Process validation: Cp, Cpk, standard deviation... statistical methods

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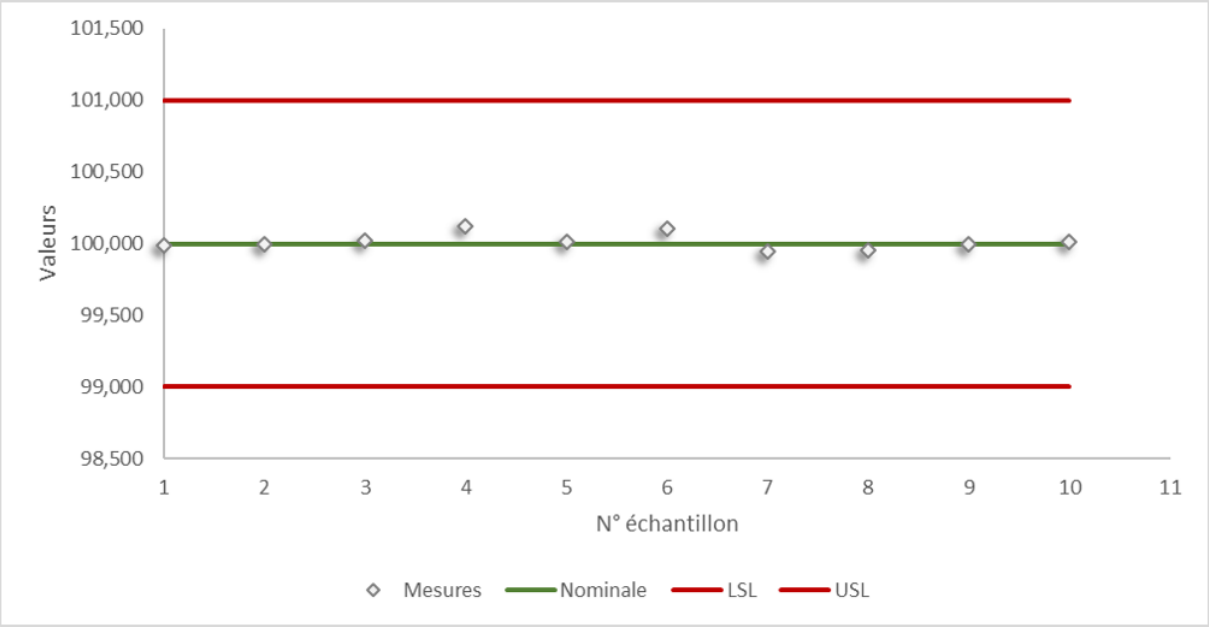
When production quantities are large enough, it can be useful for manufacturers to validate production, rather than performing unit tests on each device.

These validations use mathematical tools that need to be understood to be used correctly.

Note: This topic is covered in the ISO/TC 69/SC 4 series of standards.

Defining production requirements



Before validating the production, it is necessary to define the requirements for the devices manufactured: these requirements are quantitative and relate to the critical physical characteristics of the product (e.g. length, diameter, rate, etc.)

We set :

- A nominal value (the expected value): X

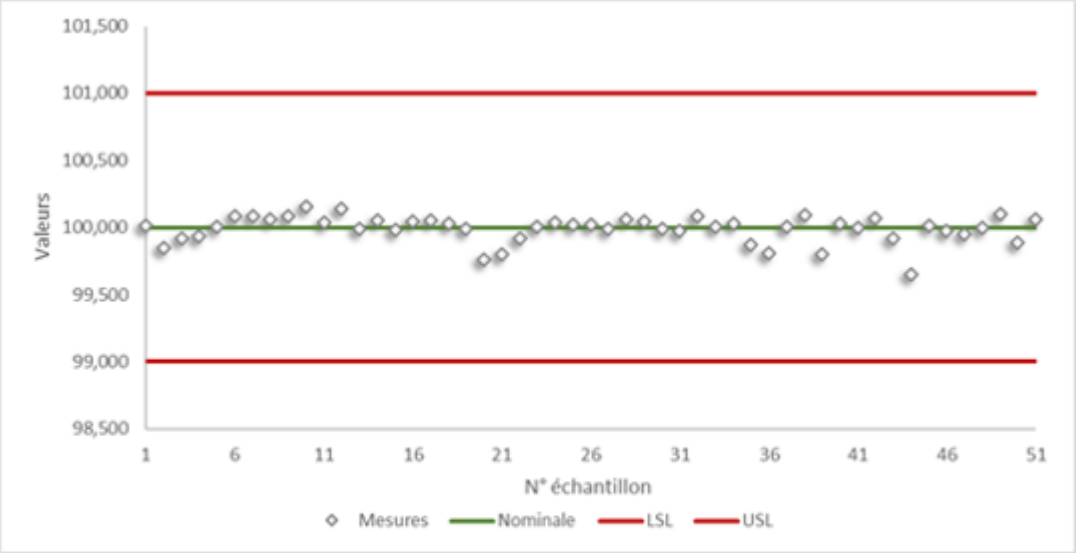
- The high tolerance: USL

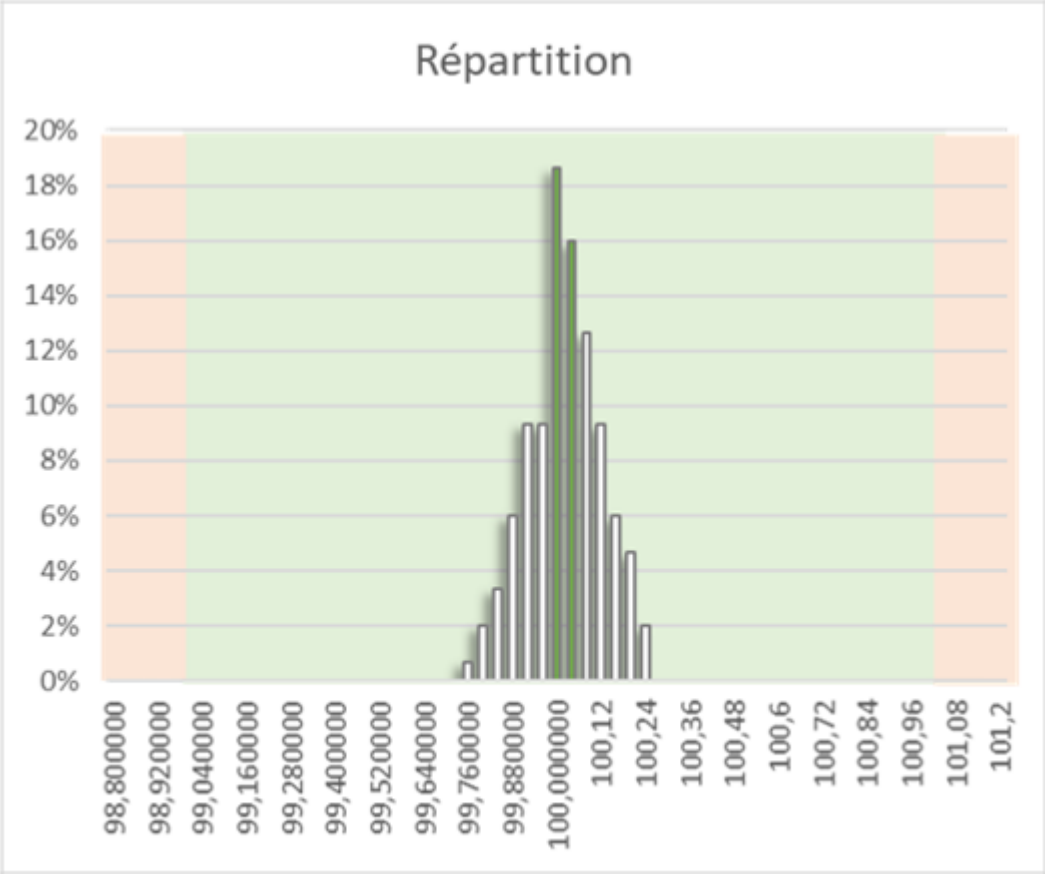
- The low tolerance: LSL

Thus, parts outside the tolerance range will be non-conforming.

Normal distribution of measured values

For several manufactured devices, a measurable characteristic will vary according to a normal distribution: the distribution of measurements (the number of parts for each value range) follows a Gaussian curve:





In this example, the 50 measurements are used to draw the histogram of the distribution of values, the green background covers the conforming values, the NC measurements are in the red zone. Most of the points are close to the mean value.

The further the NC (red) zone is from the curve, the more likely the product is to be compliant

The validation of the production will show that :

- the curve is sufficiently narrow, so as not to exceed the tolerance zone, the production is then capable.

- the curve is sufficiently centred around the nominal value, so as not to go outside the compliance zone, the production is then repeatable.

The centring and the width of the curve depend on the settings of the production tool and its possible drifts.

Average value and standard deviation of the measured values

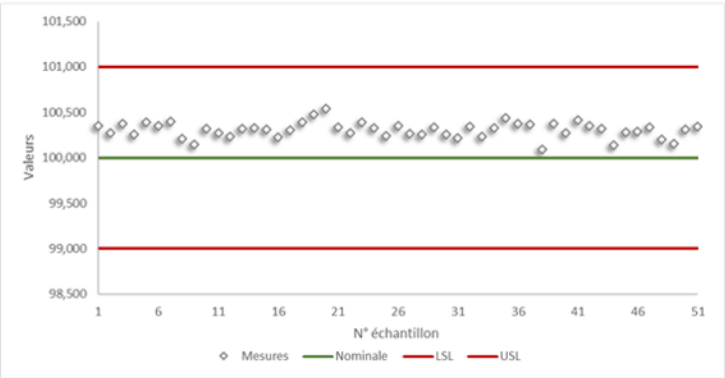
For a batch of n parts produced and the associated measurements x, we calculate :

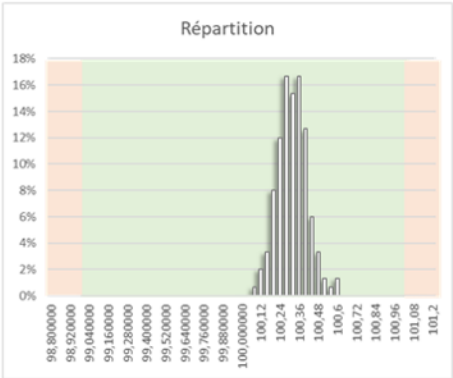
- the mean value μ: Σ (measurements) / n

- the standard deviation σ : $\sqrt{}$ (Σ((x - μ)^2) / n)

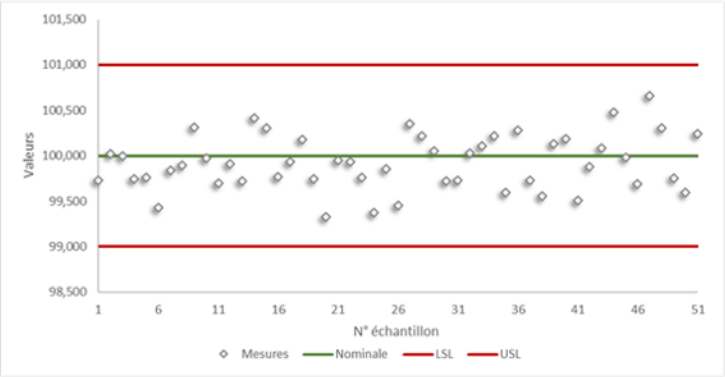
The mean value is easy to understand (a value "in the middle" of all the measurements), the standard deviation is less intuitive: it represents how much the measurements "go around".

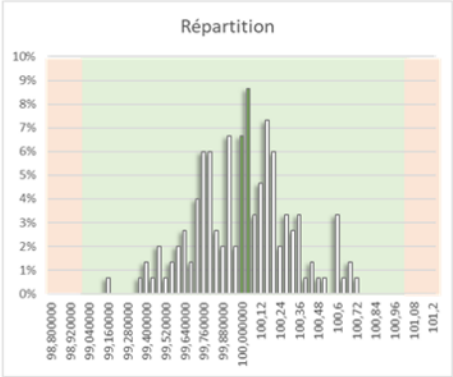
μ = 100,3
σ = 0,1





μ = 100
σ = 0,33

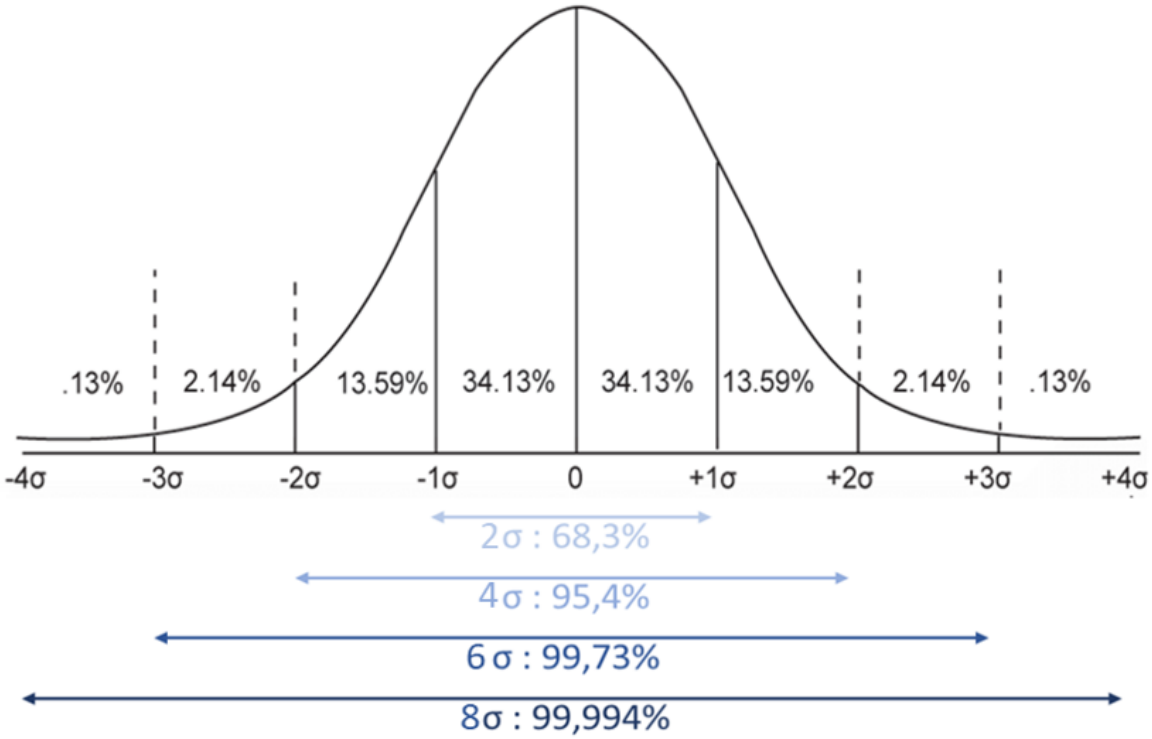




Probability of non-conformity

This is where the mathematical tool comes in handy: once the mean value and standard deviation have been identified, it is possible to know the probability of a point being in a given value range.

The probability P of having a value in an interval around the mean value is a function of the number of standard deviations that make up this interval:



This gives the probability that the value is outside the range (that the product is non-compliant):

- x outside [-σ/2; σ/2]: 62%.

- x [-σ; σ]: 32%.

- x [-2σ; +2σ]: 5%.

- x [-3σ; +3σ]: 0.27%.

- x [-4σ; +4σ] : 0.006%.

- x [-6σ; +6σ] : 0.0000002%.

The aim is to have tolerances (USL and LSL) very far from the mean value, typically 4σ each: with a probability of conformity of 99.994% and a non-conformity rate of 66ppm (parts per million).

Capacity coefficients Cp, Cpk, Cpm

Calculations

Indices are needed to analyse the production results:

- Process capability index: Cp = (USL - LSL) / 6σ

The coefficient Cp looks at "how close the tolerance range is to 6σ": the larger Cp is, the more capable your process is of producing compliant results.

With Cp = 1 the compliance range covers 6σ, the probability of being non-conforming is 0.27%.

With Cp = 1.33 the compliance range covers 8σ, the probability of being non-compliant is 0.007%.

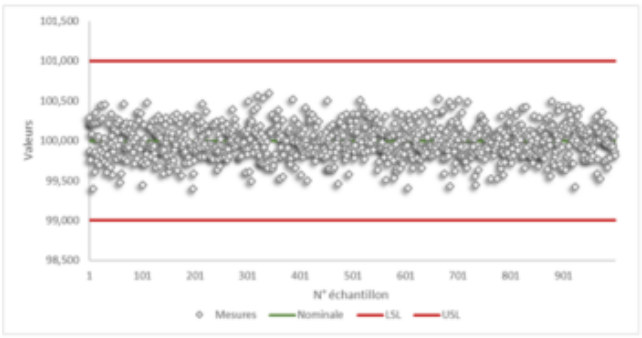
- Minimum process capability index $Cpk = \min((USL - \mu)/3\sigma ; (\mu - LSL)/3\sigma)$

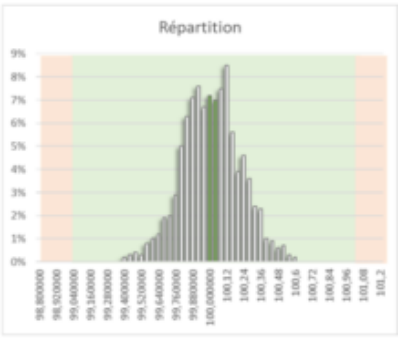
The coefficient Cpk takes into account a possible decentring, which despite a high Cp would make the process not very repeatable

- Machine capacity index: $Cpm = Cp / \sqrt{(1 + 9.(Cp - Cpk)^2)}$

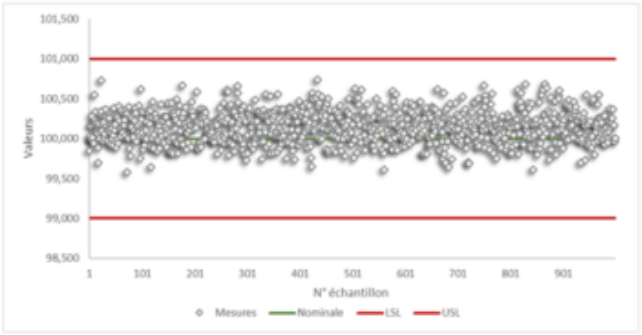
The Cpm coefficient (very useful as it is very reactive) takes into account the decentralisation of results and is commonly used to monitor the deviation of a machine.

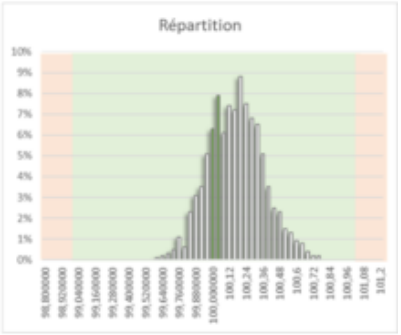
Cp = 1,59
Cpk =158
Cpm = 1,59



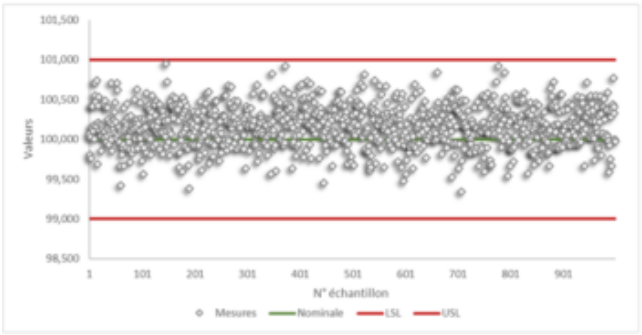


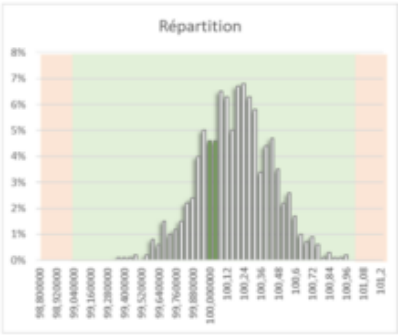
Cp = 1,7
Cpk =1,44
Cpm = 1,06



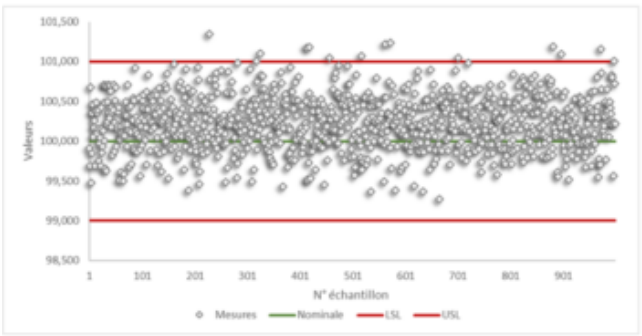


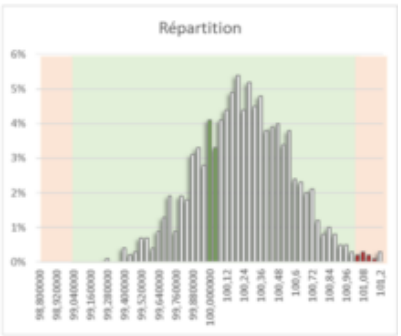
Cp = 1,32
Cpk =1,09
Cpm = 0,88





Cp = 0,98
Cpk =0,76
Cpm = 0,67





Useful thresholds

The thresholds for deciding whether the coefficients Cp, Cpk and Cpm are satisfactory depend on the desired confidence:

The common thresholds and associated confidence probabilities are given below, a threshold of 1.33 is very often used, 1.66 is for excellence productions (needed for large quantities of parts).

Thresholds	Sigma's (z-score)	Cofidence	NC
0,67	2,01	95,56%	44'431ppm
1	3	99,73%	2'700ppm
1,33	3,99	99,9934%	66ppm
1,66	4,98	99,999936%	1 ppm
2	6	99,9999998%	0ppm

The "z-score" is noted: z = 3.S

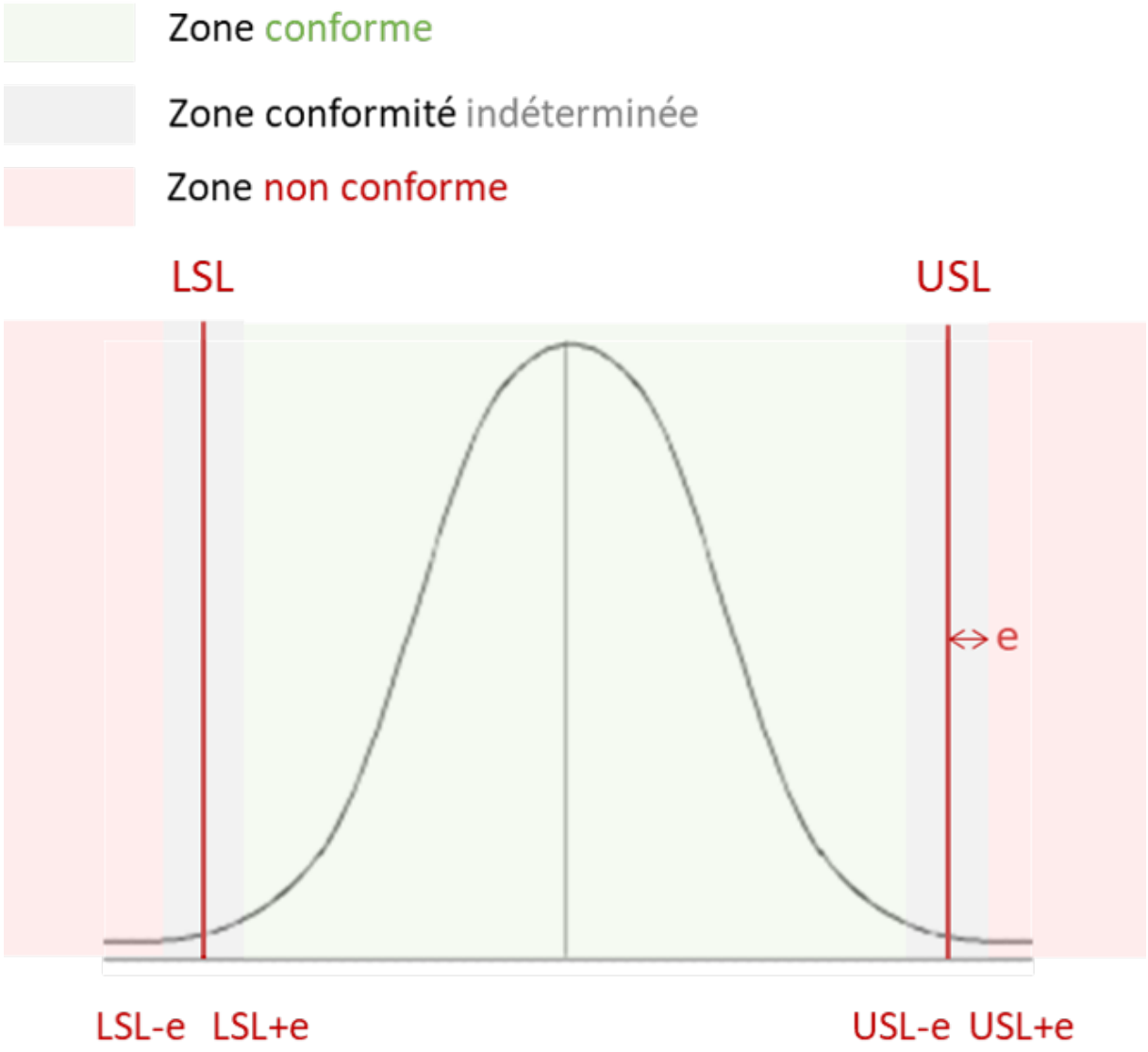
Number of samples used and induced error

The error e can be calculated as a function of σ, the number of samples n and z :

$e = z.\sigma/\sqrt{n}$

The error will reduce the compliance range, in fact: around the values LSL +/- e and USL +/-1 you do not know if the measurement is compliant.

You now have three zones: compliant, non-compliant and unknown :



How to use all this?

For each validation test (there is often one test per influence factor and production cycle):

1. Take a few dozen samples (usually more than 20)
2. Calculate the coefficients Cp, Cpk, Cm and the error
3. Continue until you have stable coefficients and a tolerable error

You will take into account the number of devices produced to set a threshold for the capability indices. A high threshold - above 1.3 - will be necessary for large production runs where even low probabilities of non-conformity are critical.

The number of samples required ranges from a few dozen to several hundred depending on the standard deviation and your production volumes.

Below: the evolution of the estimation of the coefficients and the error as a function of the number of samples, for a low standard deviation (less than 1/5 of the tolerance), one can see that the values are correctly estimated after about 40 samples: