Process Capability Analysis

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ISO 9000 is a family of standards related to quality management systems and designed to help organisations ensure that they meet the needs of customers and other stakeholders.


In Italy, 13'066 certificates had been issued. Italy is the European leader and among the first in the world for number of ISO 9001 certificates. (ISO Survey 2009)
It can be defined:

- **quality**: the degree to which a set of inherent characteristics fulfils requirement;
- **management**: coordinated activities to direct and control;
- **quality management system**: to direct and control an organization with regard to quality.

**Monitoring and Measurement of Product**: The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met.


**Process capability**: ability of the process to realize a characteristic that will fulfill the requirements for that characteristic. (ISO 25517-4)

**Specification**: an explicit set of requirements to be satisfied by a material, product or service. Specifications are mandatory if adopted by a business contract. Specifications must be respected to avoid sanctions.
The capability analysis is carried out in the following steps:

1. select the process to be analysed and collection of data;
2. identify specific limits according to which capability analysis will be evaluated;
3. verify the process is under statistical control;
4. analyse data distribution;
5. estimate capability indices.

For the capability analysis to be performed the process needs to be under statistical control.

Specification limits can be: the Upper Specification Limit (USL), the Lower Specification Limit (LSL) and eventually a target value. Specification limits are usually provided from outside (production requirements, market requirements). Specifications can either be two-sided (when USL and LSL are both specified) or one-sided (either USL or LSL is specified).
To sum up, a process is capable when:

★ it is under statistical control;
★ it has a low variability rate compared to the range of specified limits;
★ process distribution is possibly centered on specification limits (centering).

★ If a process respects specifications and is under statistical control it can be foreseen that specifications will not change in the future. If a process respects specifications but is not under statistical control, specification could change in the future.

★ Process variability indicates the spread within which 99.73% of the process distribution is contained. A normal distribution has a $6\sigma$ width range centered on the mean ($\mu \pm 3\sigma$).

The two distributions have same mean and specification limits. However, dispersion in the distribution on the right is higher. Therefore, the process capability of the distribution on the right is lower than the process capability of the distribution on the left.
The two distributions have the same characteristics as far as shape, position and dispersion are concerned. The limit spread is the same. The process on the right is not centered with respect to its specification limits. Therefore process capability on the right will be lower.

The process is both under statistical control and capable.

This process will produce conforming products as long as it remains in statistical control.
The process is under statistical control but it is not capable.

If the specifications are realistic, an effort must be immediately made to improve the process (i.e. reduce variation) to the point where it is capable of producing consistently within specifications.

The process is out of control but it is capable.

The process must be monitored: it cannot be expected it will respect specifics in the future.
The process is both out of control and it is not capable.

The process must be adjusted to be under control, then the capability analysis must be performed again.
★ The **CP index** is the most widely used capacity index.

★ It can be calculated only when **USL and LSL are both specified**.

★ Its theoretical value is:

\[ CP = \frac{USL - LSL}{6\sigma} \]

if data is normally distributed.

★ CP can be seen as the ratio between the “acceptable” variability spread and the process variability spread.

★ In practical terms, “real” \( \sigma \) values are never known and need to be **estimated** according to one of the following estimation procedures.

★ Another capacity index is Parts per Million (**PPM**). This index indicates the ratio between the number of pieces exceeding the specification limits and a million produced units.

★ For example, the following CP values produce the PPM shown below:

★ \( CP = 1 \rightarrow PPM = 2700 \);

★ \( CP = 1.33 \rightarrow PPM = 64 \);

★ \( CP = 1.5 \rightarrow PPM = 7 \).

★ PPM can be estimated based on empirical data (i.e. the number of exceeding elements over one million) or with the cumulative distribution function of the theoretical distribution.
**Case 1: CP > 1.33**

A fairly capable process

This process should produce less than 64 non-conforming PPM.

This process will produce conforming products as long as it remains in statistical control. The process owner can claim that the customer should experience least difficulty and greater reliability with this product. This should translate into higher profits.

This process is contained within four standard deviations of the process specifications.

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**Case 2: 1 < CP < 1.33**

A barely capable process

This process will produce greater than 64 PPM but less than 2700 non-conforming PPM.

This process has a spread just about equal to specification width. It should be noted that if the process mean moves to the left or the right, a significant portion of product will start falling outside one of the specification limits. This process must be closely monitored.

This process is contained within three to four standard deviations of the process specifications.
**Case 3: CP < 1**

A not capable process

This process will produce more than 2700 non-conforming PPM.

It is impossible for the current process to meet specifications even when it is in statistical control. If the specifications are realistic, an effort must be immediately made to improve the process (i.e. reduce variation) to the point where it is capable of producing consistently within specifications.

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**Case 4: CP < 1**

A not capable process

This process will also produce more than 2700 non-conforming PPM.

The variability and specification width is assumed to be the same as in case 3, but the process average is off-center. In such cases, adjustment is required to move the process mean back to target. If no action is taken, a substantial portion of the output will fall outside the specification limit even though the process might be in statistical control.
The table presents some recommended guidelines for minimum values of CP and PPM (source: AIAG):

<table>
<thead>
<tr>
<th>Specifications</th>
<th>One-Sided CP</th>
<th>One-Sided PPM</th>
<th>Two-Sided CP</th>
<th>Two-Sided PPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Existing processes</td>
<td>1.25</td>
<td>88.42</td>
<td>1.33</td>
<td>66.07</td>
</tr>
<tr>
<td>New processes</td>
<td>1.45</td>
<td>6.81</td>
<td>1.50</td>
<td>6.80</td>
</tr>
<tr>
<td>Critical existing process</td>
<td>1.45</td>
<td>6.81</td>
<td>1.50</td>
<td>6.80</td>
</tr>
<tr>
<td>Critical new process</td>
<td>1.60</td>
<td>0.79</td>
<td>1.67</td>
<td>0.54</td>
</tr>
</tbody>
</table>

The Figure below shows control charts for a process.
The capability analysis performed on firsts twenty batches returns a CP greater than 1.33.

The capability analysis performed on lasts twenty batches, where the process goes out-of-control, returns a CP less than 1.33.
The CP alone does not provide thorough information about the correspondence of the process to the production specifications. The CP index is exclusively based on the ratio between the width of the tolerance spread and the width of the variability spread. It is not based on process centering, i.e. it does not take into consideration the central tendency of the process with regards to specification limits. In theory, processes with very good CP values can be obtained but they would be positioned beyond specification limits.

The CPK index is used to take into consideration the process centering. It is defined as:

\[
CPK = \min(CPL, CPU)
\]

CPL and CPU estimate the coherence of the process with regards to the Lower Specification Limit (CPL) and the Upper Specification Limit (CPU) respectively. In the event of a normal distribution formulas are as follows:

\[
CPL = \frac{\mu - LSL}{3\sigma} \quad CPU = \frac{USL - \mu}{3\sigma}
\]

CP and CPK indices are the same if the process is centered, i.e. if:

\[
\mu = \frac{USL - LSL}{2}
\]

CP index is defined only if USL and LSL are simultaneously defined. CPK, being the minimum between CPL and CPU, is always defined.

CP index calculates the tolerance with respect to two-sided specifications. CPL, CPU and CPK indices estimate the tolerance of one-sided specifications.
The calculation of the CPM index is possible if and only if a target value $T$, i.e. an ideal value of the production process, is specified. The $T$ value does not necessarily need to be equal to the midpoint between the USL and LSL.

If both USL and LSL are specified, the CPM index is calculated with:

$$CPM = \frac{\min(T - LSL, USL - T)}{3 \times \sqrt{\frac{\sum_{j=1}^{k} \sum_{i=1}^{n_j} (x_{ij} - T)^2}{\sum_{j=1}^{k} n_j - 1}}}$$

If only CPL or CPU is specified, the numerator of the above-mentioned formula becomes $T - LSL$ and $USL - T$ respectively.
The values of the $\mu$ and $\sigma$ parameters are usually unknown and need to be estimated with sample data.

In the event of normal distributed data, the variance process can be estimated with:

- The overall variance (overall capability). CP, CPK, CPU and CPL capability indices computed using overall capability are also known as PP, PPL, PPU and PPL performance indices.
- The within variance (potential capability). The within variance is an estimation of variability common causes.

Within standard deviation can be estimated using the pooled standard deviation:

$$ s_W = \frac{s}{c_4} = \sqrt{\frac{\sum_{j=1}^{k} \sum_{i=1}^{n_j} (x_{ij} - \bar{x}_k)^2}{\sum_{j=1}^{k} (n_k - 1)} c_4} $$

The above formula numerator ($s$) is not an unbiased estimator of $\sigma$. Can be shown that if the underlying distribution is normal, then $s$ estimates $c_4 s$ where $c_4$ is a constant that depends on a sample size ($n$) and group numbers ($k$). $\frac{s}{c_4}$ is so an unbiased estimator of $\sigma$.

CP and CPK capability indices are estimated from sample data. Confidence intervals can be found.
Which standard deviation to use - overall or within?

Although both indices show similar information, they have slightly different uses.

CPK$_{\sigma_{\text{overall}}}$ attempts to answer the question “does my current production sample meet specification?”

On the other hand, CPK$_{\sigma_{\text{within}}}$ attempts to answer the question “does my process in the long run meet specification?” Process capability can only be evaluated after the process is brought into statistical control. The reason is simple: CPK$_{\sigma_{\text{within}}}$ is a prediction, and only stable processes can be predicted.

The difference between $\sigma_{\text{overall}}$ and $\sigma_{\text{between}}$ represents the variability due to special causes.

The difference between PPM$_{\sigma_{\text{overall}}}$ and PPM$_{\sigma_{\text{within}}}$ represents the loss of quality due to lack of statistical control.

BrakeCap data frame contains shoes soles hardness measurements (Rockwell scale). 50 batches of 5 elements each have been sampled. The LSL is 39, the USL is 43 and the target is the midpoint, 41.

```r
> brakeCap = read.table("BrakeCap.TXT", header = TRUE, sep = "|")
```

Data frame has 250 observation and 4 variables. Three variables measure different settings of the same process; the fourth variable identifies the batch.

```r
> str(brakeCap)
'data.frame': 250 obs. of 4 variables:
$ Hardness     : num 39.1 38.5 40.3 39.2 39.4 ... $ Centering    : num 40.9 38.8 41.1 41.8 40.1 ... $ Quenching    : num 40.7 41.1 40.6 40.5 41.6 ... $ Subgroup     : int 1 1 1 1 2 2 2 2 2 2
```
Analysis requires three steps:

1. Verify that the process is under statistical control.
2. Identify the distribution.
3. Perform the capability analysis.

Control charts are used to verify if the process is under statistical control. Data is contained in Hardness variable.

```r
library(qcc)
Hardness.group = qcc.groups(brakeCap$Hardness, brakeCap$Subgroup)
qcc(Hardness.group, type = "S")
qcc(Hardness.group, type = "xbar")
```
The Anderson-Darling test verifies the hypothesis of normal distribution of data.

> library(qualityTools)
> adTest = qualityTools::myADTest
> with(brakeCap, {
+  qnorm(Hardness, main = "Hardness")
+  qqline(Hardness)
+  adTest(Hardness, "normal")
+ })

Anderson Darling Test for normal distribution data:
A = 0.4277, mean = 40.273, sd = 0.986, p-value = 0.3097
alternative hypothesis: true distribution is not equal to normal

Once verified the process is under control and data are normally distributed then overall capability analysis is performed.

> pcr.Hardness.overall = pcr(brakeCap$Hardness, "normal",
+  lsl = 39, usl = 43, target = 41)

Process Capability using normal distribution for brakeCap$Hardness

<table>
<thead>
<tr>
<th>Expected Fraction Nonconforming</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>p = 0.101183</td>
<td>ppm = 2.5e+07</td>
</tr>
<tr>
<td>P = 0.0983474</td>
<td>ppm = 2.4e+07</td>
</tr>
<tr>
<td>Pu = 0.00289522</td>
<td>ppm = 1e+06</td>
</tr>
</tbody>
</table>
Potential (within) capability analysis can be performed to improve the process.

```r
> pcr.Hardness.within = pcr(brakeCap$Hardness, "normal",
+   lsl = 39, usl = 43, target = 41, grouping = brakeCap$Subgroup)
```

![Process Capability Analysis for Normal Distributions](image)

**PPM**

```r
> (pcr.Hardness.overall$ppt - pcr.Hardness.within$ppt) * 10^-6
```

4012

This value represents the loss of quality due to special causes.
As a result of the previous analysis, engineers adjust the process to get a process mean closest to 41, the target value. Data is contained in Centering variable. Process control charts are shown below.

The Anderson-Darling test verifies the hypothesis of normal distribution of data.

Anderson Darling Test for normal distribution data:

\[ A = 0.2139, \text{ mean } = 41.028, \text{ sd } = 0.979, \text{ p-value } = 0.8496 \]

alternative hypothesis: true distribution is not equal to normal
Once verified the process is under control and data are normally distributed then overall capability analysis is performed.

Potential (within) capability analysis can be performed to improve the process.
Although the process is centered on the target, CP and CPK values are not satisfactory. An experiment shows that a large proportion of variability is due to oil temperature variability. Engineers adjust the process to obtain smallest variability of the oil temperature. Data is contained in Quenching variable. Process control charts are shown below.

The Anderson-Darling test verifies the hypothesis of normal distribution of data.

Anderson Darling Test for normal distribution

data: brakeCap$Quenching

\[ A = 0.2868, \text{ mean } = 40.926, \text{ sd } = 0.517, \text{ p-value } = 0.6199 \]

alternative hypothesis: true distribution is not equal to normal
Once verified the process is under control and data are normally distributed then overall capability analysis is performed.

Potential (within) capability analysis can be performed to improve the process. CP and CPK indices show that the process is now (barely) capable.
Capability analysis formulas are based on the percentiles of the distribution of reference. Therefore, verifying if the empirical distribution can be considered Gaussian is fundamental. For example, applying the formulas of the measurement distribution of origin to very asymmetrical segments can result in an incorrect estimation of the CP index.

When data is not normally distributed, possible approaches fall into two categories:

A. Identification of a distribution able to describe data;
B. Transformation of data to obtain a normal distribution, e.g. Box-Cox transformation.
Formulas of capability indices for non-normal distributed data are based on percentiles. The first thing to do is identifying another probability distribution which can be adapted to original data.

Goodness-of-fit tests, such as those of Anderson-Darling and Kolmogorov-Smirnov, can help identify the best distribution for the analysed sample.

If control charts indicate a stable process, even if not modelled by a normal distribution, a useful model which is suitable for data needs to be defined. A tool to identify the distribution can be used assuming no previous knowledge of a reasonable model for the examined process.

This tool tests the adaptation of data to different distributions and successively selects a distribution according to the probability plot, the results of the goodness-of-fit test and the physical and historical knowledge about the process.
In this case, the calculation of \( CP \) and \( CPK \) indices is based on the percentiles of the chosen distribution. The percentiles contain the same “amount of data” as the \( \mu \pm 3\sigma \) interval of the normal distribution:

\[
CP = \frac{USL - LSL}{x_{0.99865} - x_{0.00135}}
\]

where \( x_{0.99865} \) is the 99.865th percentile.

\[
CPK = \min(CPL, CPU)
\]

\[
CPL = \frac{x_{0.5} - LSL}{x_{0.5} - x_{0.00135}}
\]

\[
CPU = \frac{USL - x_{0.5}}{x_{0.99865} - x_{0.5}}
\]

For a capability analysis to be carried out, the process is assumed to be, approximately if not thoroughly, describable by a theoretical distribution. A suitable distribution ought to be used to create a significant inference, for example on the ratio of pieces situated beyond specification limits.

Capability estimations of CP, CPK and so on tend to assume normality. When normality is mistakenly assumed, the estimated ratio of points falling beyond specification limits can be over- or underestimated.

An attempt to transform original data to render it more similar to normal data is possible. The Box-Cox and Johnson transformations can often result in an “acceptably Gaussian” distribution. Once the best transformation has been chosen, it has to be applied to control limits as well. Consequently, capability formulas for normal distributions can be used on the sample and on transformed control limits.
The **Box-Cox transformation** changes original data so that the **normal distribution for capability analysis** can be used.

The Box-Cox transformation uses a power transformation for original data:

\[
y^{(\lambda)} = \begin{cases} 
  y^{\lambda} - 1 & \text{if } \lambda \neq 0 \\
  \frac{\lambda}{\ln y} & \text{if } \lambda = 0 
\end{cases}
\]

When the \( \lambda \) parameter changes, different distributions of changed data are obtained.

Some of notable values of \( \lambda \):

<table>
<thead>
<tr>
<th>( \lambda )</th>
<th>power transformation</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1.0</td>
<td>( 1 - 1/y )</td>
<td>inverse function</td>
</tr>
<tr>
<td>0.0</td>
<td>( \ln y )</td>
<td>logarithmic function</td>
</tr>
<tr>
<td>0.5</td>
<td>( 2\sqrt{y} - 1 )</td>
<td>square root</td>
</tr>
</tbody>
</table>

We look for the \( \lambda \) value which transforms the data into a distribution as similar as possible to a Gaussian distribution. The sought for \( \lambda \) value is the value which stabilizes the variance (which coincides with the value of that parameter for which the variance is lowest).
Once the transformation has been performed, the adaptation of the normal distribution to changed data is estimated by assessing the probability plots and the results of the Anderson-Darling test.

The use of the highest p-value alone is not always the most intelligent approach to choose the best model, especially when the suitability of a particular distribution is historically and theoretically known.

Final remarks on capability analysis for non-normal distributed data:

- To decide which transformation results are better it is useful to take into consideration the validity of the selected model using:
  - the knowledge about the process;
  - the probability plot.
- For a reliable process capability estimation to be obtained, the process needs to be stable and data ought to follow the above-mentioned distribution curve.
- The use of goodness-of-fit test and probability plots can affect the identification of the model but the knowledge about the process plays a useful role too.
Ceramic data frame contains data about ceramic isolators. Isolators are cylinders with a hole in the center. 20 batches of 10 elements each have been sampled. Specifics require that hole diameter is less than 30 micrometre (micron).

```r
> ceramic = read.table("Ceramic.TXT", header = TRUE, sep = "|",
+   stringsAsFactors = F)
```

Data frame has 200 observation and 2 variables. The Concentricity variable contains the distance of the hole from the required one, the Date.Time variable contains the batch id.

```r
> str(ceramic)
'data.frame': 200 obs. of 2 variables:
  $ Concentricity: num 14.62 9.23 7.89 3.18 10.38 ...
  $ Date.Time : chr "1/5 10am" "1/5 10am" "1/5 10am" "1/5 10am" ...
```

Control charts are used to verify if the process is under statistical control.

```r
> library(qcc)
> concentr.group = qcc.groups(ceramic$Concentricity, ceramic$Date.Time)
> qcc(concentr.group, type = "S")
> qcc(concentr.group, type = "xbar")
```

![S Chart for concentricity.group](image1)

![xbar Chart for concentricity.group](image2)
The Anderson-Darling test verifies the hypothesis of normal distribution of data.

```r
> library(qualityTools)
> adTest = qualityTools:::.myADTest
> with(ceramic, {
+   qnorm(Concentricity, main = "Concentricity")
+   qline(Concentricity)
+   adTest(Concentricity, "normal")
+ })
```

Anderson Darling Test for normal distribution data:

\[ A = 6.7131, \text{mean} = 11.442, \text{sd} = 7.240, \text{p-value} < 2.2e-16 \]

alternative hypothesis: true distribution is not equal to normal

Test rejects the hypothesis of normal distribution of the data. The Weibull distribution of data can be tested.

```r
> qqPlot(ceramic$Concentricity, "weibull")
> adTest(ceramic$Concentricity, "weibull")
```

Anderson Darling Test for weibull distribution data:

\[ A = 2.1104, \text{shape} = 1.707, \text{scale} = 12.913, \text{p-value} <= 0.01 \]

alternative hypothesis: true distribution is not equal to weibull
Test rejects the hypothesis of Weibull distribution of the data. The Log-Normal distribution of data can be tested.

> qqPlot(log(ceramic$Concentricity))
> adTest(log(ceramic$Concentricity))

Anderson Darling Test for normal distribution

data:
A = 0.3306, mean = 2.250, sd = 0.624, p-value = 0.5116
alternative hypothesis: true distribution is not equal to normal

Data can be assumed to follow a log-normal distribution. Overall capability analysis can be performed via data transformation.

> pcr.Concentricity = pcr(log(ceramic$Concentricity), usl = log(30))
Box-Cox transformation seems confirm the log data transformation.

```r
> boxcox(ceramic$Concentricity ~ 1)
```

Concentricity analysis can be performed directly on log-normal data.

```r
> usl = 30
> par(mfrow = c(1, 1))
> hist(ceramic$Concentricity, main = "Concentricity", col = "gray")
> abline(v = usl, col = "red", lwd = 2)
> concentricity.distpars = fitdistr(ceramic$Concentricity, "log-normal")$estimate
> meanlog = concentricity.distpars[1]
> sdlog = concentricity.distpars[2]
> cpk = usl/qlnorm(0.99865, meanlog, sdlog)
> ppm = (1 - plnorm(30, meanlog, sdlog) * 10^-6
```
Results obtained directly on log-normal data can be compared with transformed data.

```r
> cpk # original data
[1] 0.4886823
> pcr.Concentricity$cpk # transformed data
[1] 0.6149203

> ppm # original data
[1] 32200.77
> pcr.Concentricity$ppt * 10^-6 # transformed data
[1] 32536.18
```

Regardless the adopted methodology to estimate indices, the process is far from been capable.

References