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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 the ISO 9001: 2015 standard

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

Determine the processes needed for the QMS and their application and:

- determine the inputs and outputs
- determine the sequence and interaction

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- determine and apply the criteria and methods needed to ensure the effective operation and control
- determine the resources needed and ensure their availability
- assign responsibilities and authorities
- take into account the risks and opportunities
- evaluate these processes and implement any change
- improve the processes and the QMS

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

§ 7.1.3, 7.1.4 Determine, provide and maintain the infrastructure and the environment necessary for the operation of its processes.

§ 7.1.6 Determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

§ 8.3 Establish, implement and maintain an appropriate design and development process.

§ 8.4 Ensure that externally provided processes are conform.

Determine the controls to be applied to externally provided processes, products and services.

§ 8.5.1 f) Validate the ability of processes to achieve planned results, where the resulting output cannot be verified a posteriori.

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. From the quality policy of our organization quality objectives are defined. The performance of each process

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