random (common) causes together with any special causes that may be present. S_t is used here instead of σ_t, as the standard deviation is a statistical descriptive measure.

NOTE 3 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 Adapted from ISO 3534-2:2006, definition 2.6.2.

2.2.4
upper performance index
P_U
index describing **performance measure** (2.2.2) in relation to the **upper specification limit** U (2.1.12)

EXAMPLE The upper process performance index, $P_{\text{pk}U}$, and the upper machine performance index, $P_{\text{mk}U}$.

NOTE 1 $P_{\text{pk}U}$ is the difference between the upper specification limit, U, and the 50 % distribution quantile, $X_{50\,\%}$, divided by the difference between the upper **reference limit** (2.1.26) and the 50 % distribution quantile, $X_{50\,\%}$:

$$P_{\text{pk}U} = \frac{U - X_{50\,\%}}{X_{99{,}865\,\%} - X_{50\,\%}}$$

NOTE 2 Occasionally one sees an upper performance index defined as:

$$P_{\text{pk}U} = \frac{U - X_{50\,\%}}{3S_t}$$

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

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

$$P_{\text{pk}U} = \frac{z_{1-p_U}}{3}$$

where p_U is the **upper fraction nonconforming of the product characteristic** (2.1.28) under **performance conditions** (2.2.1) and z_{1-p_U} is the $(1 - p_U)$ quantile in the standard normal distribution.

NOTE 4 Adapted from ISO 3534-2:2006, definition 2.6.4.

2.2.5
lower performance index
P_L
index describing **performance measure** (2.2.2) in relation to the **lower specification limit**, L (2.1.13)

EXAMPLE The lower process performance index, $P_{\text{pk}L}$, and the lower machine performance index, $P_{\text{mk}L}$.

NOTE 1 $P_{\text{pk}L}$ 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** (2.1.26):

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

NOTE 2 Occasionally, one sees a lower process performance index defined as:

$$P_{\text{pk}L} = \frac{X_{50\,\%} - L}{3S_{\text{t}}}$$

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. This formula for $P_{\text{pk}L}$ can only be used when the distribution of the characteristic is normal.

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

$$P_{\text{pk}L} = \frac{z_{1-p_L}}{3}$$

where p_L is the **lower fraction nonconforming of the product characteristic** (2.1.29) under **performance conditions** (2.2.1) and z_{1-p_L} is the $(1 - p_L)$ quantile in the standard normal distribution.

NOTE 4 In ISO/TR 22514-4, the symbol for the fractile of the standardized normal distribution from $-\infty$ to α is z_α

NOTE 5 Adapted from ISO 3534-2:2006, definition 2.6.3.

2.2.6
minimum performance index
P_k
smaller of **upper performance index** (2.2.4) and **lower performance index** (2.2.5)

EXAMPLE The minimum process performance index, P_pk, and the minimum machine performance index, P_mk.

NOTE 1 The minimum process performance index can be expressed as

$$P_\text{pk} = \min\left\{P_{\text{pk}L}, P_{\text{pk}U}\right\}$$

where $P_{\text{pk}L}$ and $P_{\text{pk}U}$ are the lower and upper process performance indices, respectively.

NOTE 2 Adapted from ISO 3534-2:2006, definition 2.6.5.

NOTE 3 The term “critical” is sometimes used for this index.

NOTE 4 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) capability index.

NOTE 5 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 capability index and lower capability index but not the minimum of both. The upper and lower indices might then have different requirements.

2.2.7
position performance
statistical estimate of the two-dimensional distribution of the **product characteristic** (2.1.7) position specified under specified **performance conditions** (2.2.1)

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

NOTE 2 The position performance and its indices P_o and P_ok are used in cases where the specification is given as a positional tolerance in accordance with ISO 1101. This tolerancing method is applied e.g. to the location of axis in a hole.

2.3 Capability — Measures and indices

2.3.1
capability conditions
precisely defined external conditions under which the process is evaluated, and where statistical stability has been obtained

NOTE 1 Examples of external conditions include:

- 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 Capability conditions are the most restrictive ones among capability and performance conditions.

NOTE 3 The process must be documented to be in control.

NOTE 4 See the Introduction, 0.2.

2.3.2
capability
ability of an organization, system or process to realize a product that will fulfil the requirements for that product

[ISO 9000:2005, definition 3.1.5]

2.3.3
process capability estimate
statistical estimate of the outcome of a **characteristic** (2.1.5) from a **process** (2.1.2) which has been demonstrated to be in a **state of statistical control** (2.1.22) and which describes that ability of the process to realize a characteristic that will fulfil the requirements for that characteristic

NOTE The outcome is a **distribution** (2.1.23) the **class** (2.1.24) of which needs determination and its parameters estimated.

2.3.4
capability distribution
distribution of the product characteristic (2.1.23) under **capability conditions** (2.3.1)

2.3.5
capability measure
quantity that describes one or more properties of the **distribution of the product characteristic** (2.1.23) under **capability conditions** (2.3.1)

EXAMPLE 1 The variance (ISO 3534-1:2006, definition 4.38) of the distribution of the product characteristic under capability conditions.

EXAMPLE 2 The mean (ISO 3534-1:2006, definition 4.37) of the distribution of the product characteristic under capability conditions.

EXAMPLE 3 The **reference interval** (2.1.27) of the distribution of the product characteristic under capability conditions.

2.3.6
process capability index
C_{p}
quantity that describes the **capability** (2.3.2) in relation to given specifications

NOTE 1 Frequently, the process capability index is expressed as the value of the **specification interval** (2.1.14) divided by a measure of the length of the **reference interval** (2.1.27) for a **process in a state of statistical control** (2.1.22), namely as:

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

NOTE 2 For a normal distribution, the reference interval is equal to 6σ.

NOTE 3 For a non-normal distribution, the reference interval can be estimated using the method described in ISO/TR 22514-4.

NOTE 4 The term “potential process capability index” is often used for this index.

NOTE 5 Adapted from ISO 3534-2:2006, definition 2.7.2.

2.3.7
upper process capability index
$C_{\text{pk}U}$
index describing **process capability** (2.3.3) in relation to the **upper specification limit** (2.1.12)

NOTE 1 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** (2.1.22), namely as:

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

NOTE 2 For a normal distribution, the upper reference range is equal to $3S_{\text{w}}$, and $X_{50\ \%}$ represents both the mean and the median.

$$C_{\text{pk}U} = \frac{U - X_{50\ \%}}{3\sigma}$$

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

$$C_{\text{pk}U} = \frac{z_{1-p_U}}{3}$$

where p_U is the **upper fraction nonconforming of the product characteristic** (2.1.28) under **capability conditions** (2.3.1) and z_{1-p_U} is the $(1 - p_U)$ quantile in the standard normal distribution.

NOTE 5 Adapted from ISO 3534-2:2006, definition 2.7.4.

2.3.8
lower process capability index
$C_{\text{pk}L}$
index describing **process capability** (2.3.3) in relation to the **lower specification limit** (2.1.13)

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, L, divided by a measure of the length of the lower reference interval for a **process in a state of statistical control** (2.1.22), namely as:

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

NOTE 2 For a normal distribution, the lower reference range is equal to $3S_{\text{w}}$, and $X_{50\ \%}$ represents both the mean and the median.

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

NOTE 3 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 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** (2.1.30) under **capability conditions** (2.3.1) and z_{1-p_L} is the $(1 - p_L)$ quantile in the standard normal distribution.

NOTE 5 Adapted from ISO 3534-2:2006, definition 2.7.3.

2.3.9
minimum process capability index
C_{pk}
smaller of **upper process capability index** (2.3.7) and **lower process capability index** (2.3.8)

[ISO 3534-2:2006, definition 2.7.5]

NOTE 1 This can be expressed as $C_{\text{pk}} = \min\{C_{\text{pk}L}, C_{\text{pk}U}\}$.

NOTE 2 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 3 In the case of an envelope requirement, where specification limits are given and where the target value is different from the specification mid-point values, 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 indices might then have different requirements.

2.3.10
quality capability statistic
QCS
statistic used to quantify the **capability** (2.3.2) of a **characteristic** (2.1.5)

NOTE 1 Quality capability statistics for processes are typically either dispersion related or dispersion-and-location related.

NOTE 2 Quality capability statistics can be used in the sense of values that are observed, required, realizable, etc.

3 Symbols, abbreviated terms and subscripts

3.1 Symbols and abbreviated terms

C_{p}, C_{pk}, $C_{\text{pk}L}$, and $C_{\text{pk}U}$	process capability indices
P_{m}, P_{mk}, $P_{\text{mk}L}$, and $P_{\text{mk}U}$	machine performance indices
P_{p}, P_{pk}, $P_{\text{pk}L}$, and $P_{\text{pk}U}$	process performance indices
P_{o} and P_{ok}	position performance indices
C_{g} and C_{gk}	measurement capability 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
S_w	standard deviation representing only within-subgroup variation
PCI	abbreviation for process capability indices
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

3.2 Subscripts

g	measurement equipment
k	minimum
L	lower specification limit
m	machine
p	process
t	total
U	upper specification limit
w	within subgroup

4 Pre-conditions for application

4.1 Aspects about establishing specifications

The customers and the companies' quality management systems require products consisting of one or more 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, a condition met only when all intended functions of the product are described with unambiguous characteristics. In most cases, however, the specifications will be found to be incomplete because some functions are described imperfectly. This will result in extra uncertainty in the assessment of performance or capability.

4.2 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 behaviours and the estimated indices will depend heavily on the chosen distribution. It is therefore essential that the appropriate distribution is chosen with great care.

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

The size of the total sample from which the calculations are based should be chosen based on the type of process under investigation. The size should be large enough to provide a sound statistical basis. This will typically be larger than 100 observations.

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 may require an increase of 50 % in the amount of data required.

In special cases, e.g. measurement analysis, the sample size might be less than 100.

4.3 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.

For all studies, care must be taken not to introduce any other sources of variation than those to be studied.

4.4 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, after analysis, be put together if the customer requires only one capability index and the combined process satisfies specifications.

5 Collection of data

5.1 Traceability of data

It is important for all studies that the collected data be 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 time sequence can be plotted. This time series plot is very useful for indicating possible unexpected variations. Such occurrences should be explained, and a decision should be taken about the admissibility of such data. In connection to process analysis, a logbook would be suitable for recording all process settings and for monitoring all events during the study, such as adjustments or temperature fluctuations.

5.2 Measurement uncertainty

When reporting measurement results, it is also important to indicate the quality of these results. The always-present measurement uncertainty in measuring the characteristics of interest should be evaluated and be in reasonable relation to the actual specification. This means that the measurement equipment employed should have sufficient metrological characteristics for the measurement task.

A simplified procedure to estimate the uncertainty in geometrical measurements is to set up a measurement uncertainty budget as described in ISO 14253-2.

An often seen requirement is that the measurement uncertainty (e.g. found by a repeatability and reproducibility analysis) be not more than 30 % and preferably less than 10 % of the process variation. If the uncertainty is between 10 % and 30 %, the system may be used but a plan of improvement should be implemented. A system giving over 30 % uncertainty is usually regarded as unsatisfactory and should not be used in its current condition as it is likely to disguise the process variation.

Requirements for minimum values for measurement equipment performance, so-called C_{g} and C_{gk} values, can complement the requirements mentioned above.[1)]

5.3 Data recording

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

5.4 Outliers

Outliers are a subset of observations in a set of data that appears to be inconsistent with the remainder of that dataset. An outlier may originate from a different population or be the result of incorrect recording or gross measurement error. Graphical plots such as stem and leaf plots, dot plots and box plots, or statistical tests can be used for detecting outliers.

If it is suspected that such values do not belong to the same basic population as the other collected values, 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 has affected the result or a recording error has occurred.

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

6 Performance, capability and process analysis

6.1 Six different types of performance and capability

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

1) machine performance;

2) process performance;

3) process capability;

4) performance of the measuring equipment;

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1) Further information about the methods that can be used to calculate measurement performance indices can be found in different guidelines, e.g. FORD Motor Co. EU 1880A, *Measurement System and Equipment Capability*.

5) position performance – performance of multivariate characteristics;

6) attribute data performance.

Sometimes, it is necessary to calculate special capability indices; these are covered in 6.7.

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, the a basis of the calculation of the standard deviation.

6.2 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).

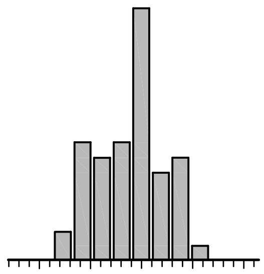


Figure 1 — Histogram

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

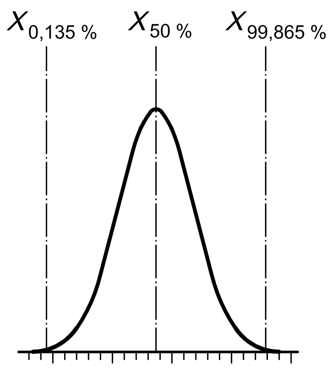


Figure 2 — Distribution model

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

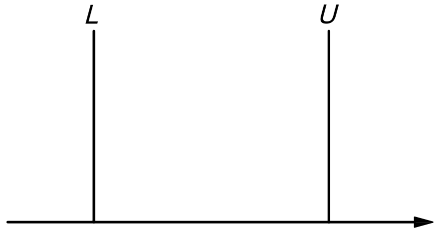


Figure 3 — Specification limits

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

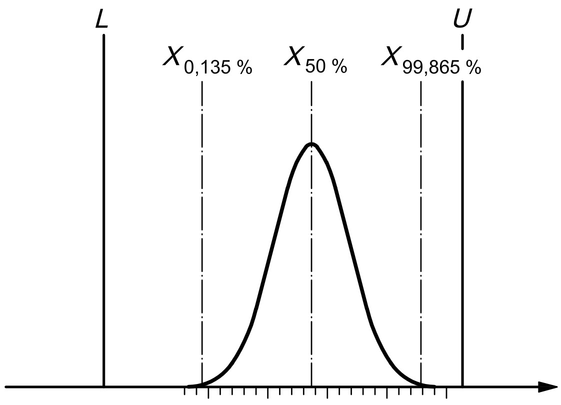


Figure 4 — Comparison

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

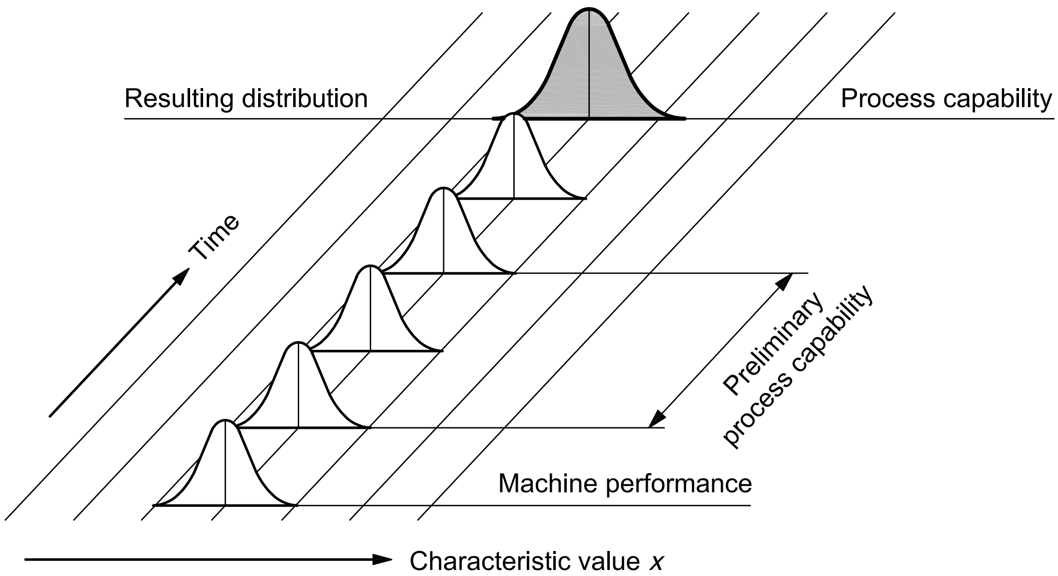


Figure 5 — Process in control and calculation of capability

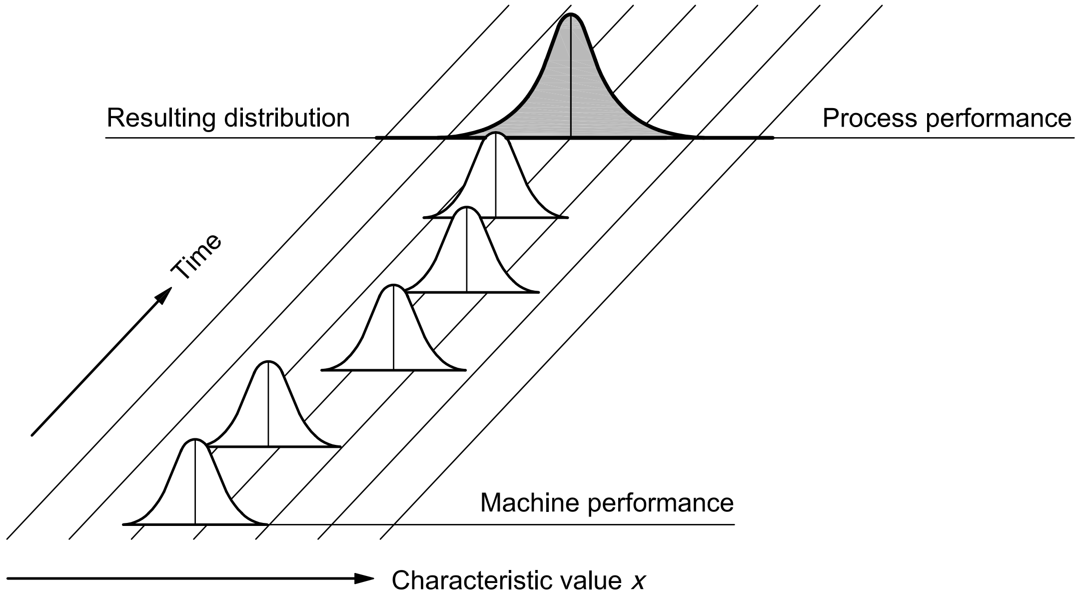


Figure 6 — Process out of control and calculation of performance

Process capability analyses, 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 critical index is calculated. The calculations can be treated in the same manner as double-sided specification limits.

6.3 Machine performance

An analysis of the production equipment, also called "machine performance", is carried out to get an early evaluation of a process performance, seen as a "snapshot" 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 machine 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.

6.4 Process performance and process capability

Process performance and process capability, which are similar analyses, deal with examining 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 process capability describe the distribution of the current characteristic of a process over time. These enable a person to evaluate the ability of the process to produce results in accordance with the given specifications or tolerances.

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

In certain cases, this initial study can supplant the machine performance analysis used up until now. Compared to this analysis, the initial process examination 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 is possible to describe its dispersion through the use of six standard deviations that 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 (theoretically) 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.

6.5 Position performance

The traditional methods used for calculation of performance are based on one-dimensional distributions. In the 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 datums, the results will form a two-dimensional distribution, which is then 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 the following.

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

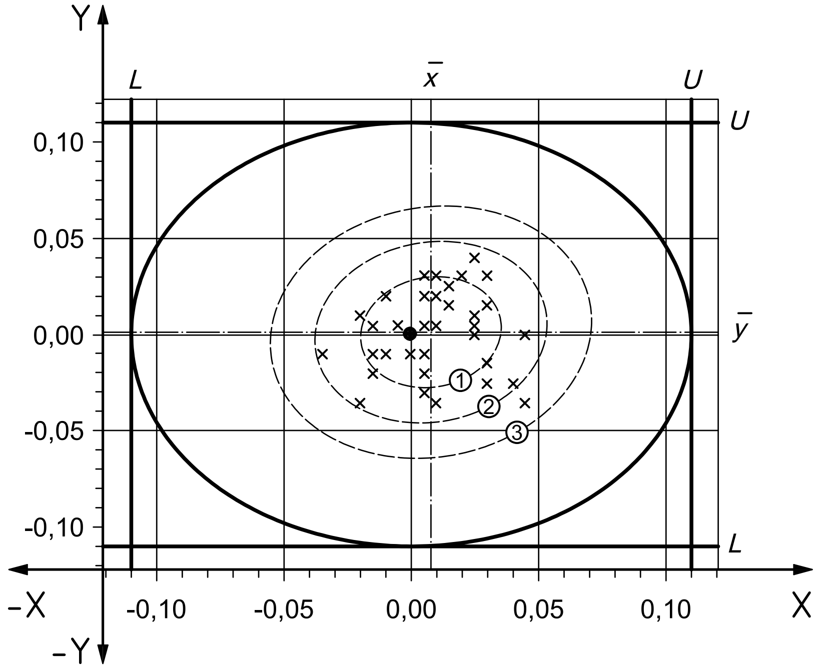
— Usually, the position tolerances are defined as a circular tolerance zone and not a rectangular one.

— As a consequence, special performance indices are used; these are called P_{o} and P_{ok} and correspond to P_{p} and P_{pk}.

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 investigated with reference to stability.

A scatter diagram (Figure 7) is used to make decisions about the observations if all measurements are inside the tolerance zone. The distribution of the datasets is to be investigated for segmentation or non-random points.



Key

X *x* position

Y *y* position

Figure 7 — Tolerance zone — Position tolerances

The same principles can be used in cases where more than two dimensions influence the characteristic under investigation.

6.6 Measurement system analysis

Measurement system analysis is a set of methods used to evaluate the uncertainty of a measurement process under the range of conditions in which the process operates. The measurement process is analysed using the same methods as all other processes.

Understanding that variation connected to the measurements always appears and obtaining the information on the factors which contribute to this variation should be fundamental steps in all process analysis. When variations in the measurement system with respect to part variation are large, it is necessary to reduce the number of uncertainty components influencing the measurement system before analysing the influence of the components on the process.

Measurement system studies are often divided into three different test types:

— a type 1 test for determining bias;

— a type 2 test for determining repeatability and intermediate precision, often called “reproducibility”;

— a particular type 2 test, called “type 3”, for determining repeatability where no operator influence is present.

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.

6.7 Performance and capability indices (PCIs)

The different types of performance and capability can be expressed by means of an index linking the current process with the specification interval. 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.

New indices such as P_p and P_{pk} or P_m and P_{mk} have been developed to improve understanding of long-term and short-term variation patterns and variations around the intentional target value of the process.

As a consequence of the varied ways in which PCIs are used, new 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 the formula:

$$C_{pm} = \frac{d}{3\sqrt{\sigma + (\mu - T)}} = \frac{d}{3\sqrt{E\left[(X - T)\right]}}$$

where

T is a "target value";

d is half the specification;

$E[.]$ 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 the fraction of nonconforming units or the frequency of nonconforming units.

The formula is then

$$C_{pk} = \frac{z_{1-p}}{3}$$

where z_{1-p} is the $(1 - p)$ quantile in the standard normal distribution.

7 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 product out of specification.

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 analyses may be used for evaluating the ability of a machine to produce or function in compliance with the company's requirements, or for purchase and acceptability of a repaired condition.

High values of process performance and capability indices (e.g. P_p or $C_p > 2$) are used for judging the acceptability of individual components or subassemblies 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. They do so by making sure that the variations for the individual characteristics are in accordance with the permissible specifications for the entire product. However, in the cases where narrow specifications are necessary, the makers of the individual components must comply with required level and process capability.

8 Benefits of use

Process capability analysis provides the opportunity to obtain both an evaluation of the natural variation pattern for a process and an estimation of the amount of nonconforming units that can be expected. This enables a company to estimate the costs in connection with nonconforming products and can guide the company in deciding which changes to make in order 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 purchase agreements for components in which the customer and supplier can specify quality requirements in the form of minimum requirements for capability indices.

9 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 when the distribution of the process deviates considerably from the normal distribution if this factor is not taken into consideration during the calculation.

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

If the calculations are based on an estimation of the percentage of the products that are non-conforming, it is usually a precondition that normal distribution be used as a model. If this precondition is not fulfilled in practice, this estimation shall be treated with caution, especially for processes with high capability indices.

Furthermore, normal distribution is a precondition for estimations of the proportion of nonconforming parts. If estimations of the proportion of nonconforming part need to be made other distributions, they should be estimated based on analysis methods that depend on the current distribution.

Bibliography

[1] ISO 1101:2004, *Geometrical Product Specifications (GPS) — Geometrical tolerancing — Tolerances of form, orientation, location and run-out*

[2] ISO 3534-1:2006, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

[3] ISO 3534-2:2006, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

[4] ISO 5725 (all parts), *Accuracy (trueness and precision) of measurement methods and results*

[5] ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

[6] ISO 14253-2, *Geometrical Product Specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Guide to the estimation of uncertainty in GPS measurement, in calibration of measuring equipment and in product verification*

[7] ISO 21747, *Statistical methods — Process performance and capability statistics for measured quality characteristics*

[8] ISO 22514-3, *Statistical methods in process management — Capability and performance — Part 3: Machine performance studies for measured data on discrete parts*

[9] ISO/TR 22514-4, *Statistical methods in process management — Capability and performance — Part 4: Process capability estimates and performance measures*

[10] ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

[11] QS 9000, *Measurement Systems Analysis Third Edition*, Automotive Industry Action Group (AIAG)

[12] QS 9000, *Statistical Process Control (SPC)*, Automotive Industry Action Group (AIAG), second edition

[13] *Bosch reference guideline, volume 10 — Measurement and Gage Process Capability*

[14] FORD Motor Co. EU 1880A, *Measurement System and Equipment Capability*

[15] GM Powertrain, SP-Q-EMS 3.4, *Measurement system analysis*

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