

1. Scope

XXXX establish, implement and maintain this ISO9001:2015 QMS to consistently provide products that meet customer and applicable legal requirements, and to continuously improve customer's satisfaction and the performance of QMS. We strive to understand the dynamic external and internal context, and the changing need & expectation of relevant interesting parties, to identify and address the risks & opportunities, by utilizing process approach, PDCA and risk-based thinking, data analysis and quality management principles.

2. Normative reference

ISO 9000:2015, Quality management systems – Fundamentals and vocabulary

- **Characteristic** - A characteristic is a distinctive feature or property of something.
- **Context of the organization** – all of the internal and external factors and conditions that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction.
- **Correction** – any action that is taken to eliminate a nonconformity, but to address root causes.
- **Corrective action** – steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence of the existing nonconformities and potentially undesirable situations.
- **Interested party** – anyone who can affect, be affected by, or believe that they are affected by a decision or activity. It is a person, group, or organization that has an interest or a stake in a decision or activity.
- **Outsource** – when an outside organization to perform part of a function or process of organization.
- **Process approach** – manage and control the processes that make up their organization, the interaction between these processes, and the inputs and outputs that tie these processes together.
- **Process-based quality management system** – using process approach to manage and control how its quality policy is implemented and how its quality objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes.
- **Quality** - the degree to which a set of inherent characteristics fulfills a set of requirements of an objective.
- **Risk** – the “effect of uncertainty on an expected result” and an effect is a positive or negative deviation from what is expected.
- **Risk-based thinking** refers to a coordinated set of activities and methods that organizations use to manage and control the many risks that affect its ability to achieve objectives.

3. Terms and definitions

‘Purchased Product’ is replaced by ‘Externally Provided Processes, Products and Services’

Iso Standard Manual

Camilla Rothe



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