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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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Foreword

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

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

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

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

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

— *Part 1: General principles and concepts*

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

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

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

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

— *Part 7: Capability of measurement processes*

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

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

Introduction

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

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

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

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

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

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

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

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

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

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

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

Statistical methods in process management — Capability and performance —

Part 1: General principles and concepts

1 Scope

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

This part of ISO 22514 is applicable to the following:

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

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

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

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

2 Normative references

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

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

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

3 Terms and definitions

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

3.1 Basic terms

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

[SOURCE: ISO 9000:2005, 3.1.2]

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

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

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

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

3.1.3
system
set of interrelated or interacting elements

[SOURCE: ISO 9000:2005, 3.2.1]

3.1.4
product
result of a process

Note 1 to entry: Four generic product categories are

— services (e.g. transport),

— software (e.g. computer program),

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

— processed materials (e.g. lubricant).

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

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

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

3.1.5
characteristic
distinguishing feature (of an item)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.1.10
specification
document stating *requirements* (3.1.1)

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

[SOURCE: ISO 9000:2005, 3.7.3]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

— the measurement;

— the time interval over which the sampling takes place;

— the frequency of sampling.

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

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

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

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

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

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

EXAMPLE 3 The unimodal continuous distributions.

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

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

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

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

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

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

3.1.25
reference limits of the product characteristic
$X_{0,135\ \%}$, $X_{99,865\ \%}$
quantile of the *distribution of the product characteristic* (3.1.22)

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

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

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

3.1.26
reference interval of a product characteristic
interval bounded by the 99,865 % distribution quantile, $X_{99,865\ \%}$, and the 0,135 % distribution quantile, $X_{0,135\ \%}$

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

EXAMPLE 2 For a non-normal distribution, the reference interval can be estimated by means of appropriate probability papers (e.g. log-normal) or from the sample kurtosis and sample skewness using the methods described in ISO/TR 22514-4.

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

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

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

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

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

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

3.1.27
upper fraction nonconforming of the product characteristic
p_U
fraction of the *distribution of the product characteristic* (3.1.22) that exceeds the *upper specification limitU* (3.1.12)

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

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

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

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