# Part 2

## ISO 9001:2015 for SMEs: sensible, uncomplicated, beneficial!

**In the second part of our series of focus topics, you will learn more about the processes in the context of quality management according to ISO 9001 and how they can be better planned and evaluated.**

Every process management always strives for continuous improvement of the processes.

According to ISO 9001, a process is *"a set of interrelated and interacting activities that transforms inputs into outputs"*.

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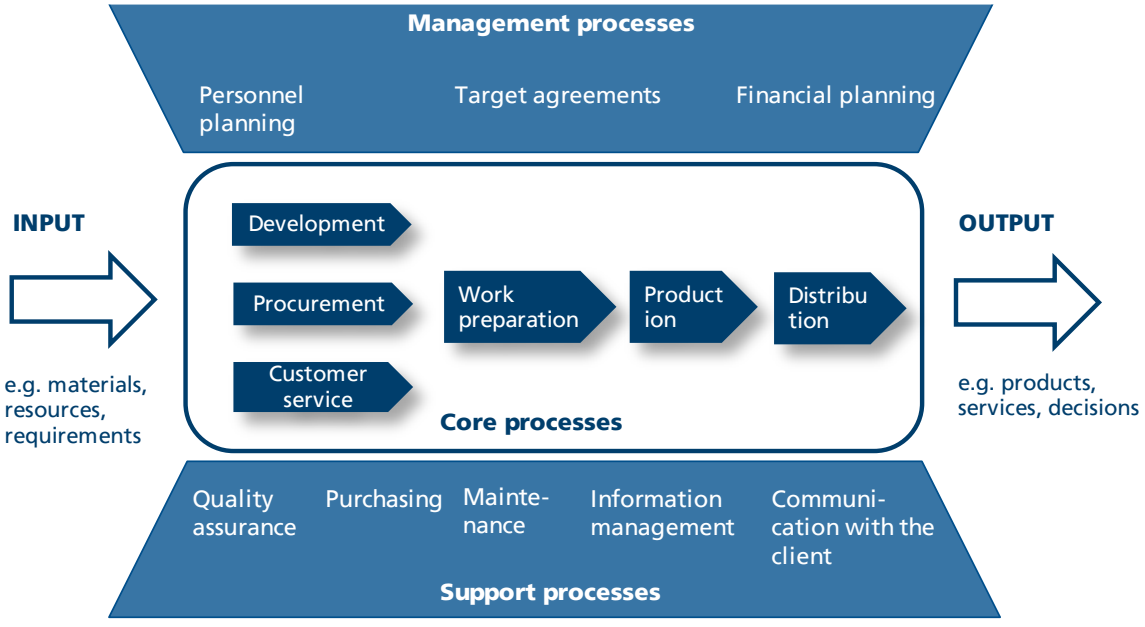
The central concern here is to increase performance in the company. ISO 9001 requires that every process must be planned, controlled, monitored and improved (PDCA). This can be done through

- Defining the requirements for products, services and processes
- Determine and provide the necessary resources
- Controlling the processes, audits
- documented information
- Change management

The focus of quality management is on optimising customer benefits.

The process-oriented approach is one of the principles of quality management that enables an organisation to plan its processes and their interactions. ISO 9000 describes it this way: *"Consistent and predictable results are achieved more effectively and efficiently when activities are understood, managed and controlled as interrelated processes that function as a coherent system"*.




**Overall process**

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The quality management system consists of processes that interact with each other. Understanding how results are achieved in this system - including all processes, resources, control tools and interrelationships - allows the organisation to optimise its performance. Thus, an organisation committed to ensuring effectiveness and continuous improvement of its QMS and to increasing customer satisfaction should definitely adopt the process-oriented approach.

## Advantages of process management for the company

- Focus on value creation
- Stronger orientation towards results through process indicators
- Increasing the effectiveness of processes
- New momentum for improvement activities
- Prioritisation of processes derived from the corporate goal
- Greater involvement of employees through process owners and teams

**Checklist for the audit**

Comprehensible definition and presentation of:

- Activities, their interactions and interrelationships
- Inputs and outputs of the defined processes
- Sequence and interactions of the defined processes and associated documented information
- defined criteria, methods, monitoring, measurements and key figures
- Resources, responsibilities and assigned authorities for the processes
- Integration and implementation of measures to address risks and opportunities
- Implement and control the changes
- Type and manner of process evaluation

In process planning, the company should define the inputs and desired outputs of their processes, their sequence and interactions. It is important not to focus mainly on outputs. Reacting quickly to changes is only possible if they are recognised at an early stage and one can still intervene. It is therefore advisable to check whether there are signs of deviations from the target state at an early stage.

The definition of process boundaries is also of great importance. As a rule, process boundaries are always associated with a change of responsibility for the implementation of the respective activities. Thus, process indicators can also be used as a control instrument and target for organisational units. Here it is important to take into account the specific conditions in the company. For example, in a larger organisation the process "work preparation" can be considered separately from the actual production, whereas in small companies the same persons are responsible for both activities and consequently both should rather be seen as a common process.

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In the following table we present which process management requirements are to be fulfilled within the framework of the PDCA cycle.

| PDCA step | Checklist for planning | Norm-kapite | Process proofs | Documented information |
|---|---|---|---|---|
| **Plan Process Planning** | Inputs and desired results of their processes, sequence and interactions are defined. | 4.3-4.4 | Personnel planning, skills matrix, organisation chart; allocation of responsibilities and authorities | Scope;<br>Documented information as support for the implementation of processes;<br>Evidence that processes are carried out as planned |
| | Responsibilities and authorities are defined or reviewed. | 4.4, 5.3 | Investment planning, strategy, project plan, catalogue of measures | |
| | Resource needs have been identified. | 4.4, 5.1, 6.2 | Risk matrix, Turtle Model, FMEA, SWOT analysis, etc. | |
| | Risks directly related to the defined processes and customer expectations and requirements are identified. | 6.1 | Production plan, measurement concept, process landscape, budget planning | |

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| PDCA step | Checklist for the Planning | Standard chapter | Process proofs | Documented information |
|---|---|---|---|---|
| Do Process control | Processes and services are carried out as planned. | 8.1 | Production plan, measurement concept, process landscape, budget planning | Identify, maintain and retain documented information to the extent necessary to provide confidence that processes have been carried out as planned and that product and service conformity is demonstrably assured. |
| | Communication with clients is regulated. | 8.2 | Advertising materials, order confirmation/modification, complaint analysis, regulation for handling emergency measures, complaints | Documented information on the results of the review and on any new requirements for the products and services |
| | Requirements for products and services are defined and can be met. Accompanying change management is established. | 8.2.2.-8.2.4 | Specifications, offer/contract, order confirmation, change management | Adaptation of documented information in the event of changes to requirements for products and services |
| | The necessary development process (if applicable) is implemented and maintained. Accompanying change management is established. | 8.3 | Development project, requirements and specifications, project plan, measurement and test plan, FMEA, test report on changes, development report | Documented information on development inputs, control activities for the development process, development results, development changes |
| | The regulation of outsourced processes, products or services is defined and controlled. | 8.4 | Supplier evaluation, supplier audit, evaluation criteria, product specification with verification requirements, performance contract | Documented information on activities: Results of assessments,<br>Selection, performance monitoring as well as re-evaluation of external providers and on any necessary measures |

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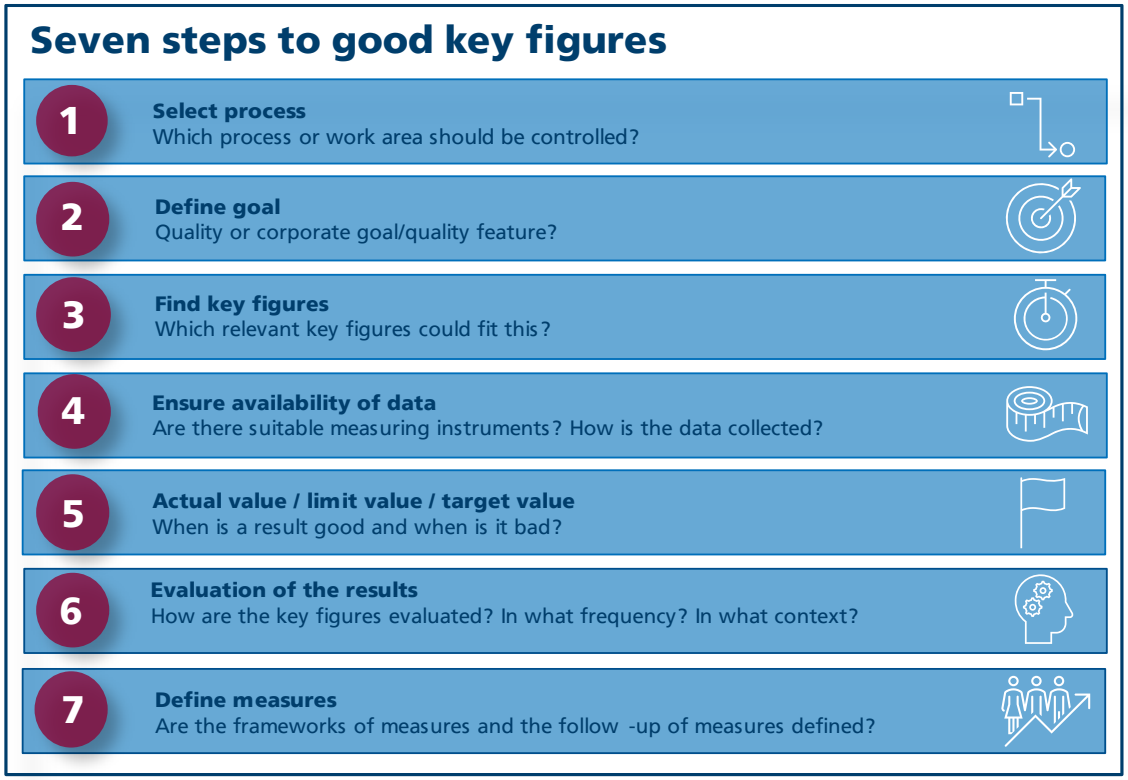
| PDCA step | Checklist for planning | Norm-kapite | Process proofs | Documented information |
|---|---|---|---|---|
| Check process monitoring | The appropriate and meaningful process metrics for the processes, production / DL and customer satisfaction are selected. | 9.1 | Process indicators, test certificates | Appropriate documented information as evidence of results on monitoring, measurement, analysis and evaluation |
| Act improvement | The causes of the non-conformities have been identified and the corrective actions are effective.<br>Process improvements are planned and implemented. | 10.2.2 | Internal audit report, overview of corrective and improvement actions | Documented information as evidence of the nature of the non-conformity as well as the measures taken and the results of corrective and improvement actions. |

In order to continuously improve processes and to be able to assess the process performance in your company, key figures are indispensable. A key performance indicator is a *"characteristic value that can be used to monitor and evaluate the performance of a process and to control it*.

ISO 9001:2015 requires in chapter 4.4.1 Quality management system and its processes that organisations determine processes that are required for the QMS. For this purpose, criteria and procedures must be defined and applied to ensure the effective performance and control of these processes through the associated performance indicators.




## QM key figures (examples)

- Product key figures (speed, consumption, service life, etc.)
- Process key figures (consumption / piece, raw material utilisation...)
- Operating figures (working hours / piece, m² / employee, energy demand / year, profits / year, sick leave...)
- Industry indicator (fleet consumption, value added / employees, resource friendliness, cyclicality, spec. energy dependency...)
- Time to recruit new employees, quota with successful probationary period, training costs / year, training hours / employee and year
- Complex: Training hours per employee and year x performance rating = training efficiency (HR department)
- Complaints per delivered unit, failure rate at customers in ppm, Scrap rate of production (QB / process capability)
  Proportion of A-rated suppliers accounting for 80% of sales, delivery punctuality, compliance with specifications (purchasing, incoming goods)
- Good parts per shift, throughput / day, cycle time, material turnover, machine times per part (production)
- Delivery punctuality, number of transport damages per delivery unit (e.g. freight forwarder)

## Typical findings on the topic of "process management" (example quotes from reports)

The most common findings in reports are on the following topics:

- **Lack of complete integration - or conversely separation of individual processes, no monitoring of the up-to-dateness of processes - e.g.**
  - The process for managing the documented information related to external communication is not integrated into the process description of communication management.
  - The existing register of hazardous substances is incomplete. The process of monitoring hazardous substances in the departments could not be traced.
  - The management of change (chapter 6.3) ISO 9001:2015 should follow a systematic process.
- **Representation of the process landscape and process description - e.g.**
  - Since the "service in house" process is currently no longer carried out, the process landscape should be revised.
  - Management documentation should be further streamlined. Processes should possibly be presented with a flow chart.
  - The process description for guiding documented information should be further specified, reviewed and, if necessary, supplemented in the area of documents by interested parties.
  - Process maps as the result of a bottom-up process (allocation of instructions) have been created for each company. An evaluation and, if necessary, adjustment of the process representations from a top-down perspective could be aimed for. A release of the process maps is not consistently recognisable. Information on document control should be integrated more clearly.

- **Selection of key performance indicators (KPI's) - e.g.**
  - Process indicators / process performance are partly only available as superordinate indicators for the company. A breakdown to individual operational processes does not take place consistently.
  - The key figures in the area of R&D do not yet specifically represent the actual performance in the projects. The formation of a key figure from the realisation of a spinning test or participation in a project meeting is not suitable for presenting performance in the sense of a process key figure.
    Key figures for the development process (monitoring of time and budget) should be introduced.
- **Measure evaluation - e.g.**
  - Process and instruments for monitoring measures (including evaluation of effectiveness) are not yet sufficient to underpin the top management's responsibility for continuous improvement and effectiveness of the system with sufficient data.
  - The use of an FMEA (Failure Mode and Effects Analysis) could support the process of action planning in action evaluation.
- **Internal audit - e.g.**
  - It is recommended that the Turtles Model already used in the process description also be used for internal audits to further improve their effectiveness.
    The questions for conducting the internal audits should take into account all processes and be supplemented with additional focal points.
- **Process audits - e.g.**
  - It would make sense for the process audits to take place more frequently. The topics could also be expanded continuously, at least twice a year.
  - A differentiation between system and process audits could be reconsidered.

## Conclusion Part 2

Process management is an essential component of any quality management. Quality refers to products and services, but above all to the processes used to produce them. If individual activities are carried out incorrectly or even omitted in the quality management processes, serious defects can occur in the products and services.

The process landscape of a company should always be oriented towards and reflect the activities of the company, not the strict requirements of the standard. Understanding the activities, their processes and interactions, the correct planning, execution and control and the appropriate action (PDCA) when errors occur is the key to effective quality management.

**In the next part of the publication series, we will look at the control concept (PDCA), its planning within a management system and effective error management.**

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