
**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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Foreword

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

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

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

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.

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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 ,

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

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 ,

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

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)

$$p_t = p_L + p_U$$

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.

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:

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

NOTE 2 For a normal distribution, the length of the reference interval is equal to $6S_t$, 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_{pkU} , and the upper machine performance index, P_{mkU} .

NOTE 1 P_{pkU} 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, $X_{50\%}$:

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

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

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

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:

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

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_{pkL} , and the lower machine performance index, P_{mkL} .

NOTE 1 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** (2.1.26):

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

NOTE 2 Occasionally, one sees a lower process 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 . This formula for P_{pkL} 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:

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

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

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

where P_{pkL} and P_{pkU} 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:

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

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_{pkU}

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:

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

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

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

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:

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

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_{pkL}

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:

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

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

$$C_{pkL} = \frac{X_{50\%} - L}{3\sigma}$$

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:

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

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

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_{pkL} , and C_{pkU}	process capability indices
P_m , P_{mk} , P_{mkL} , and P_{mkU}	machine performance indices
P_p , P_{pk} , P_{pkL} , and P_{pkU}	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;

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).

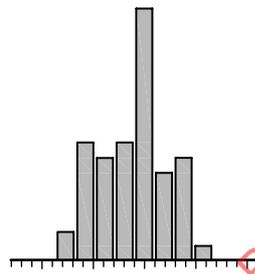


Figure 1 — Histogram

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

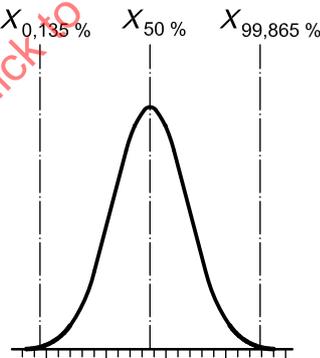


Figure 2 — Distribution model

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

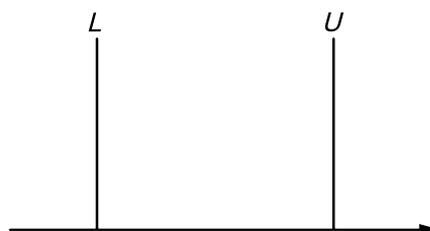


Figure 3 — Specification limits

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

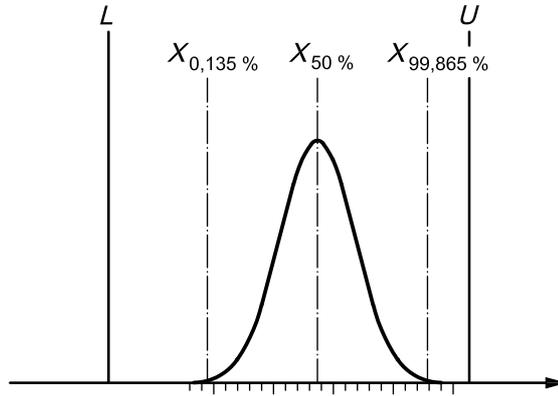


Figure 4 — Comparison

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

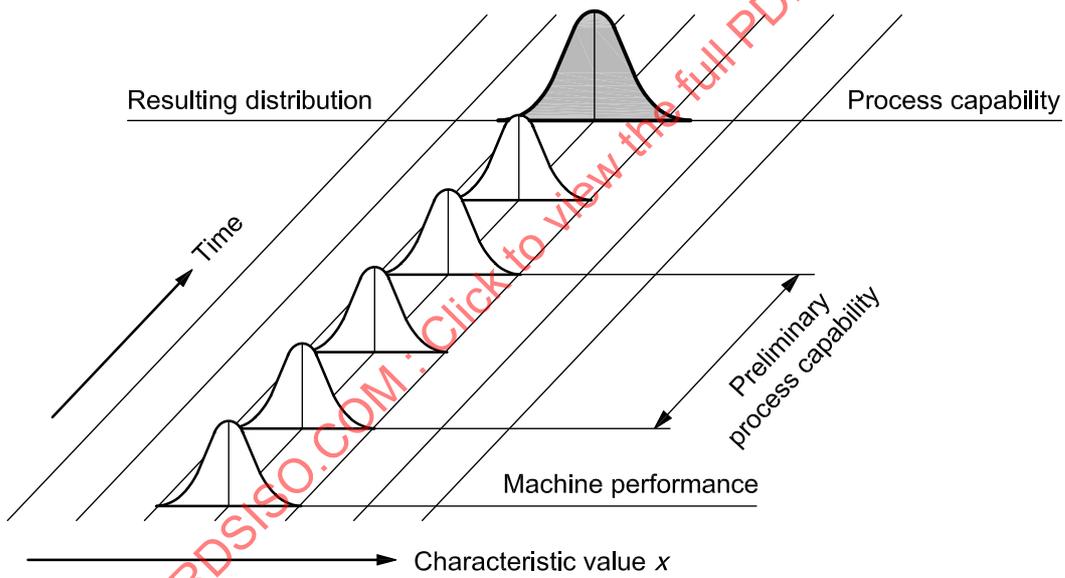


Figure 5 — Process in control and calculation of capability

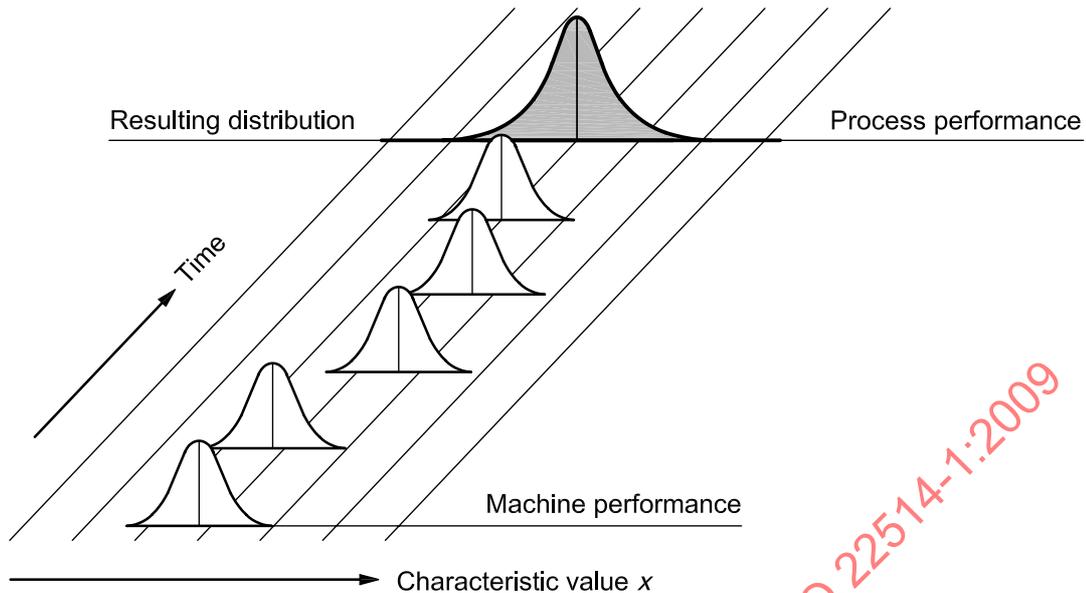


Figure 6 — Process out of control and calculation of performance

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.