# Process control



History

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## 1. Subject

### 1.1 Purpose

The purpose of this procedure is to present the different actions of process control.

### 1.2 Scope

This procedure applies to all processes in our organization. The relevant internal and external issues of the QMS and actions to address the risks identified and improvements opportunities found are taken into account.

### 1.3 Glossary

QMS - quality management system

## 2. Responsibility

The production manager has the authority to write and update this procedure. He is responsible for its implementation. The project manager is responsible for the industrialization of new products and processes used. Each process owner must respect the aspects of this procedure. The authority to decide on the frequency of process reviews is up to each owner.

## 3. Documents

### 3.1 Procedures

Changes
Operational control
Risks
Design and development
External providers

### 3.2 Instructions and records

Process review report
Process sheet
Work instruction
Process list

## 4. Requirements of ISO 9001: 2015 and IATF 16949: 2016 standards

§ 4.4.1 Establish, implement, maintain and continually improve the processes needed and their interactions.

§ 4.4.1.1 Conformance of product and processes

§ 4.4.1.2 Product safety

§ 4.4.2 Maintain and retain documented information necessary for the operation of the processes and have confidence that they are carried out as planned.

§ 7.1.3 Infrastructure

§ 7.1.4 Environment for the operation of processes

§ 7.1.6 Organizational knowledge

§ 8.3 Design and development of products and services

§ 8.3.1 General

§ 8.4 Control of externally provided processes, products and services

§ 8.4.1 General

§ 8.5.1 Control of production and service provision

## 5. Development

### 5.1 Process identification

The processes in our organization (cf. Process list) are classified into three types:

- management
- realization
- support

Each process is identified by its title (with verb to show the purpose), its owner, its inputs, its outputs, its documented information, its resources, its constraints, its objectives and indicators, its links with other processes, its risks and opportunities for improvement. More details in the Risk procedure.

### 5.2 Process map

The mapping of our business processes enables us to obtain a global vision, identify process customers, flows and interactions.

### 5.3 Process control

Each process owner is responsible for the performance of his process and outcomes. He is also responsible for the availability of spare parts and anything provided by external providers.

From the quality policy of our organization quality objectives are defined. The performance of each process is monitored using key indicators, see the Process sheet. When a process is externally provided its conformity is monitored. More details in the External providers procedure.

Each owner regularly brings together the actors of the process (see Process review report) to make a point about the situation, evaluate whether new risks have appeared, discuss the latest ideas and find improvement opportunities. More details in the Operational control procedure.

### 5.4 Process criteria

The performance criteria are determined by the process owner, the quality manager and the actors of the process on the basis of the analysis of:

- customer specifications
- customer expectations
- internal constraints of production (production capacity and existing technological equipment)
- results of FMEA studies
- results of statistical studies of similar processes
- specific quality requirements (control plan)

The control plan defines the elements applicable to each operation and process step, inspection means (monitoring and measurement) used for the product and the process, methods and criteria, the actions to implement, cf. the Work instruction.

### 5.5 Process capability study

Before the introduction of a new process a capability study is conducted over a period of one to three weeks of production. More details in the Design and development procedure.

### 5.6 Production process performance study

Production process performance (stability and capability) is monitored by a statistical process review through control cards and a histogram.

### 5.7 Process qualification

Any new process is subject to a qualification audit. This audit verifies that all QMS requirements are met, the process is stable and the indicators of the quality objectives will be achieved.

### 5.8 Documented information at work stations

To ensure stable processes and conforming products staff have at workstations adequate documented information, such as work instructions, instructions and procedures. This documented information is displayed on each workstation appropriately.

### 5.9 Change control

Any change follows strict rules to ensure process performance in all circumstances. More details in Changes procedure.

### 5.10 Special processes

A special process is one for which the resulting output cannot be verified by traditional means of inspection. This is the case when we have to perform destructive testing or when the inspection cannot be performed until after delivery.

### 5.11 Product safety

The "Guarantee product safety" process describes the provisions related to the safety of the product during manufacture.

Some of the provisions we have put in place:

- identification of the statutory and regulatory requirements for product safety
- customer notification of these requirements
- identification of the safety features of the product during manufacture
- the presence of these requirements in :
    - the product FMEA
    - the process FMEA
    - monitoring plans
    - response plans (acceptance criteria not met during monitoring and measurement)
- assignment of responsibilities including customer communication and management notification
- defining the escalation process for reporting and resolving issues
- training of personnel involved in the production of safe products and processes
- assessment of the potential safety impacts of any product or process modifications
- product safety throughout the supply chain, including for customer-imposed sources
- product traceability by batch throughout the supply chain
- lessons learned during the start-up of new products