



### **PROLOG**



### Your trainer



**Dr. Anni Koubek**Executive Vice President Innovation,
Business Development
Certification Quality

### What exactly is ISO 9001?

ISO 9001 is a management system standard, which is voluntarily agreed on, and applied across the industry. This standard includes requirements for quality management. In order to implement ISO 9001, an organization should be able to meet customer requirements and enhance customer satisfaction. Since these concerns are vital for any organization, ISO 9001 can be applied in all sectors or industries.

https://shop.austrian-standards.at/action/de/public/details/553481/DIN EN ISO 9001 2015 11

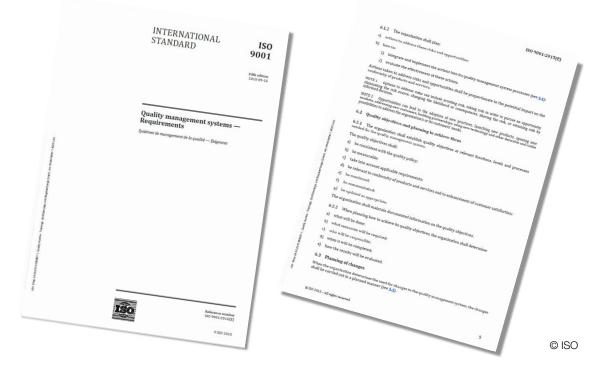


Fig. 1: ISO 9001:2015 standard



## **WHY IS ISO 9001 IMPORTANT?**



### What is "ISO"?

ISO is an abbreviation for "International Organization for Standardization", located in Switzerland. (Almost) every country in the world is represented in this organization and is working with "ISO". Each standard is subject to a voting process, in which all countries have to reach consensus. ISO has already published more than 20.000 standards, whereof ISO 9001 is the most widely used Standard, covering certification of more than 1 million companies and organizations. The work of preparing ISO Standards is normally carried out through technical committees (TCs) and sub-committees (SCs). The committee ISO TC/176/ SC2 is responsible for ISO 9001.

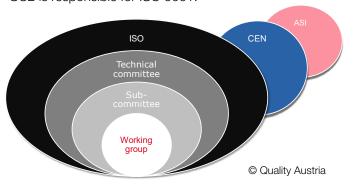


Fig. 2: Responsible parties in the development of ISO standards

CEN: European Institute for Standardization ASI: Austrian Standards International

### Quality management system

**ACHIEVING GOALS** 

#### competitive Advantage

INCREASING MARKET VALUE MARKET OPPORTUNITIES

COMPLIANCE WITH STANDARD REQUIREMENTS operative service quality

### **EMPLOYEE MOTIVATION**

SYSTEMATIC PREVENTION

promotional purposes OPTIMIZING PROCESSES legal certainty enhanced coordination

CONTINUOUS IMPROVEMENT BENEFITS OF A

RENTABILITY

Utilizing resources MANAGEMENT SYSTEM raising profits

DECREASING COSTS

decreasing error rates

AGILITY STRUCTURED KNOWLEDIGE BASE

BETTER ECONOMIC PERFORMANCE CLEAR STRATEGIC FOCUS

INCREASING OPPORTUNITIES

**COMPARABILITY** audits as opportunities

### improvement of material and energy efficiency

STRATEGIC PLANNING © Quality Austria

### **DECISION BASIS FOR MANAGEMENT**

SUSTAINABLE GROWTH

© Quality Austria

Fig. 3: Benefits of a management system

A quality management system can provide many benefits, if geared towards the goal of sustained success. In many cases, the decision on implementing ISO 9001 is taken on basis of customer requirements. When implementing ISO 9001, organizations should establish a customized management system, which is suitable for their own company, in order to avoid solutions that do more harm than good.

### Why do you need an ISO certification?

- Customer or potential customer or authority requests the certificate
- Internal decision framework for organizational development
- Both





# WHAT IS IN ISO 9001?

# HOW DO I IMPLEMENT IT?



# Process approach in quality management

ISO 9001:2015 is divided into 10 sections, the clauses 4 to 10 are requirements. The relationship between the individual clauses is illustrated in the figure below. Applying a process approach in a management system enables converting requirements into products and services, using a cycle of planning, implementation, evaluation and improvement. Leadership is one (or is THE) key element, and controls all areas of an organization. As a result, a high level of customer satisfaction can be achieved.

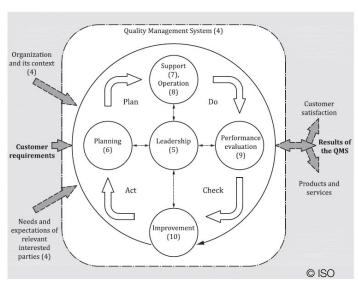
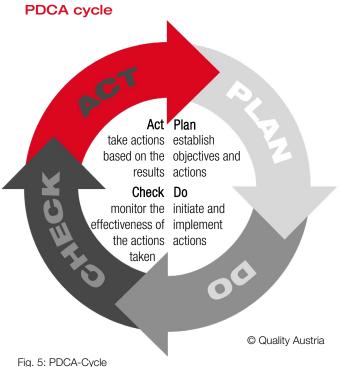


Fig. 4: ISO 9001:2015 Standard - relationships of the standard sections



The PDCA (Plan-Do-Check-Act) cycle is a key element of quality management and therefore, also of ISO 9001. It is the basis for continual improvement, learning from mistakes and the systematic achievements of objectives.

### **Process management**

The process approach, illustrated below using the example of a process flow, is another key concept of ISO 9001. The main requirements for establishing a sound process management are stated in section 4. Requirements relating to value-adding processes are described further in section 8. If your process management has already reached a high level of maturity, certification according ISO 9001 won't be a big challenge for you!

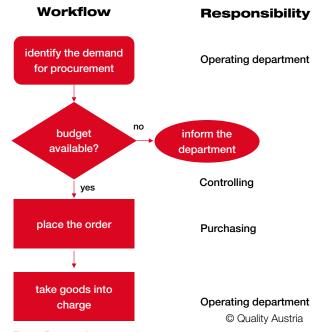
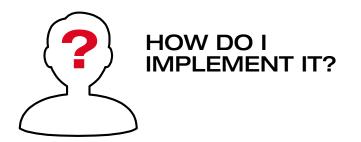


Fig. 6: Process flow example

www.qualityaustria.com 4





#### **Documentation**

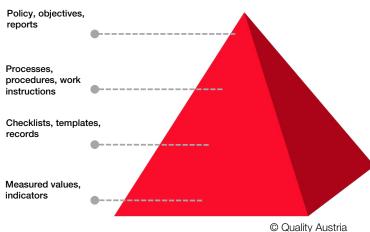


Fig. 7: Documentation pyramid

Although the importance of documentation has declined with the latest revision, it is – regardless of format or media – still a key element in structuring instructions and keeping evidence. The illustration above provides an example of a possible hierarchical structure of documentation. ISO 9001 requires, for example, to maintain policy and objectives as documented information. For other vital elements (such as processes, responsibilities ...), the standard requires to maintain and retain documented information as evidence (of competences, development results, approvals etc.).

### Risks & opportunities

The third basic concept of ISO 9001 is risk-based thinking (illustrated in the figure below as a risk matrix). Here, the primary objective is identifying opportunities and risks, and deriving actions. This can include opportunities in the field of markets, new products, or clients, and risks that affect the organization's ability to meet its objectives, whether at a strategical (e.g. changing political conditions), or an organizational level (e.g. the risk of incorrect operation of a machine). Addressing risks and opportunities is a central driving force for continual improvement.

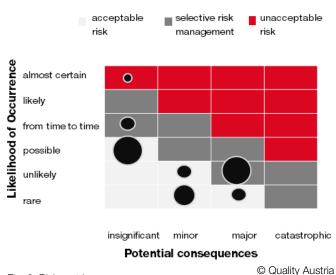


Fig. 8: Risk matrix

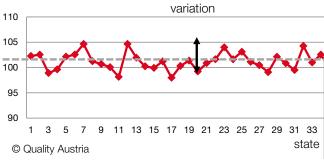


Fig. 9: State and variation measure

Key section "Operation"

- Planning the provision of products and services
- Requirements and customer communication
- Design and development
- Procurement / outsourcing
- Production / service provision
- Release
- Control of nonconforming outputs

www.qualityaustria.com 5



### **MY NEXT STEPS?**



### **International Training Programme**

We offer a variety of certification programmes, qualification programmes and online courses in different fields. All certification and qualification programmes described in the folder <a href="International Training Programme">International Training Programme</a> are offered as in-house trainings and partly as public trainings through selected international **quality**austria partners.



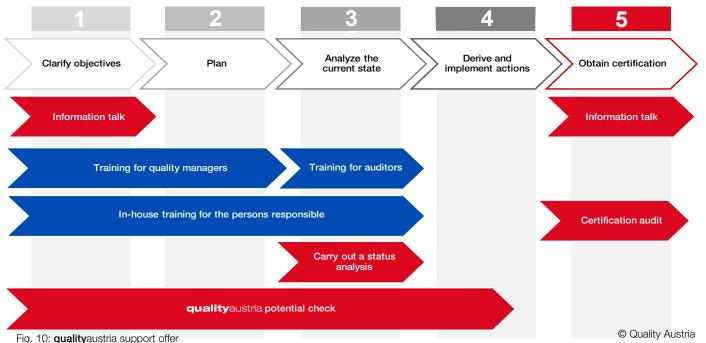






### A bit of flexibility please?

- presence training
- virtual training
- blended training



### How can we support you?

Benefit from our **quality**austria services – please feel free to contact us, we are happy to help!

If you have any questions concerning our trainings offered, please contact our Customer Service Center:

Tele.: +43 732 34 23 22 office@qualityaustria.com

In case of suggestions / feedback, please contact Ms. Andrea Schwarz andrea.schwarz@qualityaustria.com.

www.qualityaustria.com 6