INTERNATIONAL STANDARD

ISO 22514-1

First edition
2009-10-01

Statistical methods in process management — Capability and performance —

Part 1:
General principles and concepts

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

Partie 1: Principes et concepts généraux

Reference number
ISO 22514-1:2009(E)

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Published in Switzerland

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Foreword

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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.

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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.