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Statistical methods in process management — Capability and performance —

Part 4: Process capability estimates and performance measures

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

Partie 4: Estimations de l'aptitude de processus et mesures de performance

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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 Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 4, *Applications of statistical methods in process management*.

This first edition of ISO 22514-4 cancels and replaces ISO/TR 22514-4:2007, 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*

— *Part 5: Process capability estimates and performance for attributive characteristics*

— *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*

Introduction

Many organizations have embarked upon a continuous improvement strategy. To comply with such a strategy, any organization will need to evaluate the capability and performance of its key processes. The methods described in this part of ISO 22514 are intended to assist any management in this respect. These evaluations need to be constantly reviewed by the management so that actions compatible with continuous improvement can be taken when required.

The content of this part of ISO 22514 has been subject to large shifts of opinion during recent times. The most fundamental shift has been to philosophically separate what is named in this part of ISO 22514 as capability conditions from performance conditions, the primary difference being whether statistical stability has been obtained (capability) or not (performance). This naturally leads onto the two sets of indices that are to be found in their relevant clauses. It has become necessary to draw a firm distinction between these since it has been observed in the industry that companies have been deceived about their true capability position due to inappropriate indices being calculated and published.

The progression of this part of ISO 22514 is from the general condition to the specific and this approach leads to general formulae being presented before their more usual, but specific manifestations.

There exist numerous references that describe the importance of understanding the processes at work within any organization, be it a manufacturing process or an information handling process. As organizations compete for sales with each other, it has become increasingly apparent that it is not only the price paid for a product or service that matters so much, but also what costs will be incurred by the purchaser from using such a product or service. The objective for any supplier is to continually reduce variability and not to just satisfy specification.

Continual improvement leads to reductions in the costs of failure and assists in the drive for survival in an increasingly more competitive world. There will also be savings in appraisal costs for as variation is reduced, the need to inspect product might disappear or the frequency of sampling might be reduced.

Process capability and performance evaluations are necessary to enable organizations to assess the capability and performance of their suppliers. Those organizations will find the indices contained within this part of ISO 22514 useful in this endeavour.

Quantifying the variation present within a process enables judgement of its suitability and ability to meet some given requirement. The following paragraphs and clauses provide an outline of the philosophy required to be understood to determine the capability or performance of any process.

All processes will be subject to certain inherent variability. This part of ISO 22514 does not attempt to explain what is meant by inherent variation, why it exists, where it comes from nor how it affects a process. This part of ISO 22514 starts from the premise that it exists and is stable.

Process owners should endeavour to understand the sources of variation in their processes. Methods such as flowcharting the process and identifying the inputs and outputs from a process assist in identification of these variations together with the appropriate use of cause and effect (fishbone) diagrams.

It is important for the user of this part of ISO 22514 to appreciate that variations exist that will be of a short-term nature, as well as those that will be of a long-term nature and that capability determinations using only the short-term variation might be greatly different to those which have used the long-term variability.

When considering short-term variation, a study that uses only the shortest-term variation, sometimes known as a machine study and described in ISO 22514-3, might be carried out. The method required to carry out such a study will be outside the scope of this part of ISO 22514; however, it should be noted that such studies are important and useful.

It should be noted that where the capability indices given in this part of ISO 22514 are computed, they only form point estimates of their true values. It is therefore recommended that, wherever possible, the indices' confidence intervals are computed and reported. This part of ISO 22514 describes methods by which these can be computed.

Statistical methods in process management — Capability and performance —

Part 4: Process capability estimates and performance measures

1 Scope

This part of ISO 22514 describes process capability and performance measures that are commonly used.

2 Symbols and abbreviated terms

2.1 Symbols

In addition to the symbols listed below, some symbols are defined where they are used within the text.

α	fraction or proportion
β	shape parameter in a Weibull distribution
β_2	coefficient of kurtosis
c_4	constant based on subgroup size, n (see ISO 7870-2)
C_{p}	process capability index
C_{pk}	minimum process capability index
C_{pk_L}	lower process capability index
C_{pk_U}	upper process capability index
C_{pm}	alternative process capability index
C_{R}	process capability fraction (PCF)
d_2	constant based on subgroup size, n (see ISO 7870-2)
e	Eulers's number (approximately 2,718), mathematical constant
Φ	distribution function of the standard normal distribution
γ	location parameter in a Weibull distribution
γ_1	coefficient of skewness
m	number of subgroups
K_{l}, K_{u}	multipliers for estimating the confidence limits for a process capability index
L	lower specification limit

$P_{0,135\,\%}$	lower 0,135 % percentile
μ	location of the process; population mean value
N	total sample size
n	number of values or subgroup size (for a control chart)
$P_{\alpha\,\%}$	α percentile
p_L	lower fraction nonconforming
P_{p}	process performance index
P_{pk}	minimum process performance index
P_{pk_L}	lower process performance index
P_{pk_U}	upper process performance index
p_{t}	total fraction nonconforming
p_U	upper fraction nonconforming
$P_{99,865\,\%}$	upper 99,865 % percentile
π	geometric constant
Q_{k}	process variation index
θ	parameter required for the Rayleigh distribution
$\bar{R}$	average subgroup range
S	standard deviation, sample statistic
S_{t}	standard deviation, with the subscript 't' indicating total
$\bar{S}$	average sample standard deviation
S_j	observed sample standard deviation of the j^{th} subgroup
σ	standard deviation, population
$\hat{\sigma}_{\mathrm{t}}$	estimated standard deviation, total
T	target value
U	upper specification limit
$X_{\alpha\,\%}$	α % percentile
X_i	i^{th} value in a sample
$\bar{X}$	arithmetic mean value, sample
$\bar{\bar{X}}$	arithmetic mean, of a number of sample arithmetic means

ξ scale parameter in a Weibull distribution

Y_1, Y_2 values read from a graph

z_α quantile of the standardized normal distribution from $-\infty$ to α

2.2 Abbreviated terms

MSE mean square error

PCF process capability fraction

PCI process capability index

3 Basic concepts used for process capability and performance

3.1 General

The measures referred to in 4.2 to 4.6 refer only to measured data. They are unsuitable for count or attributes data and information concerning the expression of measures for such data will be found in ISO 22514-5.

3.2 Location

The characterization of location is the mean, μ, or the median, $X_{50\ \%}$. Although for symmetric distributions the mean is the most natural selection, with non-symmetric distributions the median is the preferred selection.

3.3 Dispersion

3.3.1 Inherent dispersion

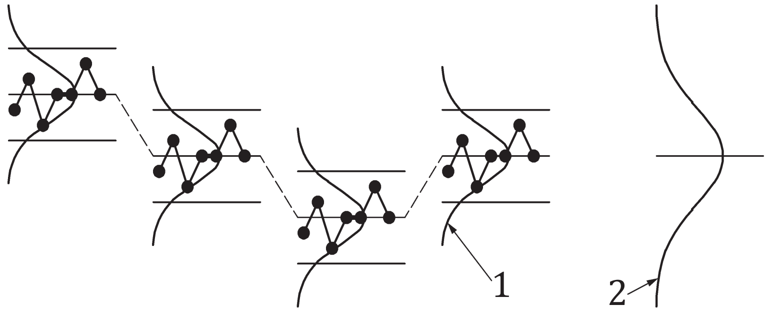
The preferred selection to quantify inherent dispersion is the standard deviation σ. This is often estimated from the mean range value, $\overline{R}$, taken from a range (R) chart or $\overline{S}$ from a standard deviation (S) chart when the process is stable and in a state of statistical control as indicated in 4.1. Methods used to estimate the process standard deviation are given in Annex A.

3.3.2 Total dispersion

It is necessary to differentiate between a standard deviation that measures only short-term variation and that which measures longer-term variation. The total dispersion is the dispersion that is inherent in the long-term variation. Methods of calculating the standard deviations representing these variations are given in Annex A. Very often, when data are gathered over a long period of time, the standard deviation is made larger by the effects of fluctuations in the process, σ_t.

3.3.3 Short-term dispersion

A process may have a short-term dispersion effect that is a part of the total dispersion. Figure 1 illustrates this. The short-term dispersion includes the inherent dispersion and can also include some short-term instability effect.



Key

1 short-term dispersion

2 overall dispersion

Figure 1 — Short-term dispersion and its relationship to the total dispersion

The total dispersion can be any shape and not necessarily normal as illustrated here.

3.4 Mean square error (MSE)

When minimizing variation, some practitioners use the mean square error as the preferred measure. It is compatible with the methods used in off-line quality techniques.

3.5 Reference limits

The lower and upper reference limits are respectively defined as the 0,135 % and the 99,865 % percentiles of the distribution that describe the output of the process characteristic. They are written as $X_{0,135\ 5\ \%}$ and $X_{99,865\ \%}$.

3.6 Reference interval (also known as process spread)

The reference interval is the interval between the upper and the lower reference limits. The reference interval includes 99,73 % of the individuals in the population from a process that is in a state of statistical control.

4 Capability

4.1 General

Process capability is a measure of inherent process variability. The variability that is inherent in a process when operating in a state of statistical control is known as the inherent process variability. It represents the variation that remains after all known removable *assignable causes* have been eliminated. If the process is monitored using a control chart, the control chart will show an *in control* state.

Capability is often regarded as being related to the proportion of output that will occur within the product specification tolerances. Since a process in statistical control should be described by a predictable distribution, the proportion of out-of-specification outputs can be estimated. As long as the process remains in statistical control, it will continue to produce the same proportion out-of-specification.

Management actions to reduce the variation from *random causes* are required to improve the process' ability to consistently meet the specification requirements.

In short, the following will be necessary:

— define the process and its operating conditions. If there is a change to those conditions, it will necessitate a new process study;

— assess the short-term and long-term measurement variabilities as percentages of the total variability and minimize them;

— preserve the process stability and maintain its statistical control;

— estimate the remaining inherent variation;

— select an appropriate measure of capability.

The following are the conditions that will apply for capability:

— all technical conditions, e.g. temperature and humidity, shall be clearly stated;

— the uncertainty of the measurement system shall be estimated and judged appropriate (see ISO 22514-7);

— multi-factor, multi-level aspects of the process should be allowed;

— the duration over which the data has been gathered shall be recorded;

— the frequency of sampling and sample size shall be specified and the start and finish dates of data collection;

— the process shall be controlled with a control chart;

— the process shall be in a state of statistical control.

It is necessary to check the control chart from which the data have been taken for statistical control and to examine a histogram of the data with any specification limits superimposed upon it. A valid test for normality should be used in assessing the data such as the Anderson-Darling test[15] or any other suitable method. This test is powerful in detecting departures from normality in the tails of the distribution and is suggested here as this is the region of interest for capability and performance indices. Additionally, a normal probability plot can be used to look for the following:

a) verification of normality;

b) outliers;

c) data beyond any specification limit;

d) whether the data are well inside the specification limit(s);

e) evidence of asymmetry (i.e. skewness);

f) evidence of “long tails” in the data (i.e. kurtosis);

g) off-centre distribution;

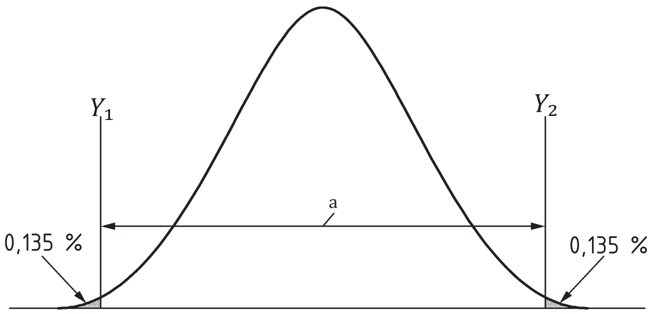
h) any unusual patterns.

Explanations of anomalies should be sought in relation to these mentioned features and appropriate action taken on the data prior to the calculation of any measure. It would be inappropriate to just discard data that do not appear to fit any preconceived pattern. Such departures might be very revealing about the process’ behaviour and should be thoroughly investigated.

4.2 Process capability

4.2.1 Normal distribution

Process capability is defined as a statistical measure of inherent process variability for a given characteristic. The conventional method is to take the reference interval that describes 99,73 % of the individual values from a process that is in a state of statistical control with the 0,135 % remaining on each side. This applies even if the population of individual values is not normally distributed. For a normal distribution, this process interval is represented by six standard deviations (see Figure 2).



Key

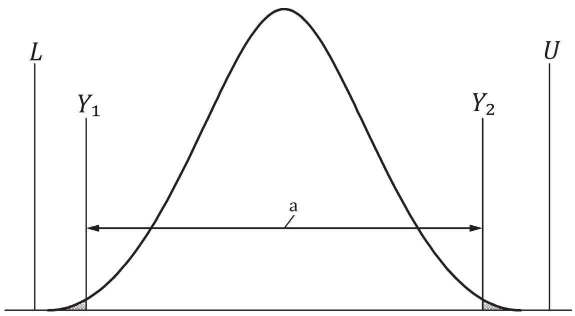
a Reference interval 99,73 %.

Figure 2 — Normal distribution

On occasions, process capability is taken to account for extra sources of variation such as a multiple stream process, for example, output from a multi-cavity injection moulding press. Under these circumstances, the distribution of all values from all cavities could still be approximately normal, but with extra variability so that the standard deviation shall represent the total variation, σ_t. It is important to state how the standard deviation has been calculated, as well as the sampling strategy used, sample size and the quantity and variability of output produced between samples as these will, in practice, affect the validity of the capability assessment (see ISO 22514-2 for further information).

Data will usually be taken from a control chart. If the control chart had relaxed control lines or modified control lines, the real process standard deviation will be larger than that estimated from data taken from a control chart with standard control lines. Issues such as these and those given earlier will influence the reference interval and it is important that they are stated in any capability assessment.

“Capable” processes will be those whose reference intervals are less than any specified tolerance by a particular amount. An example of this is shown in Figure 3.



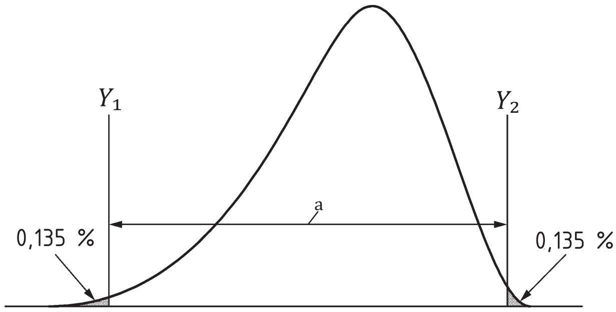
Key

a Reference interval 99,73 %.

Figure 3 — Normal distribution with specification limits

4.2.2 Non-normal distribution

If the distribution of individual values does not form a normal distribution, but is skewed, then the reference interval may appear as in Figure 4. The values Y_1 and Y_2, which will usually be the 0,135 % and the 99,865 % percentiles, can be estimated using a suitable probability paper (see Figure 5 for an example using an extreme value distribution probability paper) or by the use of suitable computer software. They can also be computed using tabular values (see Annex B) or using the particular probability function as suggested in Annex C.



Key

a Reference interval 99,73 %.

Figure 4 — Non-normal distribution

4.3 Process location

Even if a process can be deemed capable by the above definition (in 4.2.1), if the process distribution has been poorly centred relative to the specification limits, out-of-specification items might be produced. For this reason, it is necessary to assess the location in addition to the process interval.

