
Lecture Quality Management

02 Normative Quality Management Systems

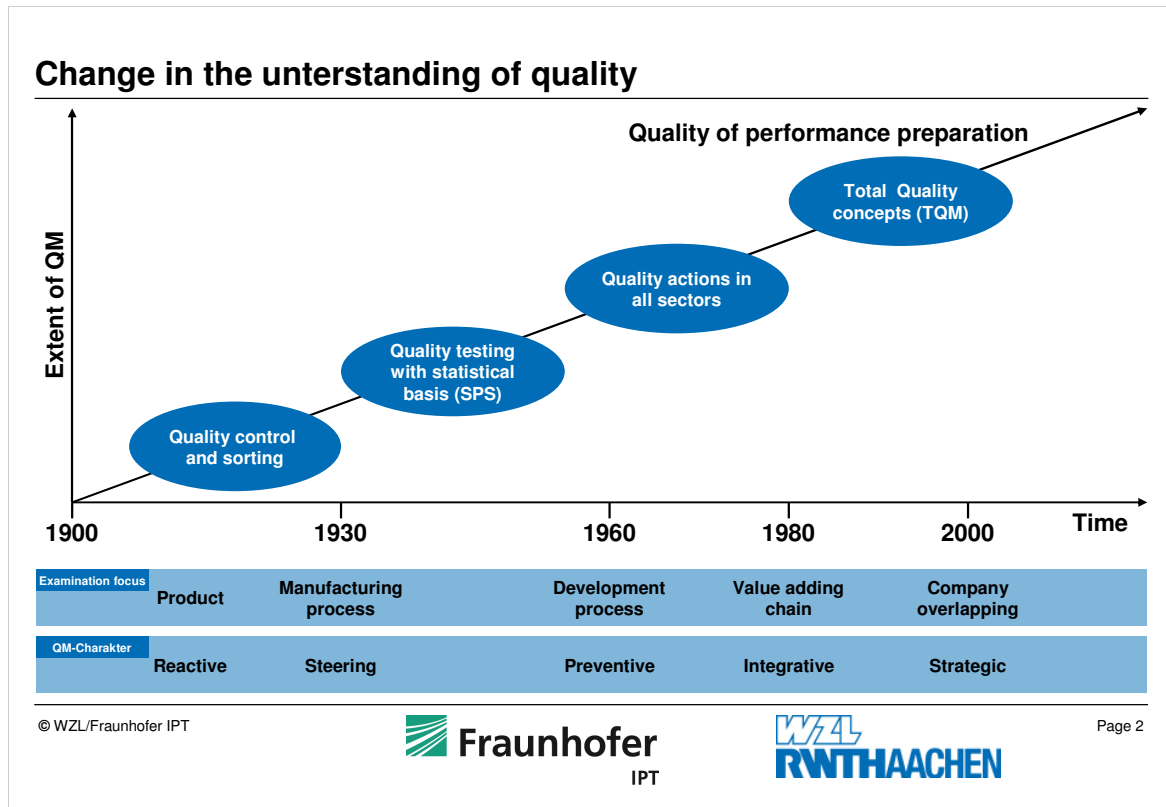
Prof. Dr.-Ing. Robert Schmitt

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Contents

- **Total Quality Management (TQM)**
 - Quality Management and Standards**
 - Basics of Quality Management Systems**
 - Implementation of QM Systems**
 - Documentation of QM Systems**
 - Auditing and Certification**



Total Quality Management (TQM)

In the 20's Quality was only seen as product quality. There was a separate department, called „quality control“, which did a final inspection, followed by sorting out nonconforming parts.

With the progressing industrialisation and increasing mass production in the 30's, controlling methods for quality assurance like Statistical Process Control (SPC) have been developed. Quality assurance became a task of the production. The objective was not to make failures during the production process.

In the 60's preventive methods have been developed like the Failure Mode and Effect Analysis (FMEA) or Design Reviews. Thereby, product as well as process quality are considered. Quality has already been considered from the development and as an interdisciplinary approach. But the main focus of the quality assurance still laid in the technical sector.

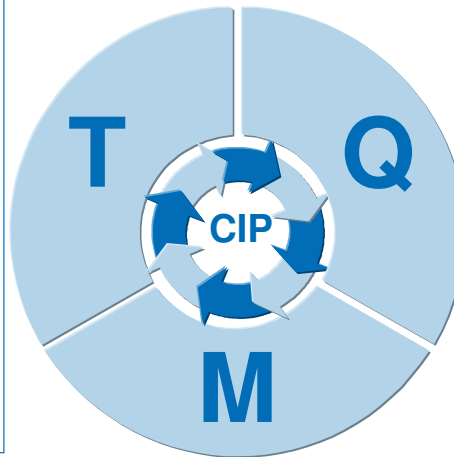
Total quality concepts which focus on the customer requirements have been developed in the 90's. Every employee and company sector should be qualified to make the right decisions. Department thinking should be replaced by process thinking. Quality is seen as a strategic competition factor.

This new understanding of quality reflects the principles of Quality Management.

The Term „Total Quality Managements“

TOTAL

- **Process orientation**
Trans-sectoral
- **Customer orientation**
Good relationship to customers and suppliers
- **Employee orientation**
Involvement of the whole personnel of the organisation
- **Society orientation**
Dialogue- and participation-oriented public relations



QUALITY

- Quality of the company
- Quality of work
- Quality of potentials
- Quality of processes
- Quality of results

MANAGEMENT

- Quality as leadership task
 - Well-considered actions
- Leadership quality (exemplar role)
 - Team- und learning capability
 - Perseverance

CI: Continuous improvement

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Page 3

The term Total Quality Management (TQM) consists of three constituents, which should be understood in the context of this management concept as follows:

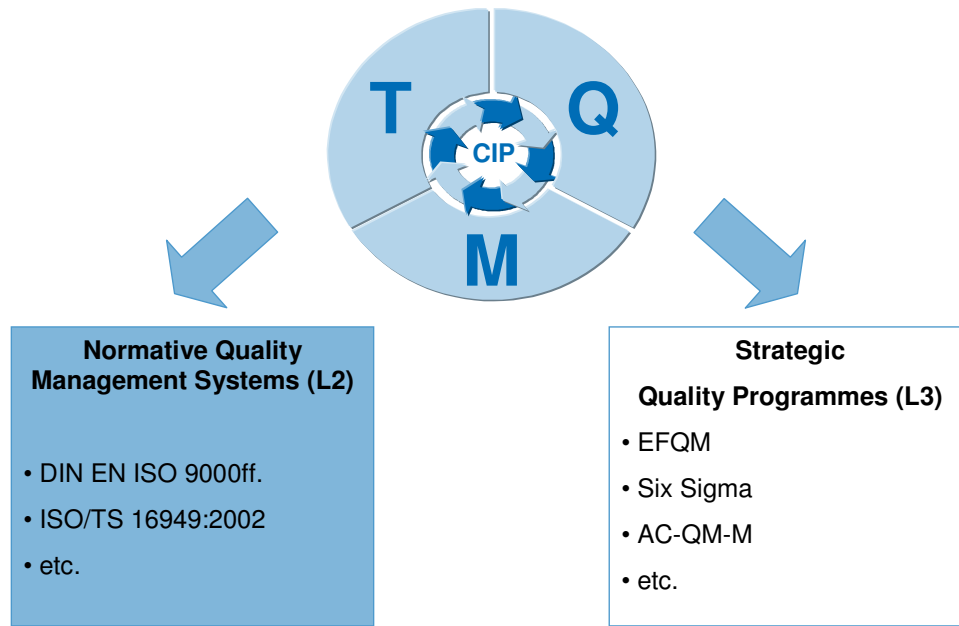
Total shows that TQM is concerned with a comprehensive approach. TQM asks for

- company-wide introduction,
- participation of all employees,
- optimisation of the company processes,
- partnership relation with customers and suppliers as well
- orientation of the company to the interests of the public,

The second term Quality refers not only to the products but also to the aspects of working environment, resources, employees, processes and thus to the entire company quality.

The third term of TQM is Management. It defines all active guidance, planning, control and monitoring activities in the company.

Characteristics of TQM



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- Implementation of QM Systems**
- Documentation of QM Systems**
- Auditing and Certification**

Literature:

- DaimlerChrysler, Ford, General Motors: *QS-9000 Quality System Requirements*. Detroit, 1998 – Firmenschrift
- DIN EN ISO 9000:2005: *Quality management systems: Fundamentals and vocabulary*
- DIN EN ISO 9001:2008: *Quality management systems: Requirements*
- DIN EN ISO 9004:2000: *Quality management systems: Guidelines for performance improvements*
- Gaster, D.: DGQ – Schrift 12-63: *Systemaudit*. 2. Auflage. Berlin: Beuth, 1993
- Gaster, D.: DGQ – Schrift 13-41: *Produkt- und Verfahrensaudit*. 2. Auflage. Berlin: Beuth, 1995
- Griese, J.; Sieber, P.: *Betriebliche Geschäftsprozesse: Grundlagen, Beispiele, Konzepte*. Bern; Stuttgart; Wien: Haupt, 1999
- ISO/TS 16949:2002: *Quality management systems -- Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations*
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- Prefi, Th.: *Entwicklung eines Modells für das prozessorientierte Qualitätsmanagement*. Dissertation an der RWTH Aachen; Beuth Verlag (FQS-Schrift 92-02) Frankfurt am Main, 1995
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- VDA Band 6: *Grundlagen für Qualitätsaudits*. 1. Auflage, 1998
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Industry-Specific Requirements for QM Systems

Demands for QM systems	Mechanical & plant eng.	Automotive Industry	Aerospace	Medical Technology	Telecommunications	Comestibles	Service	External testing laboratory
DIN EN ISO 9001	●	●	●	●	●	●	●	●
ISO TS 16949		●						
VDA 6.1		●						
VDA 6.2						●		
VDA 6.4	●							
KTQ				●				
DIN EN ISO 13485				●				
ALS 9100			●					
TL 9000					●			
HACCP						●		

Quality Management and Standards

The requirements of DIN EN ISO 9001 are not sector-specific.

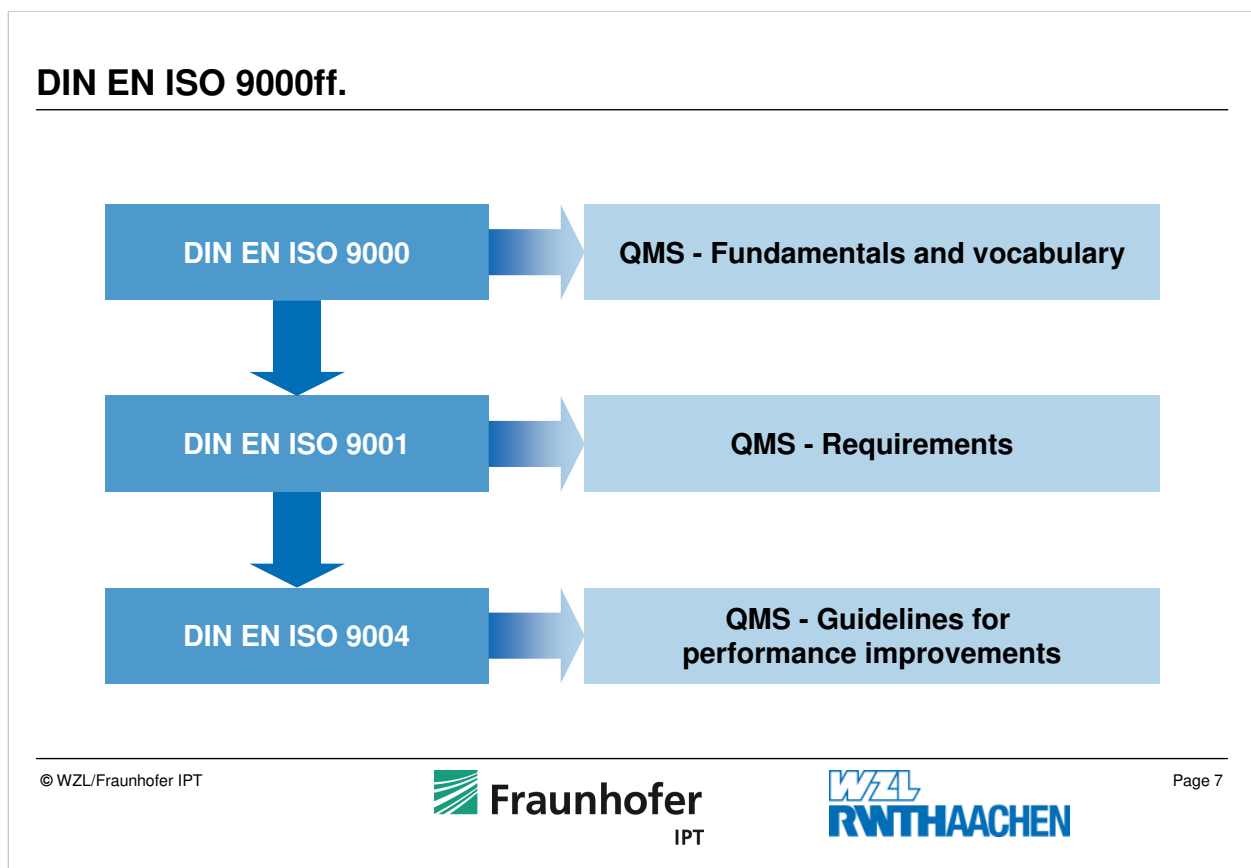
Above is a collection of sector-specific requirements to QM systems without any claim to be complete. The list of existing requirements to QM systems is considerably longer.

QS Quality System Requirements

VDA Verband der Automobilindustrie (Automotive industry association)

KTQ Kooperation für Transparenz und Qualität im Gesundheitswesen
(Cooperation for transparency and quality in health care)

HACCP Hazard Analysis and Critical Control Point



The objective of DIN EN ISO 9000ff. is not to standardize the quality management itself but the requirements. The standard has a general character because of its validity for every sector and company size.

The series of standards is divided in the following standards:

- DIN EN ISO 9000: QM Systems – fundamentals and vocabulary; This standard is the basis to understand the standards by explaining the principles of Quality Management Systems, the significant terms and their definitions.
- DIN EN ISO 9001: QM Systems: Requirements; The certification is based on this standard. It establishes the international requirements for Quality Management Systems. It provides a basis for the evaluation of the organisation's capability by fulfilling the requirements of customers and other interested parties.
- DIN EN ISO 9004: Guidelines for performance improvements; The guideline is an interpretation amendment and support of the DIN EN ISO 9001:2008 and bases on these principles. It gives suggestions and recommendations for a continuous improvement of the QM System to satisfy sustainably every interested party.

Quality Management Principles

Customer focus

Leadership

Involvement of people

Process approach

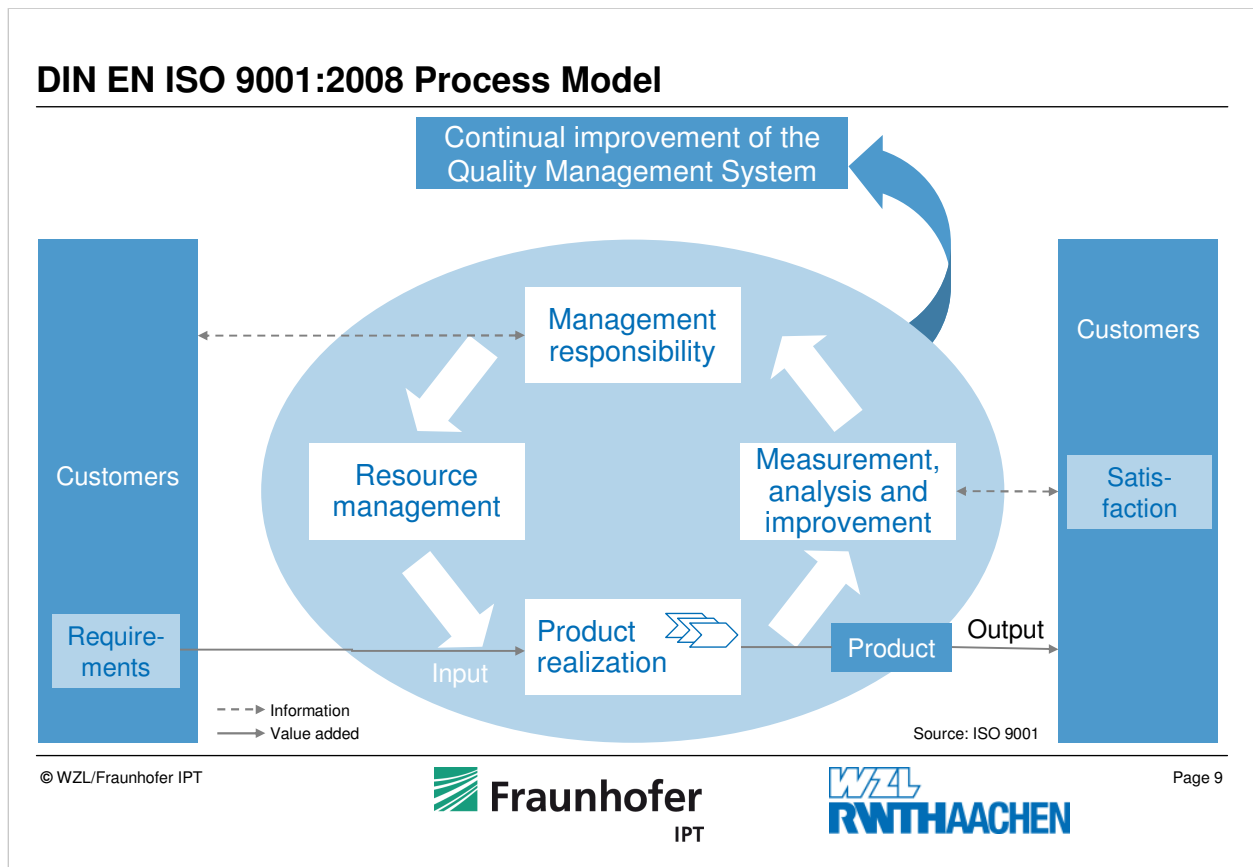
System approach to management

Continual improvement

Factual approach to decision making

Mutually beneficial supplier relationships

According to the ISO 9000ff. eight Quality Management principles have been identified that can be used by top management in order to lead the organisation to improved performance.

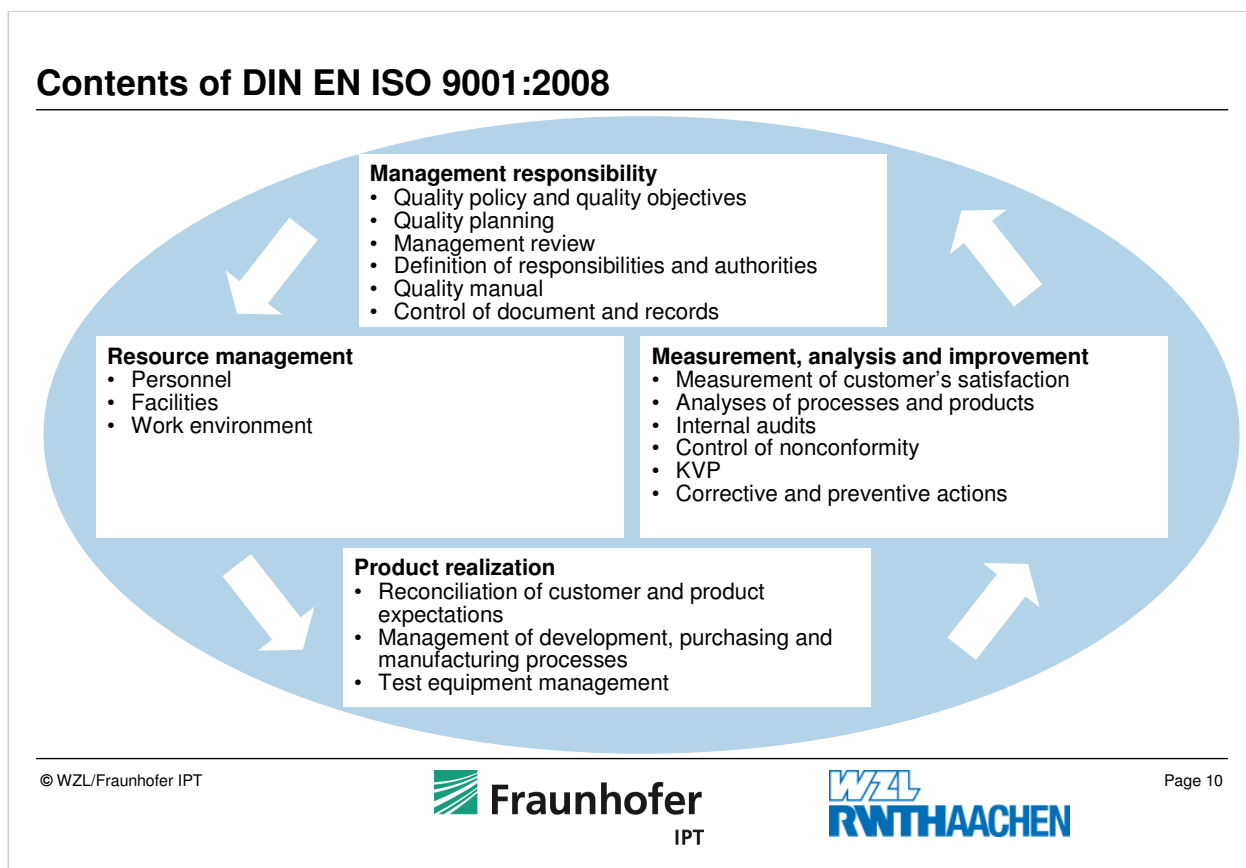


The standard DIN EN ISO 9001:2008 is based on a process model, which demonstrates the structural relation between the components of a QM system.

The most important quality control loop in the QM process model extends beyond the organisation and includes the customer and all stakeholders or other interested parties (thin arrows). The management specifies which group of customers should be served by the company's output. The demands of these defined target groups are the basis for the main specifications for the company-specific (core) processes. The quality of these processes essentially determines the level of satisfaction of the stakeholders. This satisfaction is systematically and continuously recorded by the analysis processes of the QM System and corresponding reports are submitted to the management.

The resultant corrective actions, taken in order to improve customer satisfaction and to increase the effectiveness of the QM System, trigger the operation of the quality control loop. The result is continuous improvement.

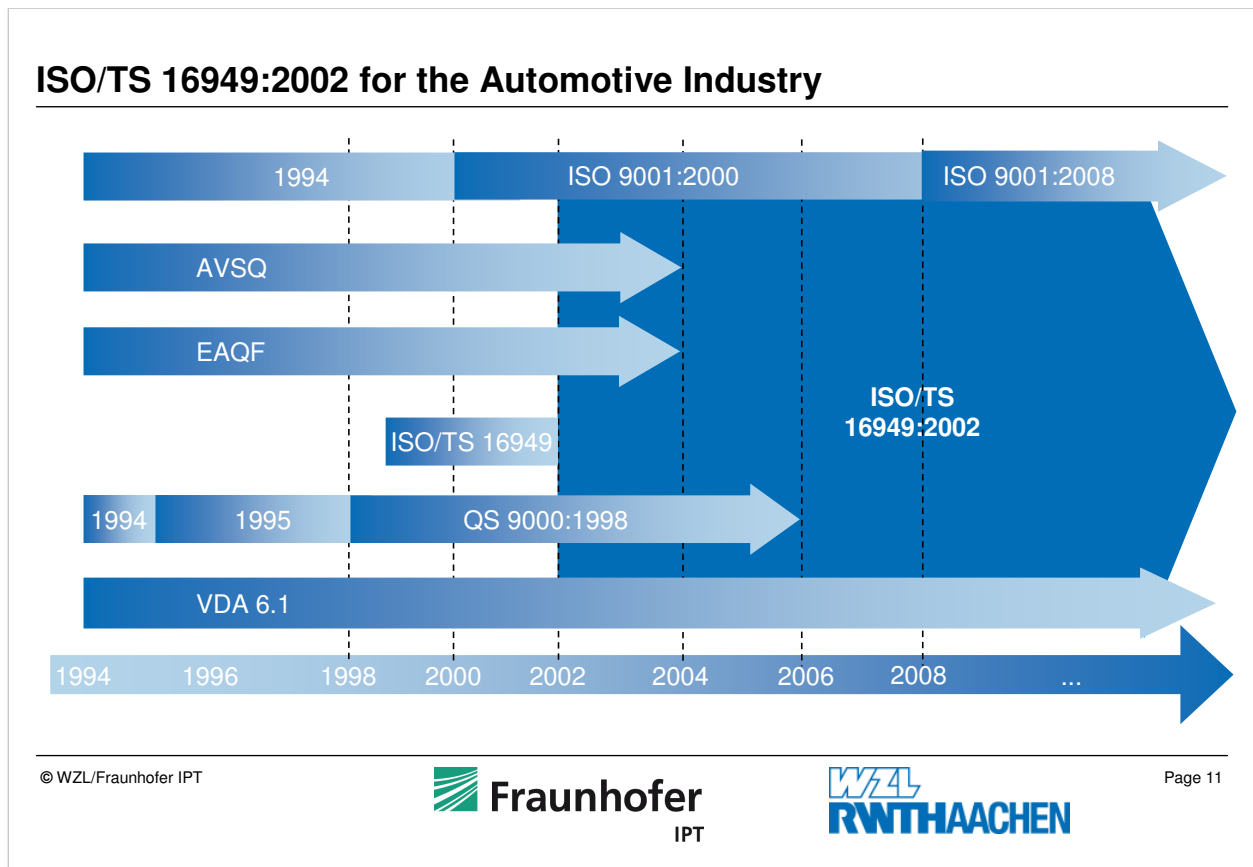
The inner quality control loop (thicken arrows) symbolises the correlation of the demands for QM systems.



The requirements, defined in DIN EN ISO 9001, are divided in four modules:

- The headline „management responsibility“ defines all requirements directed to the management.
- The organisation must demonstrate, how every needed action for customer oriented product realisation is identified and provided.
- Embraced by the term product realisation the steps planning and checking of inputs, realization and evaluation are summarised (cp. PDCA-cycle).
- The organisation must plan and establish actions for measurements, analysis and improvement of processes.

The picture above summarises the requirements of DIN EN ISO 9001. Please check the standard for detailed requirements.



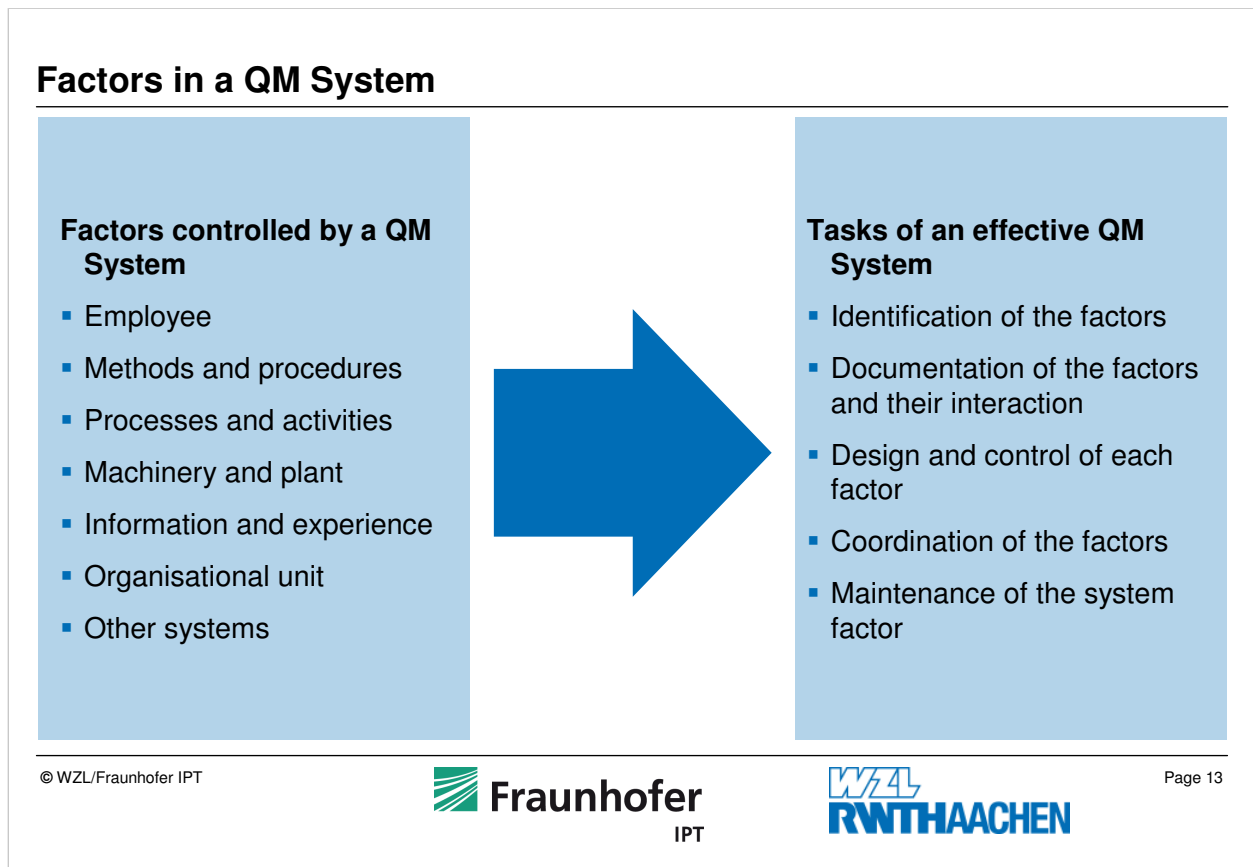
ISO/TS 16949:2002 is based on ISO 9001:2000 but includes additional requirements for the automotive industry. It was developed by the International Automotive Task Force (IATF) and published by the ISO.

In the past, there were often multiple certifications because there were different certifications in the different European countries and in America e.g. QS 9000 in the USA, VDA 6.1 in Germany, EAQF in France and AVSQ in Italy. The ISO/TS 16949:2002 changes this situation, all European and American automotive producers have approved it as the overall producer standard.

EAQF:	Evaluation Aptitude Qualité Fournisseur (Citroen, Peugeot, Renault)
AVSQ:	Associazione nazionale die valutatori di sistemi qualità (Fiat)
QS:	Quality System (DaimlerChrysler, Ford, GM)
VDA:	Verein der Automobilindustrie (Volkswagen, Audi) (Automotive industry association)

Contents

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Fundamentals of Quality Management Systems

In Quality Management a multiple number of factors must be considered, coordinated and controlled.

Quality Management Systems have to integrate these factors in a continuous system to manage and design them successfully in the company. Therefore, relevant factors like core processes must be identified, documented and displayed transparently for every involved employee. Besides the factors, the system describes their control and coordination.

Another function of the Quality Management System und its documentation is the provision of the basis to retain and maintain the integrated factors in the system to facilitate continuous improvement of the companies' performance in that way.

Quality Management Systems Approach

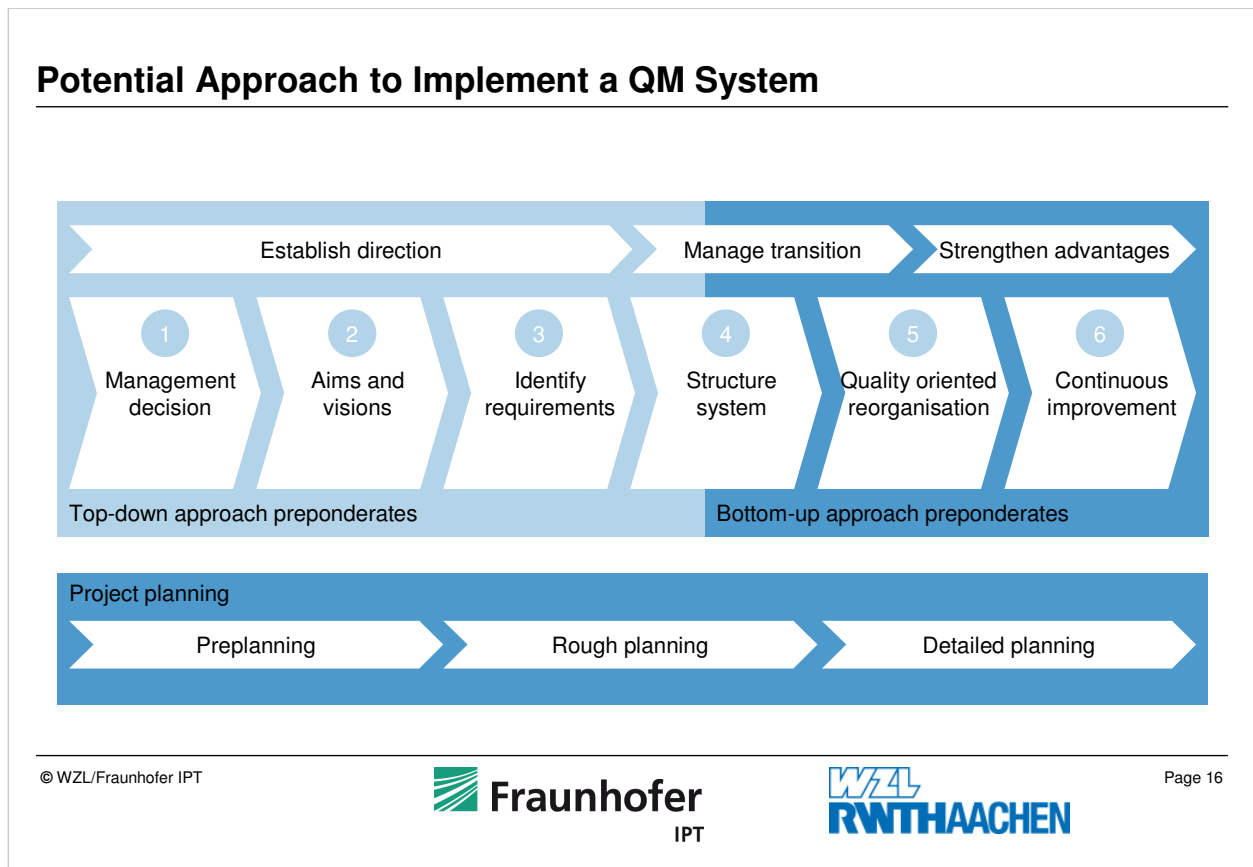
1. Determine the needs and expectations of customers and other interested parties.
2. Establish the quality policy and quality objectives of the organisation.
3. Determine the processes and responsibilities that are necessary to achieve the quality objectives.
4. Determine and provide the resources necessary to achieve the quality objectives.
5. Establish methods to measure the effectiveness and efficiency of each process.
6. Apply these measures to determine the effectiveness and efficiency of each process.
7. Determine means of preventing nonconformities and eliminating their causes.
8. Establish and apply a process for continuous improvement of the quality management system.

The ambition of every company is to fulfill at best and, if applicable, to exceed every requirement of every interested party into the internal environment of the company. Interested parties are customers and investors, but also employees, cooperation partners/suppliers and the public. The company provides excellent quality if the expectations of these interested parties are completely satisfied.

In this area of conflicts the Quality Management System describes every needed procedure and process, competencies and needed equipment/resources, that are used to ensure quality. The principles of QM Systems are the formulation and the spreading of the quality policy, where the management demonstrates their commitment to quality, validates their understanding of quality and procure them to the employees and defines unambiguous, measurable quality objectives stated at assessed improvement of quality and proved effectiveness of a QM System.

Contents

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- Basics of Quality Management Systems**
- **Implementation of QM Systems**
- Documentation of QM Systems**
- Auditing and Certification**



Implementation of Quality Management Systems

The implementation of a Quality Management System is a complex project, involving changes to the whole organisation and for each employee. That's why the implementation should be figured out and planned well. Specific objectives, tasks and products of the organisation must be accounted.

The risk that the Quality Management System is not accepted or does not work should be kept as small as possible. In this context the implementation strategy is important.

The implementation strategy is described by the three stages „establish direction“, „manage transition“ and „strengthen advantages“. Furthermore the tasks are divided in top-down approach managing tasks and tasks consisting of self dependent partial results and which therefore need a bottom-up approach.

The presented approach of the implementation of a quality management system is divided in six sections, which can be divided in further single steps.

Management Decision



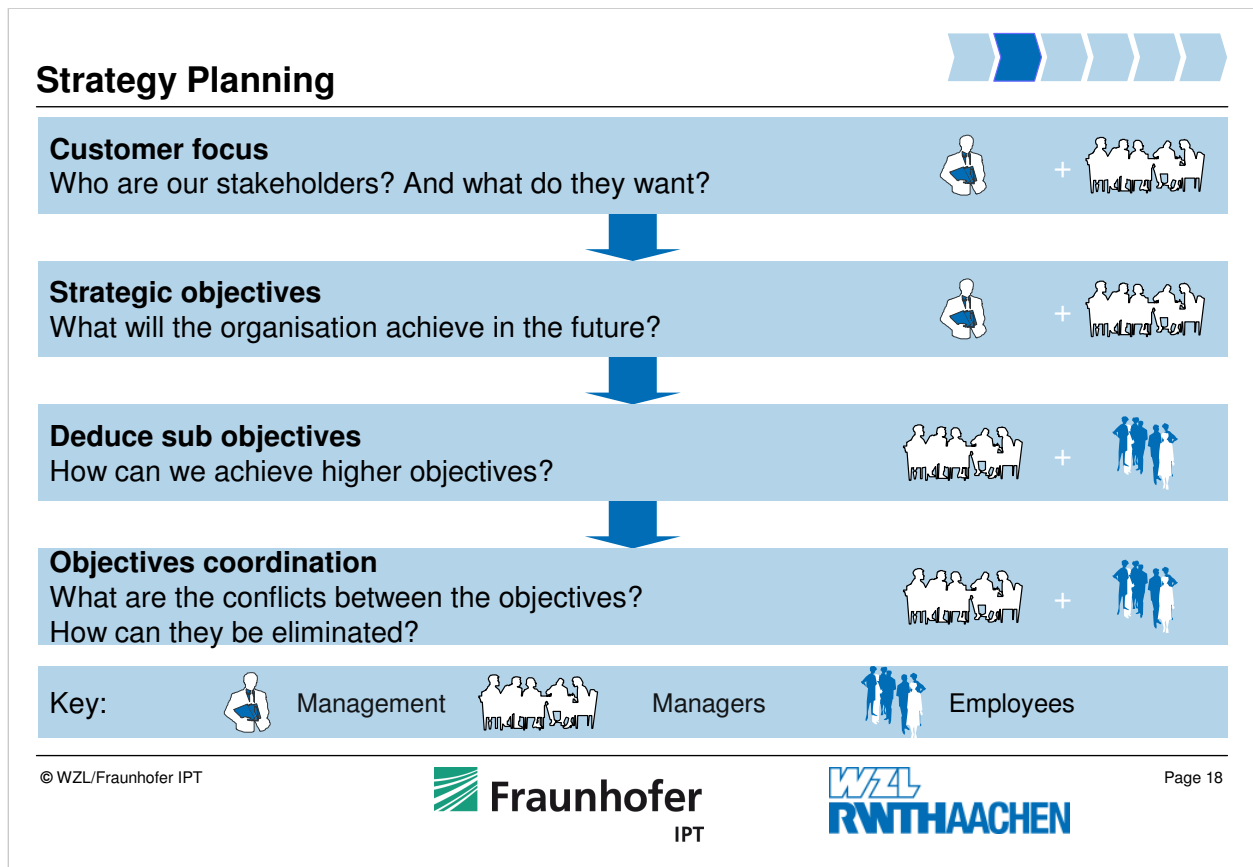
- Management decision
- Training managers
- Informing employees

Before the implementation starts, the management must decide if they want to take the chance to improve the procedure and structure of the organisation by implementing a continuous QM system. At the same time they must decide if they are ready to get involved and actively support the implementation.

After the decision the management must reveal the relevance, the possibilities and advantages of a total Quality Management to the managers.

The managers must become promoters who not only understand the concept but carry it out because they recognise the advantages and see the possibilities for their personal development. They must be able to procure the ideas and objectives of a systematic Quality Management to the employees.

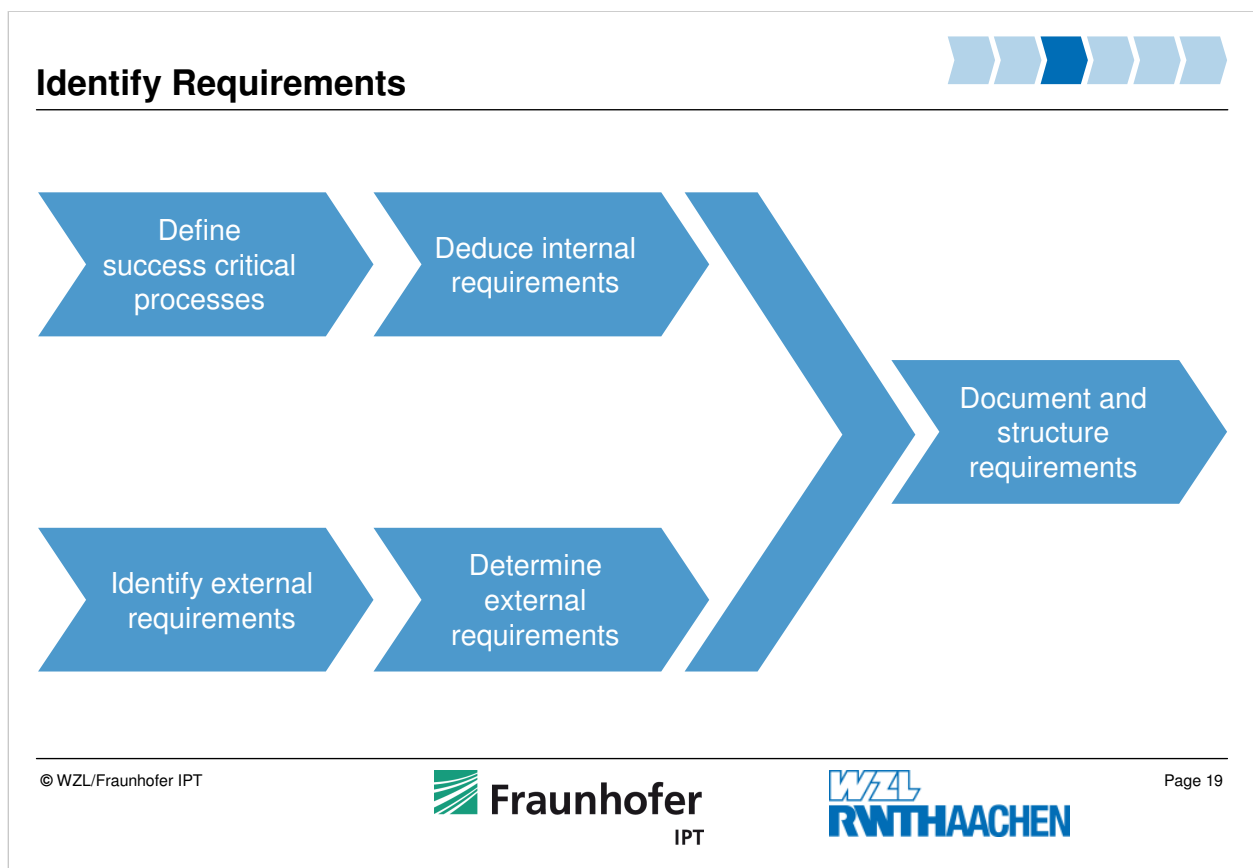
Generally, the employees must be informed extensively right from the beginning and usually the information demand increases in the course of the project.



A task of strategic planning is to develop a structured objective system for a company.

In principle, the strategic planning is a management task and occurs after the Top-down principle. It can be divided into four steps.

Every employee should be continuously informed during the strategic planning because the information demand of the employees is generally very high.

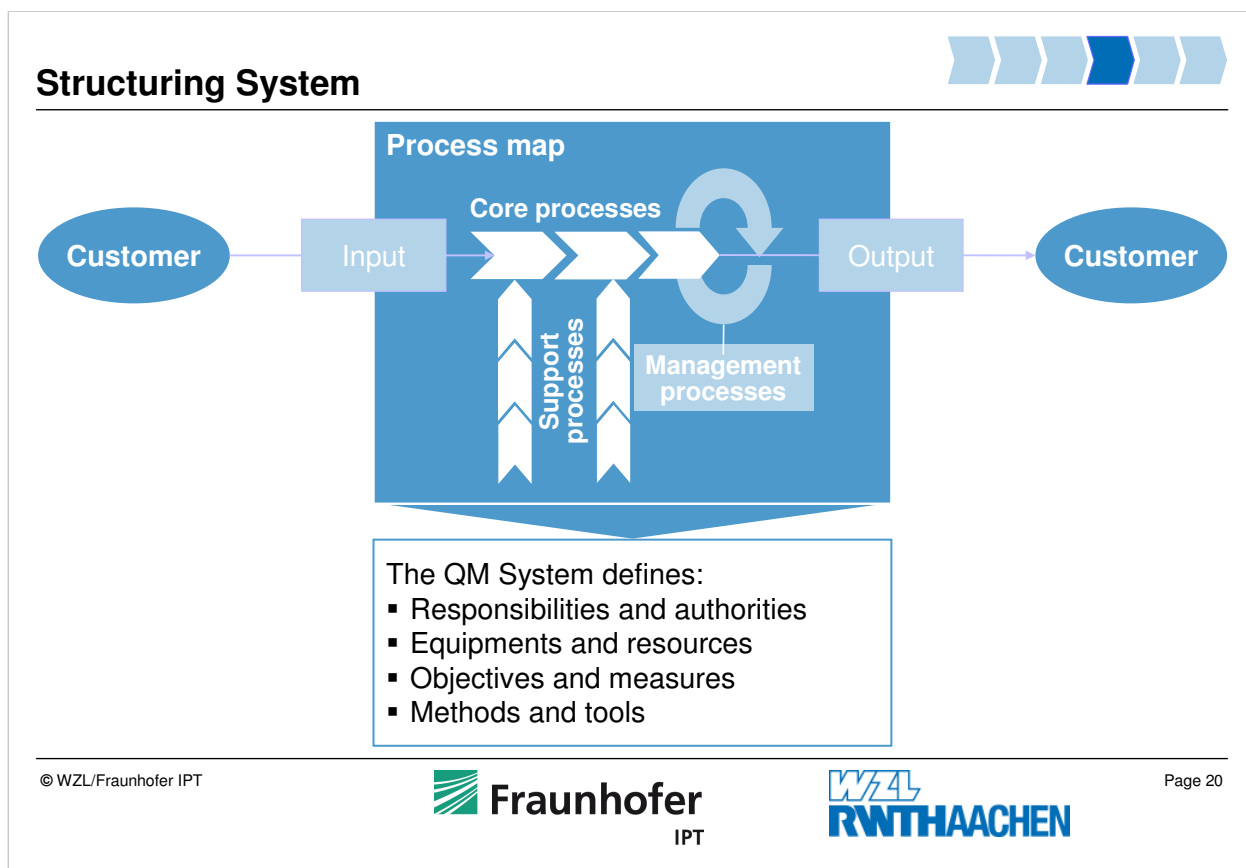


Once a system of objectives has been set up and the structures and processes have been analysed, internal requirements for the Quality Management and its structure must be established on the basis of these results.

According to obtaining certification at a later date it makes sense, to take account of the external demands, e.g. those imposed on systematic Quality Management by DIN EN ISO 9001 and the EFQM-model, as well as of the internal demands.

As a rule, the internal demands previously specified cover the majority of the external ones.

Consideration of both internal and external demands ensures that a consistent system is developed.



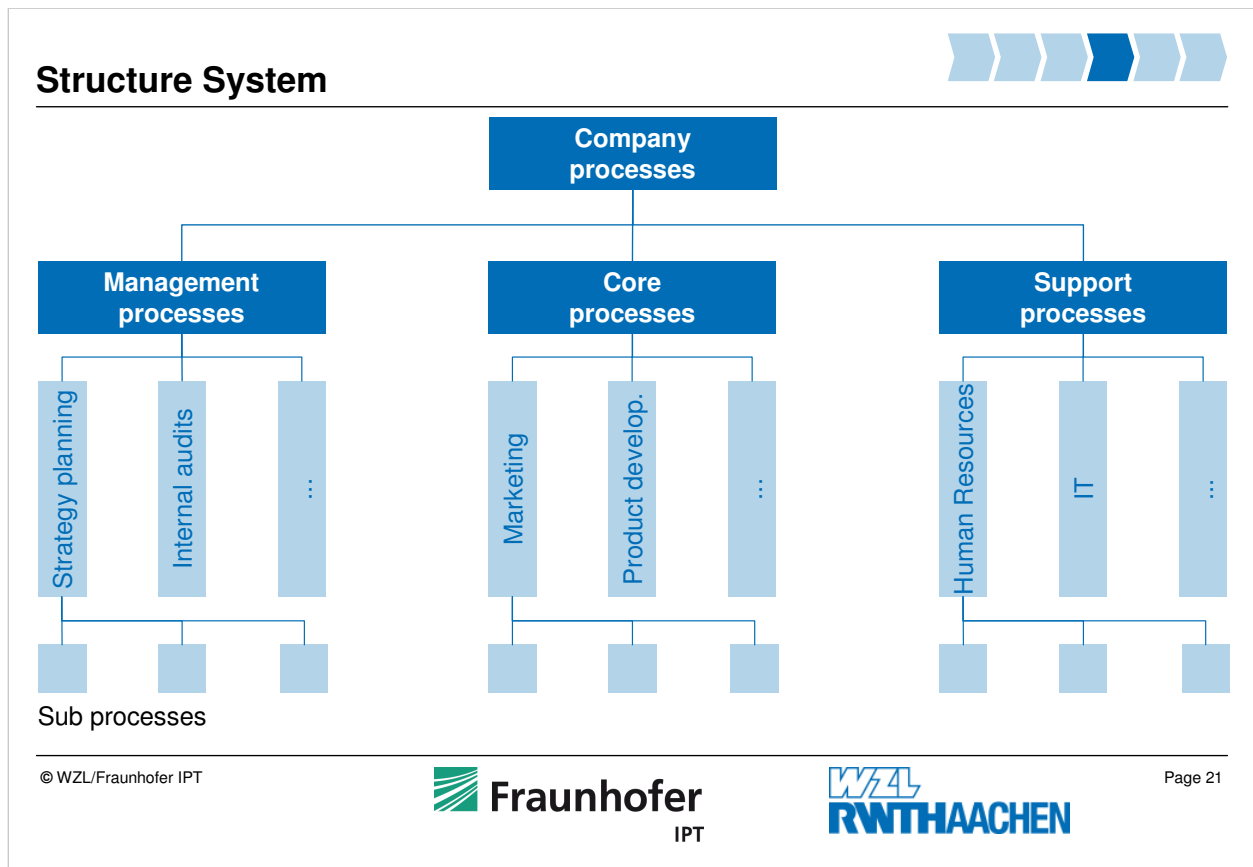
The company processes can be divided into three categories in order to simplify process identification:

- Management processes
- Core processes
- Support processes

The types of processes listed can coherently be presented in one company's process road map.

The process-oriented QM System organises the provision of quality assurance measures for each of these processes via

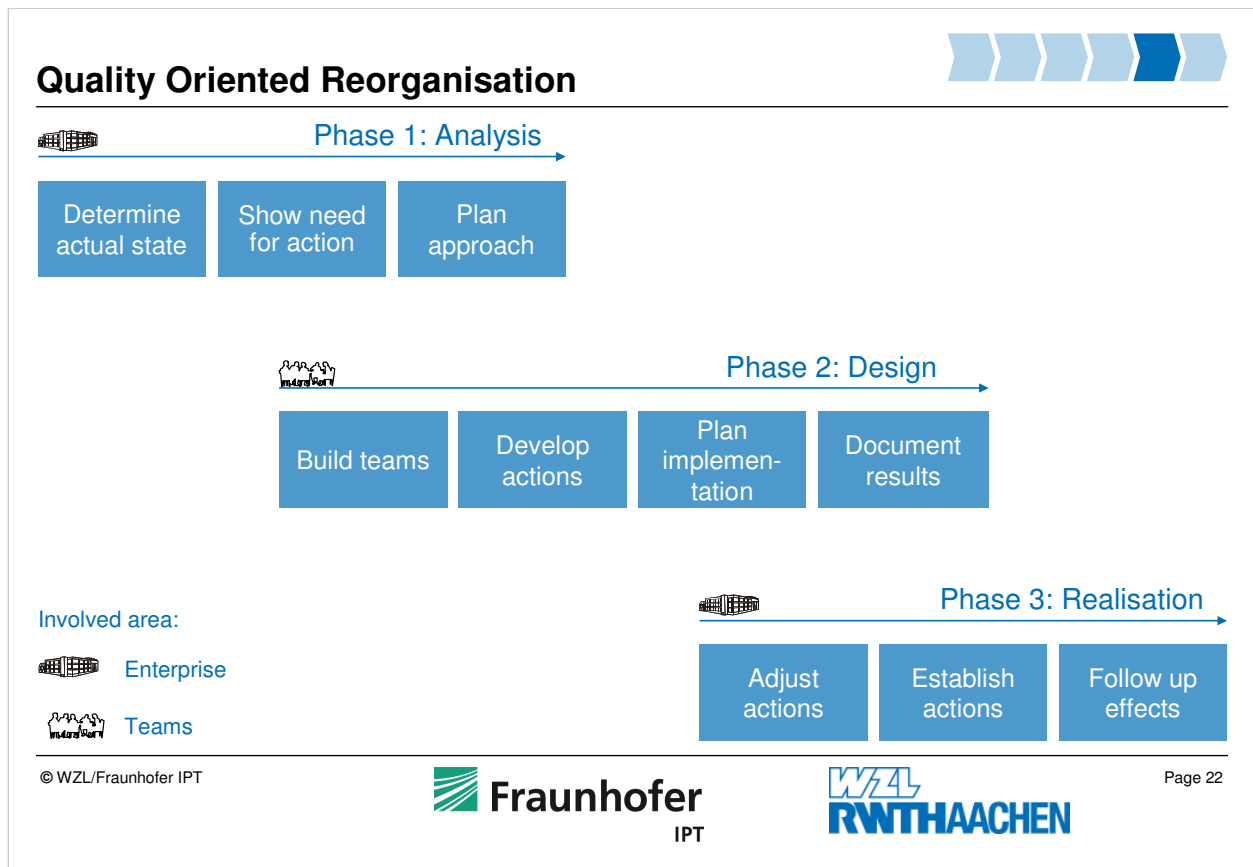
- Definition of responsibilities and authority
- Process-related assignment of funds and resources
- Specification of process objectives and assignment of measuring quantities in order to determine process quality and
- assignment of techniques, tools and instruments to assure and continuously improve quality



Like the process analysis, the Quality Management System is structured using an approach which structures the higher levels deductively, i.e. top-down and the lower levels inductively, i.e. bottom-up.

On the first structural level, a distinction should be drawn between three groups: “management processes”, “core processes” and “support processes”.

A process encompasses various sub-processes, measures and controls which are developed from the internal and external requirements in the design phase of the quality-oriented reorganisation operation. The outcome is a Quality Management System structure spanning three levels.



Quality-oriented reorganisation comprises three phases: analysis, design and realisation. Each of the individual phases again consists of various steps. Each step and each phase generally base on previously acquired information or on obtained results. The steps and phases should therefore be performed sequentially.

It is important that these ten steps are mainly performed by employees. The design of the quality system is bottom-up and not top-down like the first steps of the introduction. A cooperative leadership and the participation of all employees decrease the risk, that the system will not be accepted and not be assimilated by the employees.

Contents

- Total Quality Management (TQM)**
- Quality Management and Standards**
- Basics of Quality Management Systems**
- Implementation of QM Systems**
- **Documentation of QM Systems**
- Auditing and Certification**

Documentation of Quality Management Systems

Documentation enables communication of intent and consistency of action.

Its use contributes to

1. achievement of conformity to customer requirements and quality improvement,
2. provision of appropriate training,
3. repeatability and traceability,
4. provision of objective evidence, and
5. evaluation of the effectiveness and continuing suitability of the quality management system.

Generation of documentation should not be an end in itself but should be a value-adding activity.

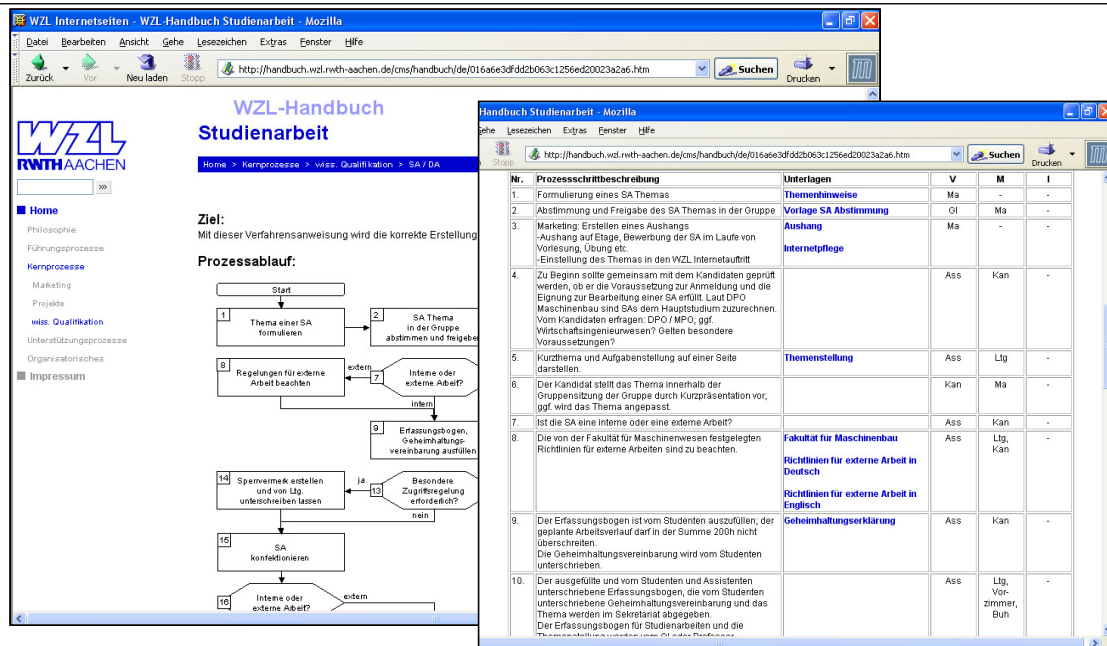
Types of Documents

Quality manuals	Information about the Quality Management System
Quality plans	Description how Quality Management is applied
Specifications	Requirements
Guidelines	Recommendations or suggestions
Documented procedures, work instructions and so on	Information, how to perform activities and processes consistently
Records	Objective evidence of activities performed or results achieved

The Following Types of Documents Are Used in Quality Management Systems:

1. Quality manuals: provide consistent information, both internally and externally, about the organisation's Quality Management System.
2. Quality plans: describe how the Quality Management System is applied to a specific product, project or contract.
3. Specifications: state requirements.
4. Guidelines: state recommendations or suggestions.
5. Documented procedures, work instructions, drawings and so on provide information about how to perform activities and processes consistently.
6. Records: provide objective evidence of performed activities or achieved results.

Electronic Documentation of a QM System



Ziel:
Mit dieser Verfahrensweisung wird die korrekte Erstellung

Prozessablauf:

```

    graph TD
      Start([Start]) --> 1[1. Thema einer SA formulieren]
      1 --> 2[2. SA Thema in der Gruppe abstimmen und freigeben]
      2 --> 3[3. Marketing: Erstellen eines Aushangs  
-Aushang auf Etage, Bewerbung der SA im Laufe von Vorlesung, Übung etc.  
-Einstellung des Themas in den WZL Internetauftritt]
      3 --> 4[4. Zu Beginn sollte gemeinsam mit dem Kandidaten geprüft werden, ob er die Voraussetzung zur Anmeldung und die Eignung zur Bearbeitung einer SA erfüllt. Laut DPO Maschinenbau sind SAs dem Hauptstudium zuzurechnen. Vom Kandidaten erfragen: DPO / MPO, ggf. 'Wirtschaftsgenuewessen'? Gelten besondere Voraussetzungen?]
      4 --> 5[5. Kurzthema und Aufgabenstellung auf einer Seite darstellen.]
      5 --> 6[6. Der Kandidat stellt das Thema innerhalb der Gruppensitzung der Gruppe durch Kurzpräsentation vor, ggf. wird das Thema angepasst.]
      6 --> 7[7. Ist die SA eine interne oder eine externe Arbeit?]
      7 --> 8[8. Die von der Fakultät für Maschinenwesen festgelegten Richtlinien für externe Arbeiten sind zu beachten.]
      7 --> 9[9. Der Erfassungsbogen, Geheimhaltungsvereinbarung ausfüllen]
      8 --> 10[10. Der ausgefüllte und vom Studenten und Assistenten unterschriebene Erfassungsbogen, die vom Studenten unterschriebene Geheimhaltungsvereinbarung und das Thema werden im Sekretariat abgegeben. Der Erfassungsbogen für Studienarbeiten und die...]
      9 --> 10
      10 --> 11[11. Sperrmemek erstellen und von Ltj. unterschreiben lassen]
      11 --> 12{12. Besondere Zugangsregelung erforderlich?}
      12 -- ja --> 13[13. Sperrmemek erstellen und von Ltj. unterschreiben lassen]
      12 -- nein --> 14[14. SA konfektionieren]
      13 --> 14
      14 --> 15[15. Interne oder externe Arbeit?]
      15 --> 16[16. Interne oder externe Arbeit?]
    
```

Nr.	Prozessschrittbeschreibung	Unterlagen	V	M	I
1.	Formulierung eines SA Themas	Themenhinweise	Ma	-	-
2.	Abstimmung und Freigabe des SA Themas in der Gruppe	Vorlage SA Abstimmung	GI	Ma	-
3.	Marketing: Erstellen eines Aushangs -Aushang auf Etage, Bewerbung der SA im Laufe von Vorlesung, Übung etc. -Einstellung des Themas in den WZL Internetauftritt	Aushang Internetpflege	Ma	-	-
4.	Zu Beginn sollte gemeinsam mit dem Kandidaten geprüft werden, ob er die Voraussetzung zur Anmeldung und die Eignung zur Bearbeitung einer SA erfüllt. Laut DPO Maschinenbau sind SAs dem Hauptstudium zuzurechnen. Vom Kandidaten erfragen: DPO / MPO, ggf. 'Wirtschaftsgenuewessen'? Gelten besondere Voraussetzungen?		Ass	Kan	-
5.	Kurzthema und Aufgabenstellung auf einer Seite darstellen.	Themenstellung	Ass	Ltj	-
6.	Der Kandidat stellt das Thema innerhalb der Gruppensitzung der Gruppe durch Kurzpräsentation vor, ggf. wird das Thema angepasst.		Kan	Ma	-
7.	Ist die SA eine interne oder eine externe Arbeit?		Ass	Kan	-
8.	Die von der Fakultät für Maschinenwesen festgelegten Richtlinien für externe Arbeiten sind zu beachten.	Fakultät für Maschinenbau Richtlinien für externe Arbeit in Deutsch Richtlinien für externe Arbeit in Englisch	Ass	Ltj, Kan	-
9.	Der Erfassungsbogen ist vom Studenten auszufüllen, der geplante Arbeitsverlauf darf in der Summe 200h nicht überschreiten. Die Geheimhaltungsvereinbarung wird vom Studenten unterschrieben.	Geheimhaltungserklärung	Ass	Kan	-
10.	Der ausgefüllte und vom Studenten und Assistenten unterschriebene Erfassungsbogen, die vom Studenten unterschriebene Geheimhaltungsvereinbarung und das Thema werden im Sekretariat abgegeben. Der Erfassungsbogen für Studienarbeiten und die		Ass	Ltj, Vor- zimmer, Buh	-

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Page 25

When the electronic documentation option has been selected, the acquisition and maintenance costs for the server and costs for defining the entitlement and the filing structure for the documents arise.

Electronic documentation eliminates any need for costly and time-consuming distribution of the documents. The maintenance and revision service is significantly faster and less expensive. A further advantage is that it ensures employees to have access to the latest version of the documentation at any time.

The process flow can be graphically represented. Further details as detailed description of work steps, references to documents or information of process participants are listed in forms of tables.

The VMI differentiation is a possibility to identify the process participants. The single letters stand for

V = responsible worker

M = collaborate worker

I = to be informed worker

Contents

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- Documentation of QM Systems**
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Audit Objective

- Proficiency review of procedures and processes for product development, production and dispatch
- Use and efficiency review of the documented procedures and arrangements



Process description



QM documentation

In this context

- weak points are identified,
- interface problems are identified,
- potential process improvement defined and
- organisational improvements (e.g. qualification action) determined.

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Page 27

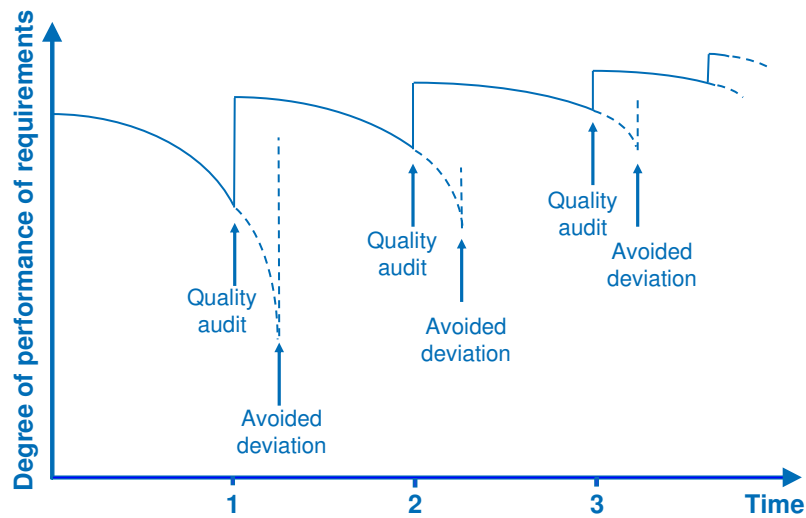
Auditing and Certification

The objectives, which a QM System strives to meet, are not simply achieved by adopting it. The system must be maintained, improved and refined continuously. The quality audit is an important instrument in this battle.

An audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

The ISO 19011 provides a guidance for auditing.

Avoidance of Error Rates by Quality Audits



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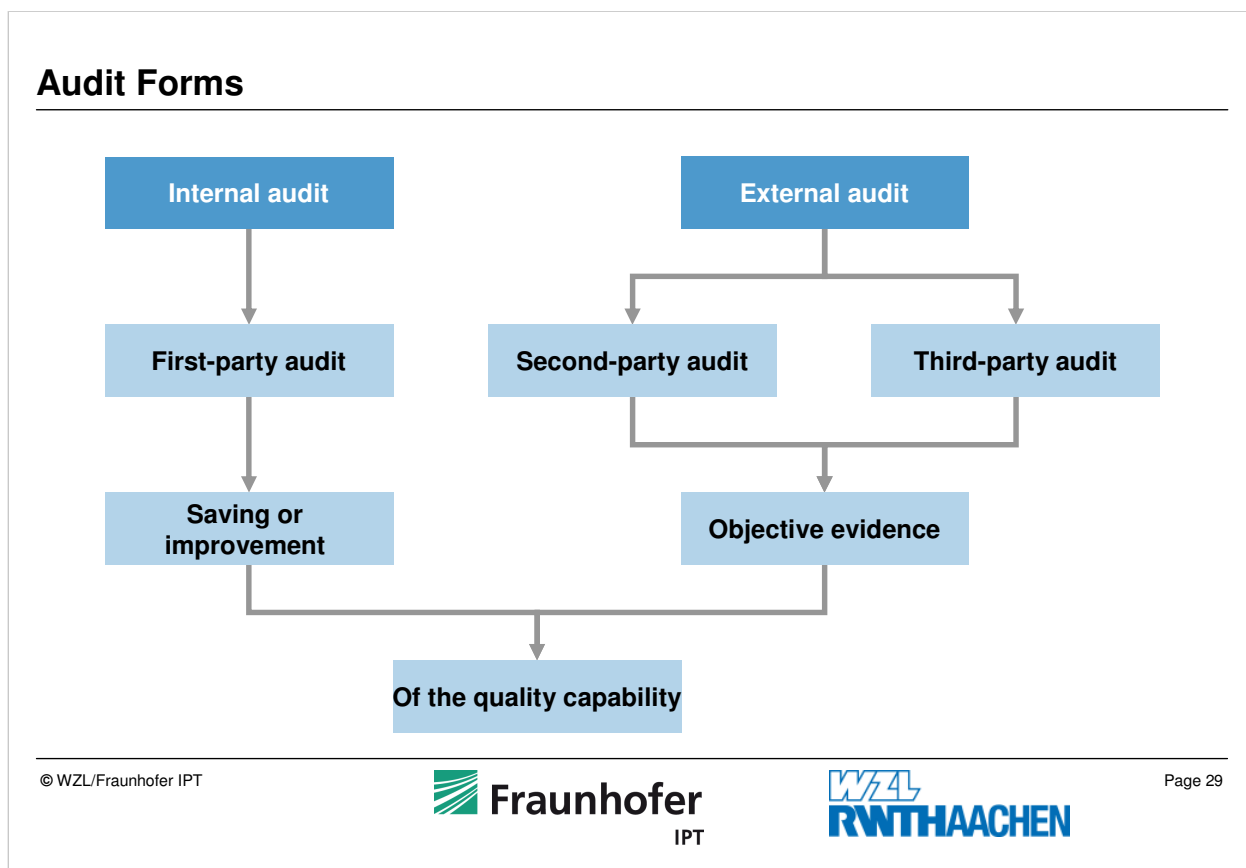
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Page 28

Planned audits are conducted in accordance with a fixed schedule. An audit plan is drawn up, specifying the subjects of review, dates and the members of the audit team.

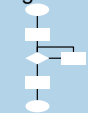
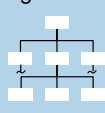



In general, when audits are carried out repeatedly, they are found to make a remarkable contribution to the improvement of the QM System, i.e. to the avoidance of unacceptable deviations.





The questions as to who carries out the audit, what is audited and what purpose does the audit serve, facilitates the classification of the different types of audit. A distinction must be drawn on one hand between internal and external audits and on the other hand, between the product audit, the process audit and the system audit.

Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organisation itself for management review and other internal purposes.

External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organisation, such as customers or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organisations, such as those providing certification of conformity to ISO 9001.

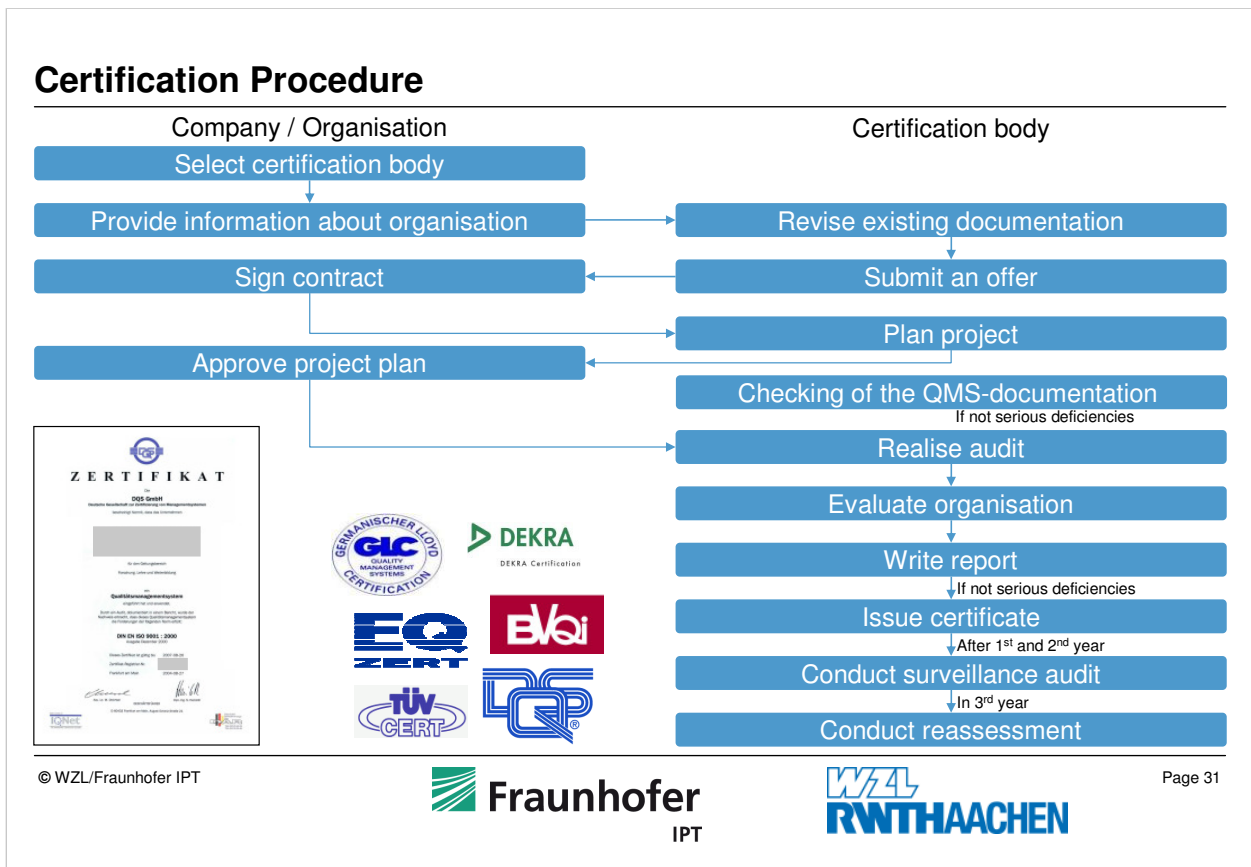
Type	Quality system audit	Process audit	Product audit
Purpose	Completeness and effectiveness evaluation of the basis requirements to the management system	Quality capability evaluation of the processes for special products and product groups	Quality characteristic evaluation of a specific number of end products and/or parts
Regarded object	Procedural organisation  Structural organisation 	Relevant processes  Personnel	Individual parts or products  
Documentation & optimisation potential	<ul style="list-style-type: none"> Quality manual QM instruction Order documents Directives of the management ... 	<ul style="list-style-type: none"> Processes (Development, production, dispatch) Documents of process performance, monitoring and inspection ... 	<ul style="list-style-type: none"> Quality directives Inspection and manufacturing procedures, documents and equipment ...

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All requirements to the QM-system are verified in the system audit. It is not only the contents of the documents which are analysed but also their application and particularly their effectiveness.

The effectiveness of a process is determined in the process audit.

The fulfilment of all specific requirements such as product measures, functionality, packing, labelling etc. are proved with the product audit.



Certification is a process whereby a third party confirms in writing that a product, a process, a service or a system conforms to the requirements specified. Certification is usually carried out by accredited certification bodies (like e.g. DQS, TÜV, DEKRA).

The procedure scheme of a certification is as follows:

The audit team tests the effectiveness and conformity of the QM system on the basis of detailed questions. The results (weak points and corrective actions) are summarised in a report and discussed with the company.

When the DQS certification committee submits a positive appraisal of the results, i.e. no serious weaknesses were identified in the QM system or when the corrective measures planned, have been successfully implemented, certification can go ahead.

The certificate awarded, is valid for three years provided annual monitoring audits.

The certificate is only renewed following a reassessment which concludes with a positive review. This re-certification (reassessment) must be carried out within three years and involves conducting another exhaustive test and review process on the QM system.