Content

1 Purpose

This company standard serves the assessment and acceptance of machines and manufacturing processes and as the basis for the determination of the capability indices.

The aim of this company standard is the following:

- Specification of the individual qualification phases
- Objective of the individual qualification phases
- Specification of the areas of responsibility
- Specification of the evaluation strategy
- Determination of the capability indices

2 Scope

This company standard shall be applicable to all orders placed by the ETO Group. The technical design is examined during machine acceptance testing using a checklist.
In case of contradiction between this company standard and the specifications sheet, the layout in the specifications sheet shall be applicable.
If special agreements are made, these shall only apply to the relevant order and shall be documented in writing. Oral agreements shall not apply.
If during acceptance testing, deviations from the delivery specification are detected, the observance of which would have been possible, a modification at supplier´s expense may be requested.

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3 Change History

2014-11 First English edition, translation of the German version of October 2012

2024-05 Applicable documents added
- short-term process performance study, long-term study, process stability
- change of indices Pm and Pmk
- update of indices Pp / Ppk und Cp / Cpk
- recommendation for reduced number of measurement values
- calculation of measurement values added
- standard evaluation Q-DAS (Q-STAT)
- determination or calculation of measurement values added
- special cases of the process performance study

2024-06 Adjustment of the terms in Chapter 8.1, Table 2

4 Applicable Documents

The following documents are referenced in the text in such a way that some or all of their content constitutes requirements of this document.

ETN021	Measurement System Analysis
Q-008	Process Capabilities Customer_Prozessfähigkeiten Kunde

5 Definition of Terms and Abbreviations

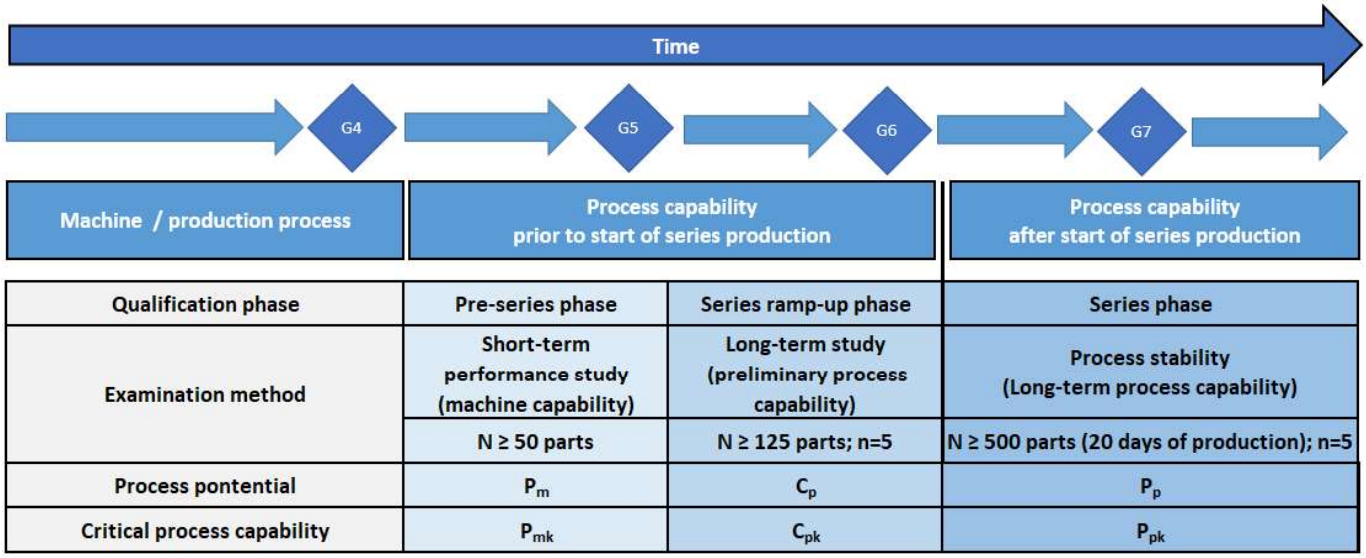
No terms and definitions are listed in this document.

6 Introduction

Process qualification serves for the evaluation and acceptance of machines and manufacturing processes by means of statistical capability studies. The aim of these studies is to verify that the machine and/or manufacturing process, under statistically controlled manufacturing conditions, is able to meet the functionally justified characteristic tolerances of the parts and assemblies to be manufactured and to manufacture products that comply with the quality standard. This is required in order to be able to realize high-quality and high-productivity series production. By achieving the required process capability indices for the relevant characteristics it is ensured that controlled processes and machines with a low process variability are available. Verification of process capability (quality capability of processes) is an important prerequisite without which it is not possible on the long term to offer the customer a high-quality product at economically justifiable means.

7 Process Qualification

Process qualification serves to determine the process capability indices and, with regard to time, is classified into the fields "Process capability prior to start of series production" and "Process capability after start of series production". The entire qualification process can generally be classified, as regards time, into the three phases pre-series, series ramp-up and series. Within these phases, the examination methods „short-term performance study“, „long-term study“ and „process stability“ are used. Image 1 shows the chronological and examination method related context.



Qualification phase	Pre-series phase	Series ramp-up phase	Series phase
Examination method	Short-term performance study (machine capability)	Long-term study (preliminary process capability)	Process stability (Long-term process capability)
	N ≥ 50 parts	N ≥ 125 parts; n=5	N ≥ 500 parts (20 days of production); n=5
Process pontential	P_m	C_p	P_p
Critical process capability	P_{mk}	C_{pk}	P_{pk}

Image 1 Qualification process for determining the capability indices

7.1 Pre-series phase – short-term performance (machine capability)

The short-term performance is determined during the pre-series phase. This serves for the evaluation and acceptance of machines and manufacturing equipment at the machine manufacturer´s and customer´s premises and is therefore often referred to as machine capability study. Within the scope of this study, all systematic and random effects of the machine are systematically recorded, since the effects of material, machine operator, working environment and tools are kept constant or are eliminated. The result of a short-term performance study is thus a preliminary statement on the suitability of the manufacturing equipment.

The capability indices determined during this phase are designated **Pm** and **Pmk**. In order to determine these capability indices, generally 50 parts are manufactured in a row, measured, separated into 10 samples of n=5 parts each and evaluated in the order of their discharge. This results in a total sample size of N ≥ 50 parts.

In special cases the realization or measurement of 50 parts can constitute an unreasonably high effort (e.g. with destructive tests) and make it necessary to get along with less parts. This results in a decrease of the statistical validity, however, i.e. increase of the confidence interval of the performance indices. To compensate this effect the minimum requirement for **Pm** and **Pmk** can be increased accordingly. This is shown in in Table 1. The requirement of 1,67 for 50 values can be increased to 1,9, for example, if only 20 parts are evaluated. The number values for **Pm** and **Pmk** are calculated in such a way, that the same level of confidence of 95% or 99% applies to them at a smaller sample size **n**, as would at n=50.

Table 1 The recommendation for Pm, Pmk at 50 and less than 50 values is derived from the confidence interval of the quality performance indices.

		P_M / P_{mk} - Recommendation
Quantity	**P_A = 95%**	**P_A = 99%**
50	1.67	1.67
40	1.72	1.74
30	1.78	1.84
20	1.91	2.03
15	2.03	2.23

7.2 Series ramp-up phase – long term study (preliminary process capability)

In the series ramp-up phase the preliminary process capability is determined. Series conditions are already in place in this phase, and thus the short-term effective influences of material, machine operator, work environment and tooling enter the examination results. This enables a meaningful assessment of the long-term process capability to be expected. Simultaneously it shows, that the process is capable under series conditions of fulfilling the customer quality requirements on the product as well as on the process.

The capability indices determined in this phase are designated Cp and Cpk. For determining these capability indices normally 25 samples with n=5 parts each are taken from running production in specified time intervals, measured and evaluated in in the order of their discharge. This results in a total sample size of N ≥ 125 parts.

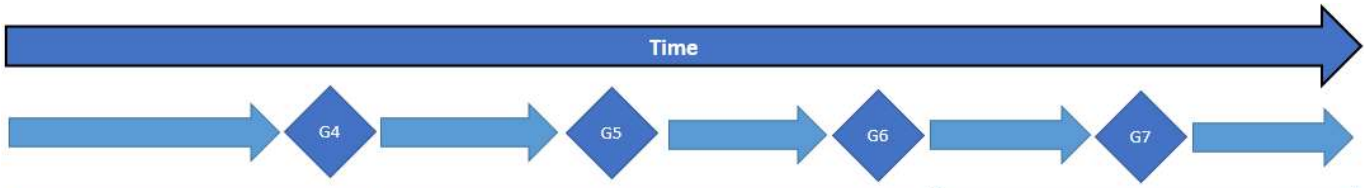
7.3 Series phase – process stability (long-term process capability)

In the series phase the long-term process capability is determined. It serves for determining the long-term behavior of the machines and the production processes under the real conditions of series production. By means of continuous data acquisition over a longer period, which ideally spans the entire product life cycle, the effects of all short- and long-term systematic and random influencing factors of the production process can be determined.

The capability indices determined in this phase are designated Pp and Ppk. For determining these capability indices normally 100 samples with n=5 parts each are taken from running production in specified time intervals over a period of at least 20 production days, measured and evaluated in in the order of their discharge. This results in a total sample size of N ≥ 500 parts.

8 Calculation and Evaluation of the Capability Indices

Prerequisite for conducting a process capability examination and calculating the capability indices, is the verification of the capability of the measuring instruments, measuring equipment and measuring systems used according to ETN021 – Measurement Systems Analysis. If the verification is available in writing, the calculation of the capability indices shall be performed with the current version of the statistics software qs-STAT by Q-DAS GmbH & Co. AG. By default the evaluation strategy for determining the capability indices, including the minimum requirements on process performance indices filed there, shall be used (see Image 2).



Qualification phase		Pre-series phase	Series ramp-up phase	Series phase
Examination method		Short-term performance study (machine capability)	Long-term study (preliminary process capability)	Process stability (Long-term process capability)
		N ≥ 50 parts	N ≥ 125 parts; n=5	N ≥ 500 parts (20 days of production); n=5
Process pontential / critical process capability		P_m / P_{mk}	C_p / C_{pk}	P_p / P_{pk}
Stable process	normally distributed	2 / 1,67	1,67	1,33
	not normally distributed	1,67	1,67	1,33
Unstable process	normally distributed	2 / 1,67	1,67	1,67
	not normally distributed	1,67	1,67	1,67

Image 2 Minimum requirements on the process performance indices depending on the project phase

Deviations from this calculation method and the associated minimum requirements on process performance indices (see Q-008_Process Capabilities Customer_Prozessfähigkeiten Kunde) shall be coordinated with the customer and recorded in writing before performing the process qualification.

Details on the calculation methods used and the valid minimum requirements on the process performance indices, depending on the examination method, sample size, distribution type and stability assessment, shall directly be taken from the evaluation strategies in the software qs-STAT under the item evaluations or read in the book „Statistische Verfahren zur Maschinen- und Prozessqualifikation“ /1/.

The evaluation and acceptance of machine and production processes by means of statistical capability examinations shall exclusively be performed in close coordination with the specialist department for process qualification of the respective ETO location. For the ETO MAGNETIC GmbH, for example, this is the central department for process qualification (Zentralbereich Prozessqualifizierung). If a capability examination is conducted by personnel outside these specialist departments, the recorded measuring values shall be provided for evaluation in chronological order in einer Excel sheet.

8.1 Determination and/or calculation of the measuring values

If SIZE ISO 14405 is indicated on the drawing, the required evaluation methods for the performance examination of a process not always make sense.

For this reason the elements according to the table in Table 2 are metrologically recorded and evaluated. If other evaluation methods are required by the ordering party, these shall be indicated.

Table 2 Metrological implementation

Description	Symbol	Example	Metrological implementation
Two-point size min / max	(LP)	10 ± 0.1 (LP)	Linear size: Calculation of mean value of two-point size min / max Diameter: Calculation according to least squares size (Gauss)
Least squares size (Gauss)	(GG)	$10^{+0.1}_{-0.2}$ (GG)	Calculation according to least squares size (Gauss)
Maximum inscribed size	(GX)	10 ± 0.1 (GX)	Calculation according to maximum inscribed size
Minimum circumscribed size	(GN)	$10^{+0.2}_{-0.1}$ (GN)	Calculation according to minimum circumscribed size
Envelope requirement	(E)	10 ± 0.1 (E)	Inside size according to maximum inscribed size Outside size according to minimum circumscribed size

9 Special Cases of the Process Performance Examination

9.1 Stamping and deep drawing process

The determination of process capability indices is reasonable only, if it is possible to intervene to control the running process. In order to control something, the influencing factors on the process must be known, and it must be possible to influence them during the running process. In stamping and deep drawing processes the control options during the production phase are very limited. For economic reasons the tools are have a one-sided design in the tolerance range in most cases to enable a longer tool life.

For these reasons **no critical indices** are evaluated in stamping and deep drawing processes, as the process position to the center of tolerance is not given by design.

9.2 Multiple cavity production process without cavity allocation

If there is a cavity allocation, the individual cavities are evaluated separately. If this is impossible due to missing allocation to the tool cavities, all components from a production operation are evaluated together.

9.3 Process stability – performance examination of small batch series (reduced sample size)

If there is an insufficient number of components for the examination of the process stability due to a small batch series to be evaluated, the long-term examination (preliminary process capability) is equated to the process stability examination (long term process capability).

Bibliography

The information contained in this company standard was taken entirely or in part from the following:

/1/ Statistische Verfahren zur Maschinen- und Prozessqualifikation; Edgar Dietrich, Alfred Schulze; 6. Auflage; Carl Hanser Verlag München Wien