VDA | Verband der Automobilindustrie

6

Quality management in the automotive industry

QM-system audit

Teil 2

- Services -

Particular requirements corresponding to ISO/TS 16949:2002 for automotive service providers

2nd Edition 2004

QM system audit

- Services -

Particular requirements corresponding to ISO/TS 16949:2002 for automotive service providers

2nd Edition 2004

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Supplementary text represents the interpretation of the standard for automotive service providers.

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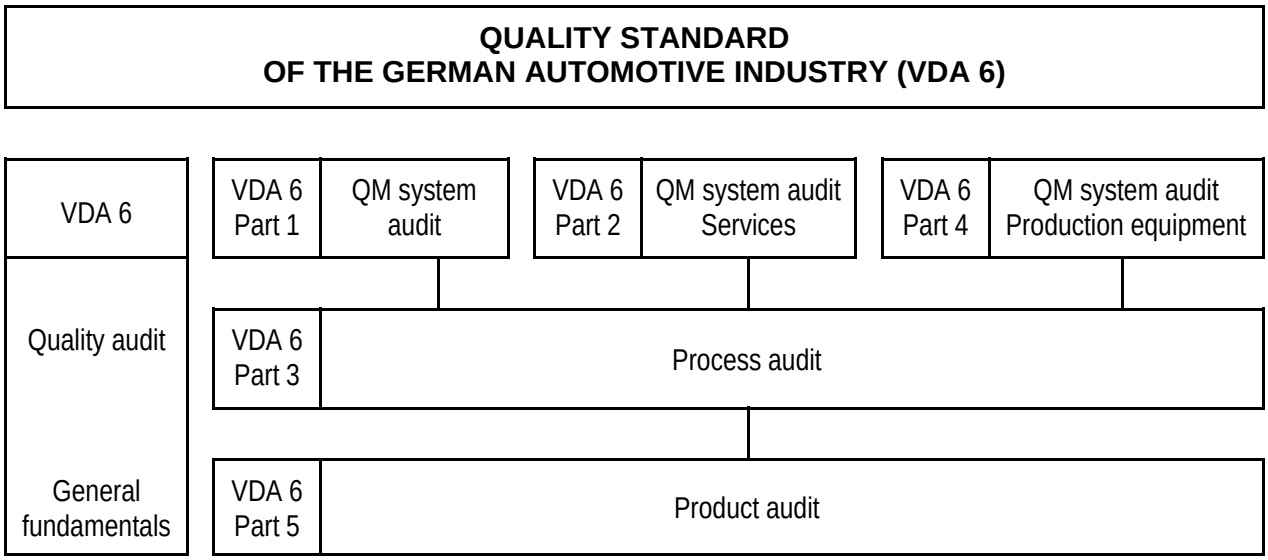
Foreword

Progress towards the delivery of a comprehensive service takes place in an environment where customers are able to take increasing advantage of stronger competition on the national as well as on the international market of service providers.

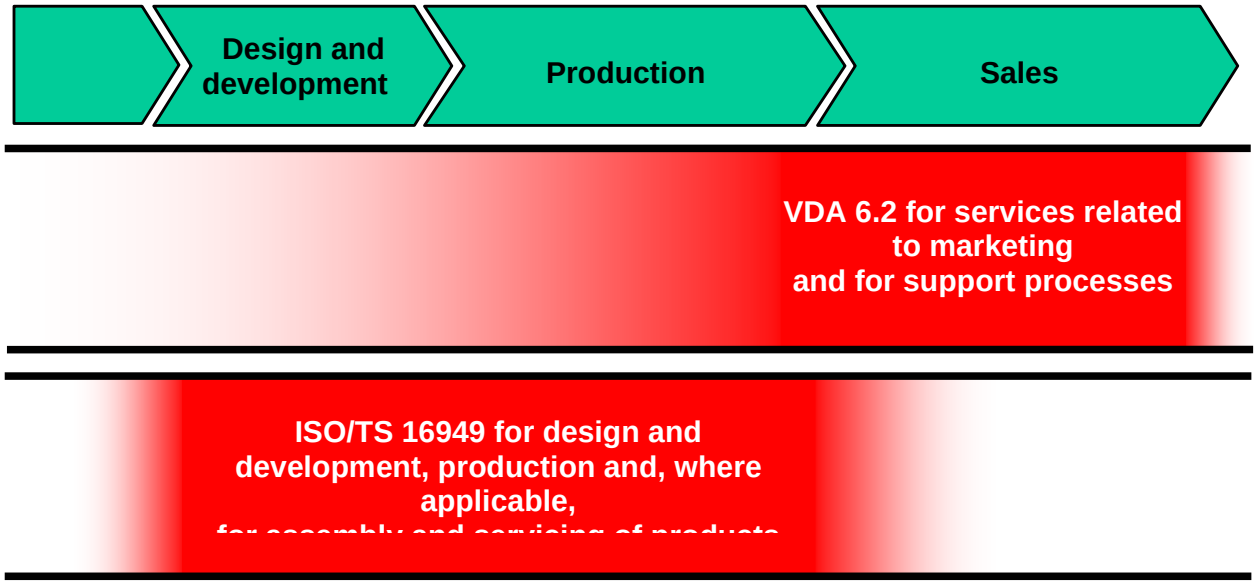
This is having an increased effect on the light and commercial vehicle sector of the automotive industry. The price-performance relationship ("value for money") is no longer the only decisive factor, but also the quality of the provided service assumes an ever more significant role.

Hence a discussion has developed within the service sector of the automotive industry, how all aspects of service quality can be incorporated into a quality management system that is automotive-specific and effective in the support it provides.

In consequence of the fact that every organization has implemented, or is in the progress of implementing, its own quality management system, which is adapted to its size, branch and product/service, the VDA positioned its 6.2 work group where the "QUALITY STANDARD OF THE GERMAN AUTOMOTIVE INDUSTRY (VDA 6)" can be monitored by means of practical quality audits.



Target group for VDA 6.2 in comparison to ISO/TS 16949



VDA 6.2 refers not only to the quality of a service, but also to all service provision processes and their results.
The main target groups are distribution units for vehicles and services, however external service providers (R&D, prototype construction, etc.) and internal services (R&D, logistics, purchasing, etc.) can also use the standard.

This second edition of the VDA 6.2, printed in 2004, replaces the first revised edition of 1997, printed in 2000, which thereby becomes invalid.

The boxed text is original ISO9001:2000 text. The branch and service sector-specific supplementary requirements are outside the boxed text.

In VDA Volume 6.2 the words "shall" or "is to…" indicate a mandatory requirement. The word "should" indicates a recommendation.

Sections beginning with "NOTE" serve to clarify understanding of the relevant requirement.

Where expressions such as "typical examples are" or "for example" are used, these examples are given only for the purposes of orientation and assistance.

Verband der Automobilindustrie e.V.
Qualitätsmanagement Center (VDA-QMC)

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VERBAND DER AUTOMOBILINDUSTRIE E. V. (VDA)

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0 Introduction

0.1 General

ISO 9001:2000, Quality management systems — Requirements

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

0.2 Process approach

ISO 9001:2000, Quality management systems — Requirements

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance

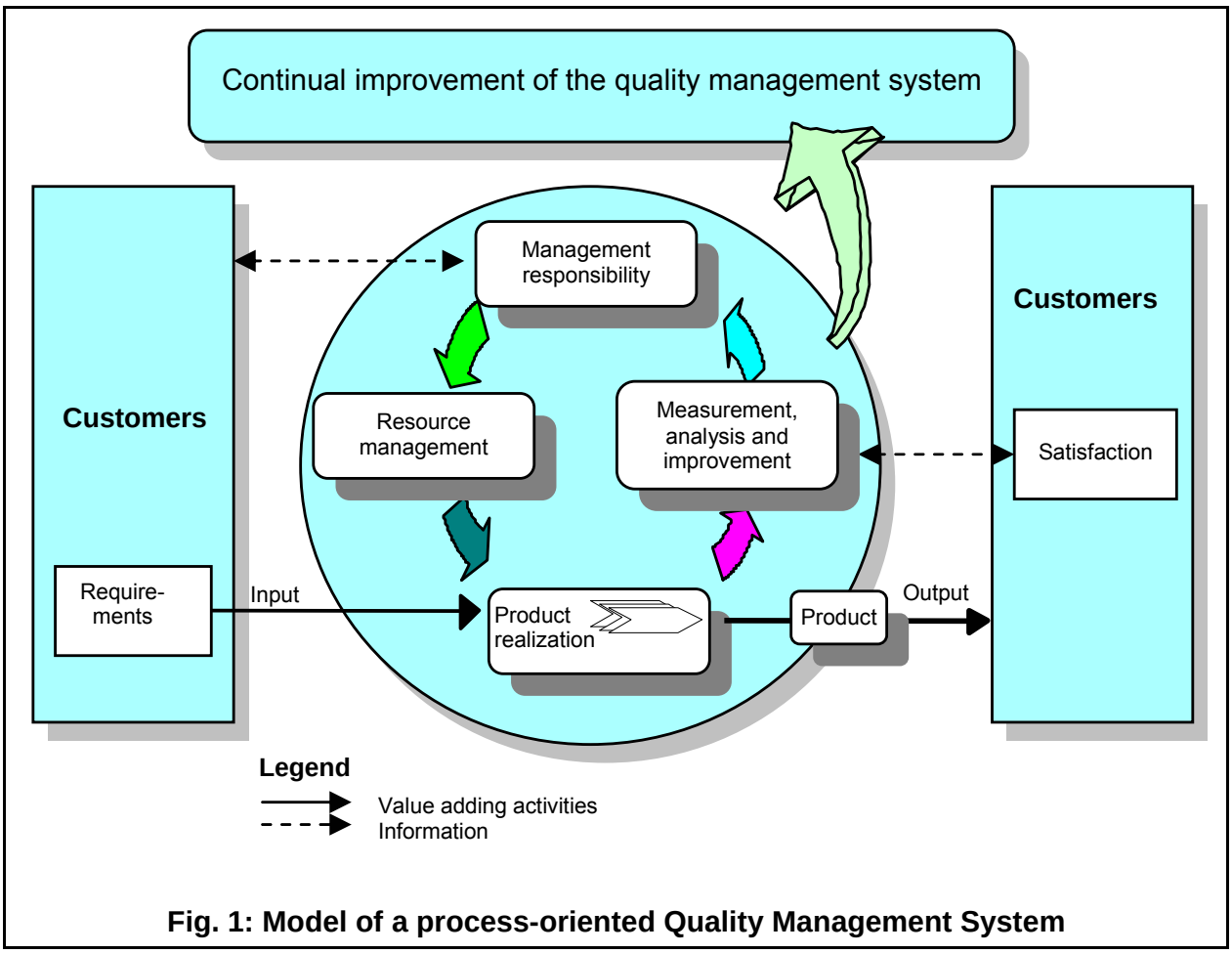
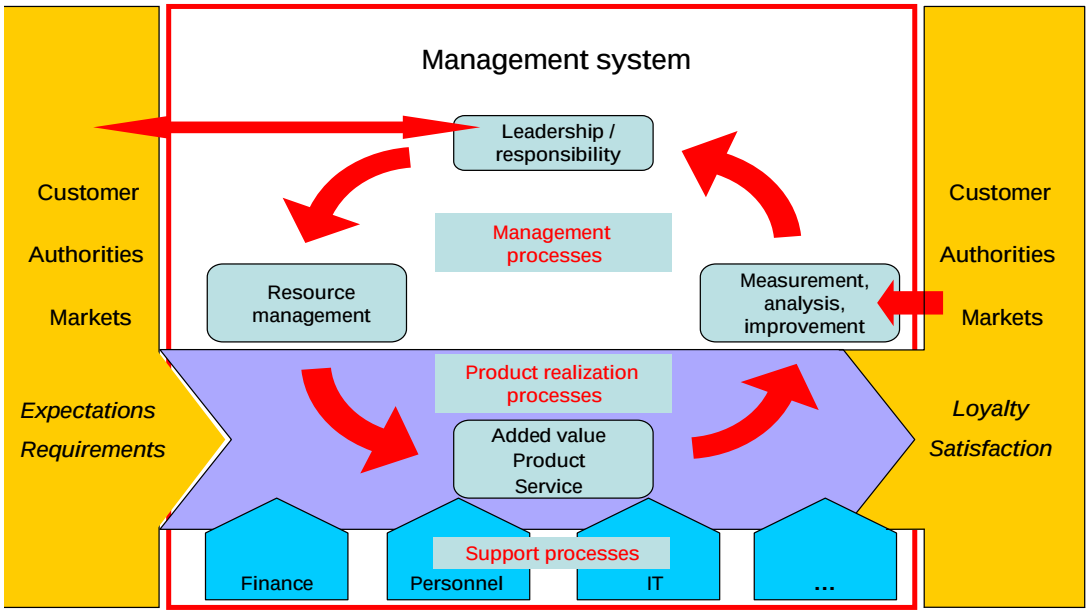


Fig. 1: Model of a process-oriented Quality Management System

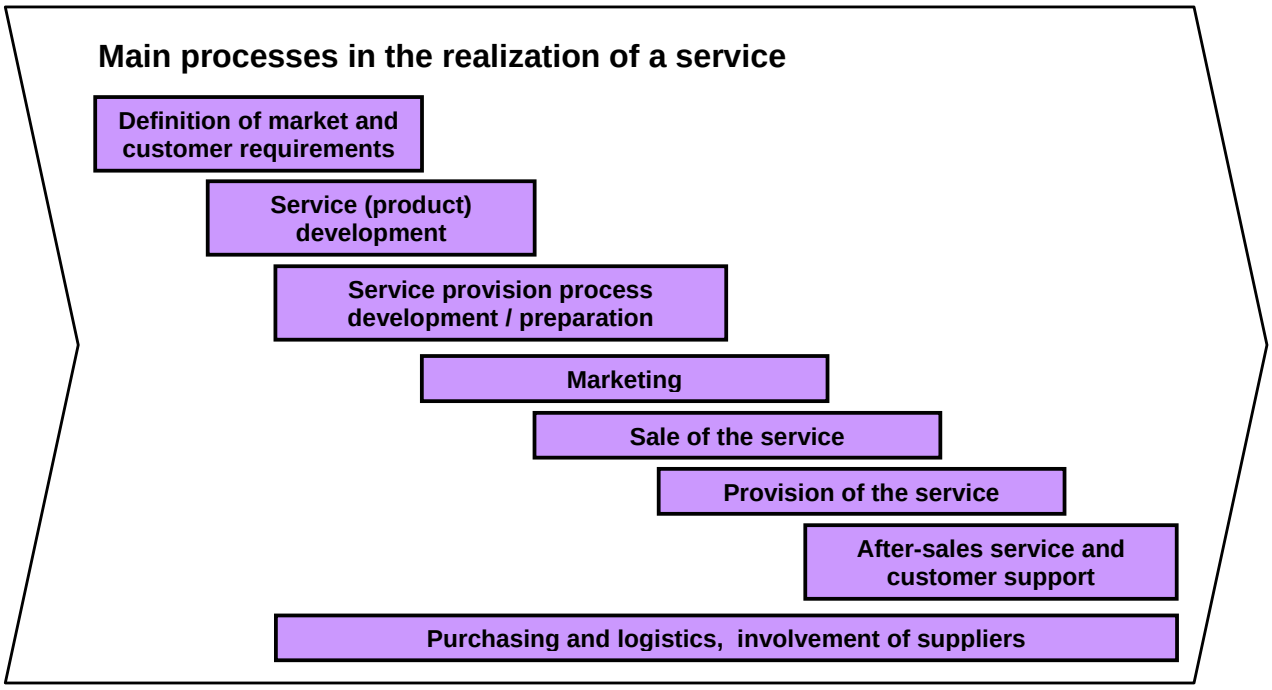
What does the ISO process-based model mean for automotive service providers?
The management system of a unit consists of value-adding processes (product and/or service provision), the necessary support processes and management processes.



Value-adding activities for products and services are generally consistent across the entire life cycle:

Definition of requirements ⇨ Design and development ⇨ Realization ⇨ Sale and delivery ⇨ Disposal (product)

The process chain for the realization of a service can be represented as follows:



0.3 Relationship with ISO 9004

ISO 9001:2000, Quality management systems — Requirements

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently.

Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

Knowledge and use of the eight Quality Management Principles referred to in ISO 9000:2000 (Chapter 0.2) and ISO 9004:2000, should be presented by top management and communicated within the organization.

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships.

These eight Quality Management Principles create the foundation for the Quality Management System Standards of the ISO-9000 family.

0.4 Compatibility with other management systems

ISO 9001:2000, Quality management systems — Requirements

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

0.5 Quality management and service provision

The process orientation of the automotive industry justifies the inclusion of service providers in the quality management system.

Both internal and external service providers may be concerned.

Every automotive product is expected by the customer to be of a consistently high quality, which also means consistently high quality in the performance of service providers.

Through this, a growing competitive environment of quality, cost and time emerges, whereby the subjective appraisal of quality by the end customer becomes increasingly decisive for business success.

Service providers must win and sustain the trust of customers. Having experienced in the past an improvement in the quality of life, customers now place higher expectations towards the service sector. Where these expectations are not fulfilled by one service provider, customers will move to another.

In order to develop successfully the provision of services in the automotive industry, it is recommended to embrace these areas in an all-inclusive quality management system.

0.6 Product and service quality

A product is understood to be, for example, a vehicle that has been manufactured by means of an industrial process. The quality of the product is then characterized primarily by its design, materials and the production equipment and processes used.

Services are processes in which the internal or external customer is directly or indirectly involved, e.g., during the purchase of a car or a tire change. In this way the quality of the service is judged directly by the customer.

Accordingly, service quality is differentiated from product quality.

While material products generally can be reworked to restore customer satisfaction, the customer often makes use of poor services only once, as he will then move on without giving a reason.

Services are considered to be fundamentally immaterial; however, they cannot be represented without tangible means.

0.7 Opportunities and risks

As in all systems, the implementation and development of a quality management system involves opportunities and risks for the organization.

Depending on the general extent of quality understanding in the organization, from top management down to apprentices, and on the example of top management in particular, the activities and measures taken will be made useful to the organization, or else simply devised as "fulfillment of requirements".

For example, are mistakes fundamentally condemned or are they taken as a basis for improvement action (i.e. a learning organization)?

Is the scope of documentation oriented towards preconditions for stable processes or is it just bureaucracy for its own sake? Are all efforts made only to achieve a short-term result in the next audit (i.e. to obtain a certificate) or to achieve a "return on investment“?

Consequently, it depends on leadership and on employees to gain benefits for the organization from its quality management system.

0.8 Objective

The objective of this VDA Volume 6 part 2 is to provide a reference for the development of a quality management system (QM system), which encompasses continual improvement with an emphasis on error prevention and reduction of variation and waste in the entire value-adding chain (i.e. the loop from the customer back to the customer).

This volume specifies the requirements of a quality management system for automotive industry-related service providers.

This enables the evaluation of an existing QM system by means of a uniform procedure. The resources required for further QM system audits, for example by other customers, can thereby be reduced.

This VDA Volume 6.2 represents a supplemental qualification to ISO 9001:2000. It can be used as a basis for customer/supplier audits.

Quality management systems – Particular requirements corresponding to ISO/TS 16949:2002 for automotive service providers

1 Scope

1.1 General

ISO 9001:2000, Quality management systems — Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE: In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

This VDA volume is intended for use by autonomous service providers and/or service organizations (i.e. units with their own quality strategy and objectives), but is also applicable to all automotive industry-related service providers.

The requirements of VDA 6.2:2004 cover the requirements of ISO 9001:2000 and, where applicable, the requirements of ISO/TS 16949:2002 for service providers.

Service providers may not apply for an individual certification according to the Technical Specification ISO/TS 16949:2002. If they are, as internal service providers, part of a product realization process (i.e. support function for a production site), they are subject to the relevant requirements of ISO/TS 16949:2002 where the production site strives to obtain such a certificate (see ISO/TS 16949:2002 clause 1.1)

1.2 Application

ISO 9001:2000, Quality management systems — Requirements

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

The only permitted exclusions from VDA 6.2:2004 relate to clause 7.3, where the organization is not responsible for the development of new, as yet not provided, services.

Permitted exclusions do not include development of the service provision process (i.e. service provision preparation activities).

Usage guidelines

Structure of the chapters

The boxed text content is original text from ISO 9001:2000 and protected by copyright. The sector-specific supplemental requirements and notes are outside the boxes and include those requirements from ISO/TS 16949:2002 which are relevant to service providers.

Fundamentals and procedures for audits are defined in ISO 19011. Further details are specified in the current VDA Volume 6, which is an applicable reference for this VDA 6.2 Volume.

The basis for internal and external auditing and certification is the fulfillment of requirements. At the core of the audit result is the statement of compliance or otherwise to these requirements.

In order to enhance the validity of the audit, it is recommended to order the use by auditors, or agree for the purposes of internal audit, the VDA evaluation system described in Annex A.

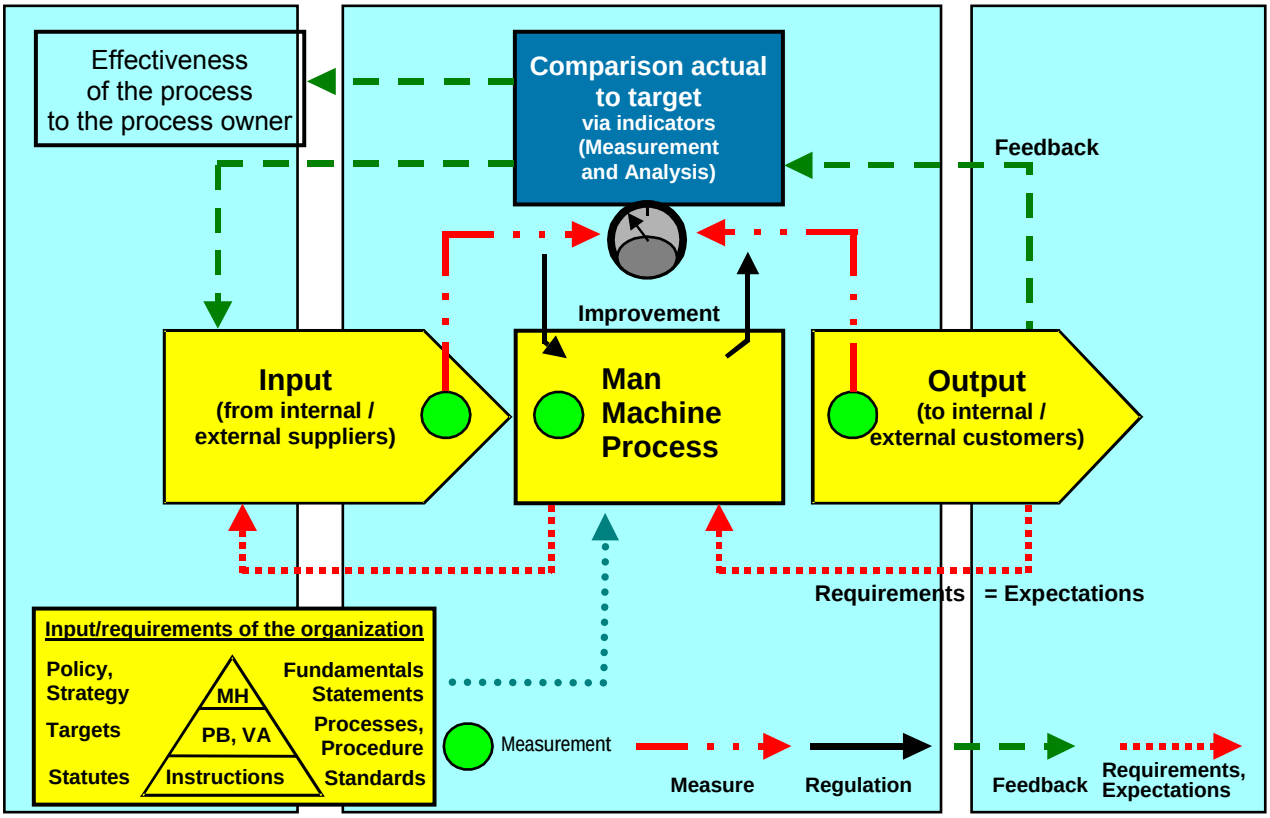
The scoring of points for each management and service realization process is a recognized practice providing additional information and transparency with regard to improvement potential. The whole of Annex A is binding where this method is used.

Consistent process-orientation

A process must always fundamentally be considered together with its interaction with other processes. Evidence shall be demonstrated, whether:

- each process having an impact on quality and economic efficiency is defined and is understood by those concerned;
- responsibilities are defined (e.g. task, competence, responsibility of process owners);
- process risks are identified;
- an appropriate and effective documentation (of requirements and evidence of compliance) is available;
- within each process there are defined indicators for the service/ product and for the process;
- processes are regularly and systematically reviewed for their effectiveness and efficiency;
- each process is subject to a closed control loop (e.g. plan – do – check – act).

A controlled process



2 Normative reference

The following normative document contains provisions, which, through reference in this text, constitute provisions of this VDA Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this VDA Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, Quality management systems — Fundamentals and vocabulary

3 Terms and definitions

ISO 9001:2000, Quality management systems — Requirements

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier ⟶ organization ⟶ customer

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

For the purposes of this VDA Standard, the terms and definitions given in ISO 9000:2000, from which a selection for the service provider is listed below, apply.

The numbers in brackets refer to the ISO 9000:2000 definition.

Those definitions not exactly corresponding to the ISO definition, as well as further terms and remarks from the VDA 6.2 work group, are printed in italics.

All terms are listed in alphabetical order.

- **Audit** (3.9.1)

Systematic, independent and documented process (3.4.1) for obtaining audit evidence (3.9.4) and evaluating it objectively to determine the extent to which audit criteria (3.9.3) are fulfilled.

Note: Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the organization (3.3.1) itself for internal purposes and can form the basis for an organization's self-declaration of conformity (3.6.1).

External audits include what are generally termed "second-party" or "third-party" audits.

Second-party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf.

Third-party audits are conducted by external independent organizations. Such organizations provide certification or registration of conformity with requirements such as those of ISO 9001 und ISO 14001.

When quality and environmental management systems (3.2.2) are audited together, this is termed a "combined audit".

When two or more auditing organizations cooperate to audit a single auditee (3.9.8) jointly, this is termed "joint audit“.

- **Audit findings** (3.9.5)

Results of the evaluation of the collected audit evidence (3.9.4) against audit criteria (3.9.3).

Note: Audit findings can indicate either conformity or nonconformity with audit criteria, or opportunities for improvement.

- **Conformity (3.6.1)**

Fulfillment of a requirement (3.1.2)

- **Continual improvement** (3.2.13**)**

Recurring activity to increase the ability to fulfill requirements (3.1.2).

Note: The process (3.4.1) of establishing objectives and finding opportunities for improvements is a continual process through the use of audit findings (3.9.5) and audit conclusions (3.9.6), analysis of data, management reviews (3.8.7) or other means and generally leads to corrective action (3.6.5) or preventive action (3.6.4).

- **Control**

A comprehensively closed feedback loop including target definition, measurement of target achievement and resulting corrective and improvement action (e.g. PDCA).

- **Correction (3.6.6)**

Action to eliminate a detected nonconformity (3.6.2).

Note 1: A correction can be made in conjunction with a corrective action (3.6.5).

Note 2: A correction can be, for example, rework (3.6.7) or regrade (3.6.8).

- **Corrective action** (3.6.5)

Action to eliminate the cause of a detected nonconformity (3.6.2) or other undesirable situation.

Note 1: There can be more than one cause for a nonconformity.

Note 2: Corrective action is taken to prevent recurrence whereas preventive action (3.6.4) is taken to prevent occurrence.

- **Customer** (3.3.5)

Organization (3.3.1) or person that receives a product/*a service* (3.4.2).

Examples: Consumer, client, end-user, retailer, beneficiary and purchaser.

Note: A customer can be internal or external to the organization.

- **Customer satisfaction** (3.1.4)

Customer's perception of the degree to which the customer's requirements (3.1.2) have been fulfilled.

Note 1: Customer complaints are a common indicator of low custommer satisfaction but their absence does not necessarily imply high customer satisfaction.

Note 2: Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

- **Defect** (3.6.3)

Non-fulfillment of a requirement (3.1.2) relating to an intended or specified use.

Note 1: The distinction between the concepts defect and nonconformity (3.6.2) is important as it has legal connotations, particularly those associated with product liability issues. Consequently the term "defect" should be used with extreme caution.

Note 2: The intended use as intended by the customer (3.3.5) can be affected by the nature of the information, such as operating or maintenance instructions, provided by the supplier (3.3.6).

- **Effectiveness** (3.2.14)

Extent to which planned activities are realized and planned results achieved.

- **Efficiency** (3.2.15)

Relationship between the results achieved and the resources used.

- **Guideline**

Guidelines create a binding framework for the entire organization regarding certain activities, e.g. travel cost claim.

- **Infrastructure** (3.3.3)

System of facilities, equipment and services needed for the operation of an organization (3.3.1).

- **Inspection** (3.8.2)

Conformity evaluation by observation and judgment accompanied by measurement, testing or gauging.

- **Management system** (3.2.2)

System (3.2.1) to establish policy and objectives and to achieve those objectives.

Note: A management system of an organization (3.3.1) can include different management systems, such as a quality management system (3.2.3), a financial management system or an environment management system.

- **Method**

A scheduled procedure (3.4.5), to given means and a given purpose which leads to the technical proficiency in the solution of theoretical and practical tasks.

- **Nonconformity** (3.6.2)

Non-fulfillment of a requirement (3.1.2)

- **Objective evidence** (3.8.1)

Data supporting the existence or verity *(applicability)* of something.

Note: Objective evidence may be obtained through observation, measurement, test (3.8.3) or other means.

- **Organization** (3.3.1)

Group of people and facilities with an arrangement of responsibilities, authorities and relationships.

Examples: Company, corporation, firm, enterprise, institution, charity, sole trader, association, or parts or combination thereof.

Note 1: The arrangement is generally orderly.

Note 2: An organization can be public or private.

Note 3: This definition is valid for the purposes of quality management system (3.2.3) standards.

- **Organizational structure** (3.3.2)

Arrangement of responsibilities, authorities and relationships between people.

Note 1: The arrangement is generally orderly.

Note 2: A formal expression of the organizational structure is often provided in a quality manual (3.7.4) or a quality plan (3.7.5) for a project (3.4.3).

Note 3: The scope of an organizational structure can include relevant interfaces to external organizations.

- **Preventive action** (3.6.4)

Action to eliminate the cause of a potential nonconformity (3.6.2) or other undesirable potential situation.

Note 1: There can be more than one cause for a potential noncomformity.

Note 2: Preventive action is taken to prevent occurrence whereas corrective action (3.6.5) is taken to prevent recurrence.

- **Procedure** (3.4.5)

Specified way to carry out an activity or a process (3.4.1).

Note 1: Procedures can be documented or not.

Note 2: When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used. The document (3.7.2) that contains a procedure can be called a "procedure document".

- **Process** (3.4.1)

Set of interrelated or interacting activities which transforms inputs into outputs.

Note 1: Inputs to a process are generally outputs of other processes.

Note 2: Processes in an organization (3.3.1) are generally planned and carried out under controlled conditions to add value.

Note 3: A process where the conformity (3.6.1) of the resulting product (3.4.2) *or the provided service* cannot be readily or economically verified is frequently referred to as a "special process".

- ***Process instruction/procedure***

Process instructions or procedures are specific instructions that are required in order to fulfill a defined quality-related activity. They come into effect according to predefined practice (e.g. when signed).

- **Product** (3.4.2)

Result of a process (3.4.1).

Note 1: There are four generic product categories:

- services (e.g. transport);
- software (e.g. computer program, dictionary);
- hardware (e.g. engine mechanical part);
- processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element. For example the offered product "automobile" consists of hardware (e.g. tires), processed materials (e.g. fuel, cooling liquid), software (e.g. engine control software, driver's manual), and service (e.g. operating explanations given by the salesman).

Note 2: **Service** is the result of at least one activity necessarily performed at the interface between the supplier (3.3.6) and customer (3.3.5) and is generally intangible. Provision of a service can involve, for example, the following:

- an activity performed on a customer-supplied tangible product (e.g. automobile to be repaired);
- an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);
- the delivery of an intangible product (e.g. the delivery of information in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restata6pt
- urants).

Software consists of information and is generally intangible and can be in the form of approaches, transactions, or procedures (3.4.5).

Hardware is generally tangible and its amount is a countable characteristic (3.5.1). Processed materials are generally tangible and their amount is a continuous characteristic. Hardware and processed materials are often referred to as goods.

- ***Product liability*** *(see sub-clause 5.7.1)*

- **Quality** (3.1.1)

Degree to which a set of inherent characteristics (3.5.1) fulfills requirements (3.1.2).

Note 1: The term "quality" can be used with adjectives such as poor, good, excellent..

Note 2: "Inherent", as opposed to "assigned", means existing in something, especially as a permanent characteristic.

- **Quality management** (3.2.8)

Coordinated activities to direct and control an organization (3.3.1) with regard to quality (3.1.1).

Note: Direction and control with regard to quality generally includes establishment of the quality policy (3.2.4) and quality objectives (3.2.5), quality planning (3.2.9), quality control (3.2.10), quality assurance (3.2.11) and quality improvement (3.2.12).

- **Quality management system; QM system (3.2.3)**

Management system (3.2.2) to direct and control an organization (3.3.1) with regard to quality (3.1.1).

- **Quality manual** (3.7.4)

Document (3.7.2) specifying the quality management system (3.2.3) of an organization (3.3.1).

Note: Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.

- **Quality plan** (3.7.5)

Document (3.7.2) specifying which procedures (3.4.5) and associated resources shall be applied by whom and when to a specific project (3.4.3), product (3.4.2), process (3.4.1) or contract.

Note 1: These procedures generally include those referring to quality management processes and to product realization processes.

Note 2: A quality plan often makes references to parts of the quality manual (3.7.4) or to procedure documents.

Note 3: A quality plan is generally one of the results of quality planning (3.2.9).

- **Quality policy** (3.2.4)

Overall intentions and direction of an organization (3.3.1) related to quality (3.1.1) as formally expressed by top management.

Note 1: Generally the quality policy is consistent with the overall policy of the organization and provides a framework for the setting of quality objectives (3.2.5).

Note 2: Quality management principles presented in this International Standard can form a basis for the establishment of a quality policy.

- **Record** (3.7.6)

Document (3.7.2) stating results achieved or providing evidence of activities performed.

Note 1: Records can be used, for example, to document traceability (3.5.4) and to provide evidence of verification (3.8.4), preventive action (3.6.4) and corrective action (3.6.5).

Note 2: Generally records need not be under revision control, *but they may not be altered.*

- **Repair** (3.6.9)

Action on a nonconforming product (3.4.2), to make it acceptable for the intended use.

Note 1: Repair includes remedial action taken on previously conforming product to restore it for use, for example as part of maintenance.

Note 2: Unlike rework (3.6.7), repair can affect or change parts of the nonconforming product.

- **Requirement** (3.1.2)

Need or expectation that is stated, generally implied or obligatory.

Note1: "Generally implied“ means that it is custom or common practice for the organization (3.3.1), its customers (3.3.5) and other interested parties (3.3.7), that the need or expectation is implied.

Note 2: A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.

Note 3: A specified requirement is one which is stated, for example, in a document (3.7.2).

Note 4: Requirements can be generated by different interested parties.

- **Review** (3.8.7)

Activity undertaken to determine the suitability, adequacy and effectiveness (3.2.14) of the subject matter to achieve established objectives.

Note: Review can also include the determination of efficiency (3.2.15).

Examples: Management review, design and development review, review of customer requirements and nonconformity review.

- **Rework** (3.6.7)

Action on a nonconforming product/*service* (3.4.2), in order to make it conform to requirements (3.1.2).

Note: *This does not influence or change the product/service per se.*

- **Service see Product (3.4.2), Note 2**

- **Specification** (3.7.3)

Document (3.7.2) stating requirements (3.1.2).

Note: A specification can be related to activities (e.g. procedure document, process specification and test specification) or products (3.4.2) (e.g. product specification, performance specification and drawing).

- **Supplier** (3.3.6)

Organization (3.3.1) or person that provides a product/*a service* (3.4.2).

Examples: Producer, distributor, retailer or vendor of a product, or provider of a service or information.

Note1: A supplier can be internal or external to the organization.

Note 2: In a contractual situation a supplier is sometimes called "contractor".

- **System** (3.2.1)

Set of interrelated or interacting elements.

- **Validation** (3.8.5)

Confirmation, through the provision of objective evidence (3.8.1), that the requirements (3.1.2) for a specific intended use or application have been fulfilled.

Note 1: The term "validated" is used to designate the corresponding status.

Note 2: The use conditions for validation can be real or simulated.

- **Verification** (3.8.4)

Confirmation, through the provision of objective evidence (3.8.1), that specified requirements (3.1.2) have been fulfilled.

Note 1: The term "verified" is used to designate the corresponding status.

Note 2: Confirmation can comprise activities such as:

- performing alternative calculations;
- comparing a new design specification (3.7.3) with a similar proven design specification;
- undertaking tests (3.8.3) and demonstrations;
- reviewing documents prior to issue.

- **Work instructions** *(according to the IATF-Guidance to ISO/TS 16949:2002)*

These instructions may take the form of process sheets, inspection and laboratory test instructions, shop travelers, test procedures, standard operation sheets, drawings and visual aids or other documents normally used by the organization to provide the necessary information that impacts product quality.

These instructions should include or reference, as appropriate:

- *current engineering level/date,*
- *customer and organization designated special characteristics if any,*
- *inspection and test instructions with acceptance criteria (see 7.1.2),*
- *material identification and disposition instructions,*
- *operation name and number keyed to the process flow diagram,*
- *part name and part number, or part family,*
- *reaction plans,*
- *relevant engineering and manufacturing standards,*
- *required tools, gauges and other equipment,*
- *revision date and approvals,*
- *SPC and other process-monitoring requirements,*
- *tool-change intervals and set-up instructions,*
- *visual aids.*

4 Quality management system

4.1 General requirements

ISO 9001:2000, Quality management systems — Requirements

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyze these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

Quality management applies to all stages of service provision. Its functionning together with a secure information flow is a precondition for the systematic fulfillment of requirements placed by customers, authorities and society in general.

Process instructions, procedures, job descriptions and organizational charts serve, among other things, to support employees, clarify relationships at all interfaces and provide evidence of relevant duties.

A central thread in the organization should be the comprehensive understanding of quality and quality management. This means, first of all, to consider errors as opportunities and to recognize continual improvement as being a means towards survival/competitive advantage.

Continual improvement is managed at system and process levels.

4.1.1 Outsourced service processes

Ensuring control over outsourced services shall not absolve the organization from the responsibility for conformity to all customer requirements. Automotive services comprise of processes such as preparation, vehicle servicing, painting, washing, renting, etc. These processes shall be monitored, managed and checked against fulfillment of customer requirements. Interfaces to outside processes shall be clearly defined and controlled.

Note: see also 7.4.1 Purchasing process

4.2 Documentation requirements

4.2.1 General

ISO 9001:2000, Quality management systems — Requirements

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1: Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2: The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,
b) the complexity of processes and their interactions, and
c) the competence of personnel.

NOTE 3: The documentation can be in any form or type of medium.

4.2.2 Quality manual

ISO 9001:2000, Quality management system — Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

The main purpose of the quality manual is to define the structure of the quality management system and at the same time serve as a constant reference for its implementation and maintenance.

Furthermore, the quality manual can be used for the following purposes, e.g.:

- building the trust of the customer and of financial institutions;
- risk management (insurance);
- development of new business partnerships;
- a marketing tool.

All required processes for business operation shall be described in the quality manual or equivalent documentation with reference to important system-related internal and external standards and norms.

The description of the quality management system should also:

- emphasize the prevention of errors in place of error correction;
- apply quality management planning to all stages of service realization;
- highlight the commitment to continual improvement;

- pay special attention to the quality cycle for services;
- illustrate the entire process through its main stages of marketing, conception, service provision and customer feedback.

4.2.3 Control of documents

ISO 9001:2000, Quality management system — Requirements

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.3.1 Service requirements

The organization shall have a process to ensure timely review, distribution and realization of all customer demands and their changes. Timely review shall be conducted as fast as possible.

Changes and their implementation times shall be fully documented.

A clear overview of all types of quality-relevant documents is required.

The system shall prevent misuse (unauthorized access, changes by third parties, virus attacks, etc.).

4.2.4 Control of records

ISO 9001:2000, Quality management system — Requirements

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

NOTE 1 “Disposition” above includes disposal.

NOTE 2 “Records” also include customer-specified records.

The control of records shall satisfy regulatory and customer requirements.

4.2.4.1 Storage of records

Storing of quality-relevant records is necessary in order to enable demonstration at a later point in time of the quality management system and the products/services having fulfilled requirements during a specified period of time.

Special attention shall be paid to:

- protection against fire, water, etc.
- storage media (file archives, microfilm, electronic data storage)
- additional backup facilities, where applicable (dual archives, safety copies, etc.).

The storage time (archiving), data preservation and erasure/disposal shall be in accordance with regulatory requirements (e.g. data protection, fiscal law), general guidelines, customer and internal requirements and aspects of product liability.

A clear overview of all types of quality-relevant records together with their storage duration is required.

5 Management responsibility

5.1 Management commitment

ISO 9001:2000, Quality management systems — Requirements

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

The term "top management" refers to the leadership team that is responsible for the organization's strategy and success.

Long-term success can only be achieved by a total approach to the business activity. Superior and stable quality, delivery performance to the agreed schedule and cost reduction on the one hand and intensive trust-building between customer and supplier on the other are present-day necessities that force many organizations to adapt their strategies.

Top management shall, together with its directly subordinated management level, engage itself in the following issues:

- business plan
- business results
- comparison of internal and external performance data
- employee satisfaction
- customer satisfaction.

5.1.1 Business plan

The business plan is a document containing company-specific, strategic projects together with objectives to be fulfilled or achieved within a specified period of time (ideally long, medium and short term), and normally includes:

a) Cost aspects
   - financial and cost planning (investments, personnel and material costs)
   - cost targets

b) Sales and marketing aspects
   - market data
   - turnover/sales targets
   - customer satisfaction targets

c) Overall corporate aspects
   - expansion projects
   - operational plans
   - personnel planning
   - comparison with other organizations (benchmarking)

d) Development aspects
   - development projects
   - competitors' services analyses

e) Process and quality aspects
   - key data from process performance
   - important quality-related figures.

All aspects mentioned in the business plan shall:

- be provided with time frames;
- address present and future customer and employee expectations;
- be comprehensible and monitored, and adapted to any circumstantial changes;
- serve the purpose of process and quality improvement.

NOTE: External auditors are to be provided with evidence of: key figures, time frames, tendencies, trend analyses but not absolute values/amounts and not for all aspects. Attention shall be paid to company-specific interests.

5.1.2 Process efficiency

Top management shall review the value-adding and support processes to assure their effectiveness and efficiency.

5.2 Customer focus

ISO 9001:2000, Quality management systems — Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

Top management shall establish a process to identify customer requirements. In many organizations this process is situated within the marketing area. Customer surveys can also be performed by external institutions. Evaluation and review of customer claims shall be included in the process.

Measurable targets shall be defined in order to continually develop customer focus.

Examples of customer-related targets:

- reduction of administrative processing time for enquiries, orders, etc. (Δ days);
- increase in customer satisfaction (e.g. Δ customer satisfaction index);
- reduction in reaction time for processing of claims (Δ days);
- improvement in service quality, e.g. schedule performance, delivery performance;
- customer confidence, retention;
- friendliness and availability.

5.3 Quality policy

ISO 9001:2000, Quality management systems — Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

The principles of an appropriate quality policy include, e.g.:

- process orientation
- target group for the service to be provided
- customer satisfaction
- the employees' role in realizing the quality policy
- employee satisfaction
- objectives relating to the service

- error prevention
- continual improvement
- environmental aspects
- social commitment.

The quality policy strives to establish a corporate culture in order to support the organization's vision.

In this respect the commitment to continually develop the organization and thereby improve its quality management system assumes an essential role.

The communication of the quality policy is achieved, for example, by:

- organizational guidelines and instructions
- presentation of the quality policy
- memoranda
- brochures
- notice board.

Measurable objectives shall be derived from the quality policy and their suitability periodically reviewed.

5.4 Planning

5.4.1 Quality objectives

ISO 9001:2000, Quality management systems — Requirements

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)] are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

Furthermore, agreed operative quality objectives shall be achievable and presented in a comprehensible format. The achievement of objectives (ongoing comparison of actual to specified) shall be thoroughly monitored at all management levels and periodically subject to management review.

Top management shall define measurable quality objectives and suitable measurement criteria that shall be included in the business plan.

Examples of typical quality objectives are:

- reduction of errors and corrections
- reduction of warranty and goodwill costs
- fulfillment of customer expectations
- increase in customer satisfaction
- increase in employee satisfaction
- profit
- continual improvement.

Objectives shall be tangible, clear and in a format that can be demonstrated to be agreed and communicated through to all employee levels.

An assessment of the level of achievement of objectives shall be made with employees via regular meetings. Deviations from targets (positive as well as negative) shall lead to improvement measures or newly defined performance indicators.

5.4.2 Quality management system planning

ISO 9001:2000, Quality management systems — Requirements

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

The application of project management supports the implementation of a quality management system.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

ISO 9001:2000, Quality management systems — Requirements

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that the responsibilities and authorities are defined and communicated within the organization.

Tasks, responsibilities and authorities shall be clearly and unambiguously defined for all employees and organizational areas. Consideration shall be given to the coordination and interfaces between various organizational areas and processes.

Definitions are duly provided in:

- organizational charts
- functional/operational instructions
- process instructions and procedures
- responsibility matrices
- job descriptions.

These come into effect according to predefined practice (e.g. when signed).

Competency, as well as the required degree of independence, shall be established concerning who, for example:

- may block non-conform products/services or processes;
- is responsible for analysis, promotion and monitoring of solutions to problems;
- monitors quality requirements, especially following changes;
- is responsible for quality-relevant documentation.

5.5.1.1 Responsibility for quality

Managers shall be promptly informed of services or processes which do not conform to requirements.

All working shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring quality.

5.5.2 Management representative

ISO 9001:2000, Quality management systems — Requirements

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

The responsibility and authority of the management representative also includes:

- reporting on the quality situation
- monitoring the achievement of operational quality objectives
- coordination and control of quality management activities during inter-disciplinary cooperation
- training of employees in quality subjects.

5.5.2.1 Customer representative

Top management shall designate a contact person who is endowed with the necessary authority to take responsibility for safeguarding customer interests (requests and claims). This person shall report to top management.

5.5.3 Internal communication

> **ISO 9001:2000, Quality management systems — Requirements**
>
> **5.5.3 Internal communication**
>
> Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

The process of internal communication shall present the flow of information in at least 3 directions:

Top down	Information from top management to employees
Bottom up	Information from the operating level up to top management
Process-oriented	Information from one organizational area to another, and/or from one employee to another.

Important factors here are how current the required information is, and what is the orientation of the receiver. Information shall be needs- and target-oriented.

Internal communication should encompass:

- transparent presentation of the quality situation
- effectiveness and efficiency of processes
- customer satisfaction
- employee satisfaction
- position on the market
- competitors
- improvement activities
- image.

5.6 Management review

5.6.1 General

ISO 9001:2000, Quality management systems — Requirements

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

The aim of the review is to enable continual optimization and adaptation to changing conditions (market, technology, etc.).

The measurements or indicators shall be aligned with target values. Trends and potential areas for improvement shall be identifiable.

The management review encompasses all areas of the organization and balances the various objectives with respect to each other. The review process includes the following subjects as a minimum:

- customer
- employee
- processes
- finances.

Reviews take place at individually defined intervals.

5.6.1.1 Review of customer satisfaction

Input for the review of customer satisfaction is provided by:

- evaluation of customer surveys
- evaluation of claims/complaints
- evaluation of warranty and goodwill cases
- feedback by word of mouth.

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5.6.1.2 Review of employee satisfaction

The impressions of employees and the way they perceive the organization are starting points for the indication of satisfaction. They are expressed in terms of, e.g.:

- flexible work times,
- communication at employee level,
- employee orientation, agreed goals, career planning,
- individual abilities and competencies,
- involvement in improvement, number of ideas,
- performance-linked remuneration,
- evaluation of employee surveys,
- work place safety,
- absenteeism, sickness and fluctuation rates.

5.6.1.3 Review of processes

The evaluation, analysis and use of company-wide performance data for value-adding and supporting processes shall provide indications on, e.g.:

- development performance or productivity
- quality situation
- economic efficiency
- market share
- capacity
- schedule and delivery performance.

5.6.1.4 Financial review

The financial review (see business plan) can draw upon financial variables such as:

- profit
- cash flow
- turnover
- working capital/investments
- liquidity.

5.6.2 Review input

ISO 9001:2000, Quality management systems — Requirements

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

The above indicators should be compared with data from competitors and other organizations in order to enable an internal site appraisal.

Trends in data and information should be compared with progress towards overall business objectives and converted into usable information for the purposes of:

- development of priorities for prompt solutions to customer-related problems;
- determination of key customer-related trends and inter-relationships to enable a review of the company situation, decision-making and longer term planning.

Note for auditors:

For the purposes of audit evaluation, the effectiveness of the existing system should be demonstrated, but not absolute results.

5.6.3 Review output

ISO 9001:2000, Quality management systems — Requirements

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

Measures shall be allocated deadlines, and results documented, in order to provide at least one evidence of the achievement of:

- the quality objectives from the business plan,
- customer satisfaction with the provided service,

as well as consideration of the cost against benefit.

Quality or non-quality has a major effect on the profit and loss situation of an organization and its units.

Losses can be reduced and customer satisfaction increased by improving the effectiveness and efficiency of processes. For this reason it is important to measure and report on the effectiveness of the quality management system from an economic perspective.

5.6.4 Financial reporting and evaluation

Preparation of financial reports can take place in parallel to or together with the normal recording of operating costs. It shall be transparent and enable long-term comparisons/trend overviews.

Methods of financial reporting of quality management system activities include, e.g. records of expenditure on:

<u>quality-related costs</u>

- error prevention
- inspection
- internal and external defects

or process-related costs (calculation of the profit/cost ratio)

- cost of conformity (fulfillment of requirements/definitions)
- cost of non-conformity

or quality-related losses (calculation of the cost of non-quality)

- internal and external material losses (non-fulfillment of quality requirements).

The organization has the responsibility to select, record and present (with linkage to causes and timeline) the financial parameters it considers appropriate. The data shall be analyzed and reviewed in such a way as to illustrate the effectiveness of the quality management system, initiate improvement and preventive action and monitor its effectiveness.

Reports shall provide information about quality and cost objectives and answers to the following questions:

- is top management able to identify problem areas from the quality-related cost analysis?
- are deviations from target values analyzed, leading to verifiable improvement measures?
- on the basis of the market- and cost-related data, does top management initiate innovation and other action for the benefit of the organization?

Note: For audit purposes, the existing system is to be evaluated, not the results. For external auditors, indicators and trends should be demonstrated, but not absolute values.

5.6.4.1 Internal losses as a result of unacceptable quality (non-conformity)

"Internal losses" are losses before handover to the customer as a result of unacceptable quality. They arise from reduced efficiency and refer to expenditure on, e.g.:

- damage
- rework (including corrections in administrative areas)
- re-acquisition
- unplanned inspection
- storage/non-productive costs
- lost work time owing to failure
- noncompliance with operational standards
- special deliveries/extra service provision.

5.6.4.2 External losses as a result of unacceptable quality (non-conformity)

"External losses" are tangible and intangible losses following handover to the customer that are identified as a result of unacceptable quality.

Tangible losses are costs of non-quality caused by a product/service not meeting quality requirements after handover to the customer and refer to expenditure on, e.g.:

- product and service warranty
- product and service guarantee and assurance of goodwill
- preventive action
- recall actions
- product liability
- consequential costs/compensation.

As far as possible, intangible losses shall also be recorded, such as:

- loss of image
- lost future sales
- loss of customers owing to dissatisfaction.

5.7 Product safety

Organizations shall include preventive quality assurance measures in their processes, in order to exclude the possibility of product/service nonconformities arising. The aim of these measures it to allow only safe products on to the market, thereby limiting the danger to life and limb and, consequently, the risk for the organization and its employees at all levels.

Management personnel at various levels shall, in accordance with their activities, be informed of the effects of product/service nonconformities and the consequences for the organization arising from product liability.

The quality management system shall be fundamentally directed towards the reliable prevention of nonconformities.

5.7.1 Principles of product liability

Product liability is understood to be "the obligation of a producer or others to recompense for loss related to personal injury, property damage or other harm caused by a (defective) product".

Liability dependent on blame is characterized by the reversal of the burden of proof. i.e. the burden of proof lies with the defendant.

Whereas paragraphs 459 of the German Civil Code (BGB) and 377 of the Trade Statute Book (HGB) regulate the direct compensation of losses arising from the defective fitness for use of a product, product liability law is concerned with the consequential damage of a defect, that is, the harm suffered by the consumer himself (life and limb, health, property) as a result of the inherent danger of the product.

Note: The legal and financial implications of product liability may vary from one jurisdiction to another.

Note: Paragraphs 823 and 831 of the German Civil Code (BGB) do not explicitly regulate questions of product liability. Rather, these paragraphs are founded on the responsibility of manufacturers, suppliers and dealers, who place products into public circulation, for traffic safety. The judicial system distinguishes the responsibility for cautionary measures into the following categories:

- development flaws
- design flaws
- manufacturing flaws
- instructional flaws
- product observation flaws.

The primary obligations concerning product liability are:

Information, documentation, development, product observation and monitoring of all people, suppliers and importers involved in manufacturing and service processes.

In the case of a liability claim therefore, evidence shall be provided that, e.g.:

- changes by the service provider to a product are, as a minimum, in accordance with the current "state of the art";
- responsibilities are defined;
- inspection and test documentation is available, with archiving;
- traceability is ensured (damage limitation), and
- the user is warned of possible risks during product utilization.

Indications concerning the knowledge of the principles of product liability can be, among others, evidence of:

- instruction and qualification of responsible individuals
- legal services (internal/external)
- product liability insurance
- observation of progress in science and technology.

5.7.2 Recognition of product/service risks

In order to be able to highlight product and service risks, a procedure shall be established. This shall serve the recognition and estimation of the hazard potential arising from a defectively conceived, processed and/or described service. Where appropriate, this shall lead to decisions concerning necessary actions.

Reduction of product/service risks can be achieved by, e.g.:

- a qualified and documented risk analysis of the service to be provided,
- a systematic review of new developments with regard to their safety and utilization risks,
- investigations addressing the risk of misuse in operation,
- upholding the "state of the art" of products, materials and processes,
- providing instructions and warnings in operational manuals
- providing printed material and advertisements to customers regarding assurances
- an early warning system for recall risks
- a recall system that ensures adequate possibilities for tracing and containing unsafe product.

5.7.3 Operational hazards

All equipment, processes and operational events without a clearly identified status regarding their potential during use to endanger or injure persons or damage materials shall be rated as a latent hazard.

Employees responsible for particular tasks or their superiors in positions of responsibility shall ensure that possible hazards are largely eliminated. Relevant measures may be, e.g.:

- identification/demarcation of danger zones
- installation of safety warnings
- definition of persons charged with monitoring/securing.

6 Resource management

6.1 Provision of resources

ISO 9001:2000, Quality management systems — Requirements

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

For the quality management system of an organization to operate effectively, management has the responsibility of providing the infrastructure, as well as the financial and personnel resources, needed to fulfill customer requirements. These include, for example:

- qualified personnel with task-related capabilities for management, implementation and inspection activities (including project management);
- facilities for service development and provision;
- IT support, e.g. for data analysis, graphic displays, statistics;
- communication equipment (internet connection, telephone, fax).

The effectiveness and efficiency of the organization and the quality management system depend on the provision of the necessary resources for the realization of the quality policy and the quality objectives.

6.2 Human resources

6.2.1 General

ISO 9001:2000, Quality management systems — Requirements

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

Employees are an essential factor contributing to the quality and performance capability of an organization. One of the management responsebilities is to promote the qualification and motivation of its employees.

Measures to train, qualify and motivate managers and employees shall be planned and implemented in all areas and at all levels of the organization. Action is needed as soon as the competency and knowledge of employees are no longer sufficient to meet the requirements of the task or customer.

Employee qualification shall be defined in, e.g.:

- requirements profiles
- job descriptions
- functional/operational instructions.

6.2.1.1 Employee leadership improvement

A lasting improvement in leadership can only be achieved when management actively assumes its role in providing an example. "Values are conveyed by good example".

A precondition for the leadership of employees is that all managers, apart from competence in their own fields, also possess the social and methodological skills needed to lead and motivate their employees in a target-oriented and quality-conscious manner.

Dynamic leadership is orientated towards the maturity level of employees in being able to take responsibility for themselves. Individuals need individual leadership.

Continual improvement of employee leadership may be achieved via. e.g.:

- the orientation of personnel issues towards leadership principles;
- agreed objectives regarding the improvement of leadership conduct;
- reviewing these objectives for their continued relevance and effectiveness;
- the application of quality tools and methods.

Evidence may be obtained e.g. by means of employee surveys.

6.2.2 Competence, awareness and training

ISO 9001:2000, Quality management systems — Requirements

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

The subject matter includes, among others:

- procedures for the recruitment of new employees;
- introduction/instruction;
- regular employee meetings, including review of progress towards the achievement of objectives;
- regular identification of training needs for each employee/function;

- differentiation of training needs according to knowledge and conduct as well as relevant quality tools and methods;
- implementation and performance of training;
- substitution planning.

Quality awareness, in particular the motivation to achieve quality objectives and the attitude towards the organization, shall be continually promoted and improved for managers and employees.

Such improvement may be achieved via, e.g.:

- promotion of a universal awareness of quality;
- transparency of customer requirements and organizational performance;
- incentive systems for employees;
- a system of improvement suggestions;
- quality circles;
- discussion about nonconformities and their consequences;
- training.

6.2.2.1 Training on the job

The training of all personnel at internal or external workstations shall be ensured for all new or modified operations of the provided service. This applies also to contract or agency personnel.

Personnel shall be informed about the consequences to the customer of nonconformity to quality requirements.

6.2.2.2 Employee motivation

The organization shall engage itself in motivating employees to achieve quality objectives, continually improve and create an environment for the promotion of innovation.

In addition, the extent to which personnel are aware of the significance and importance of their activity, and whether they know how they contribute to the achievement of objectives, shall be determined.

Employee surveys are a common method of determination.

6.2.2.3 Measurement of employee satisfaction

Employee satisfaction surveys shall be conducted in all organizational areas at regular intervals, from which measures shall be derived.

These may include:

- employee surveys;
- indications of trends, e.g. absenteeism, sickness, fluctuation, readiness to undertake professional/personal development;
- assessment of the effects of management conduct;
- training activities.

Evidence of such activities shall be provided.

6.3 Infrastructure

ISO 9001:2000, Quality management systems — Requirements

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

Necessary infrastructure shall be available or acquired for introduction of new services or for maintaining and improving existing services.

All activities, from planning, purchasing and up until approval of the required equipment, facilities, tooling and additional services shall be fully justifiable.

All infrastructure criteria (e.g. ergonomy, quality, cost, deadline) shall be clearly defined for the purposes of meeting requirements for service provision.

It is essential to monitor compliance with all prescribed targets.

6.3.1 Contingency plans

The organization shall prepare contingency plans to satisfy customer requirements in the event of an emergency such as utility interruptions, shortage of spare parts, absent personnel, key equipment failure and field returns.

6.4 Work environment

ISO 9001:2000, Quality management systems — Requirements

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

It shall be ensured that all requirements arising from the planning of the work environment for service provision are fulfilled. This can be confirmed by means of e.g. audit or review. Such a review shall involve participants from all functions/processes having an influence on service quality.

Among others, the following shall be taken into account:

- description of the provision of services;
- workstation layout and working conditions
- statutory and regulatory responsibilities.

6.4.1 Safety, order and cleanliness

A pre-condition for the provision of a quality service lies in premises and workplaces meeting defined requirements concerning their safety, state of order and cleanliness.

Monitoring can take place by means of specific audits or inspection rounds.

7 Service realization

7.1 Planning of service realization

ISO 9001:2000, Quality management systems — Requirements

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2: The organization may also apply the requirements given in 7.3 to the development of product realization processes.

Quality planning (or advanced quality planning) shall be understood to be an inter-disciplinary task and shall be documented in a form suitable to the size, structure and operational methods of the organization. Advance quality planning includes the concepts of error-proofing and continual improvement.

The application of project management supports quality planning tasks.

Specific quality practices, means and the order of activities shall be appropriately described for the planning of special service provision. This includes, e.g.:

- definition and identification of significant characteristics of the service;
- provision of facilities, processes and their means of control;
- updating of procedures and equipment;
- timely and predictive provision of measurement means and methods;
- suitable checkpoints during service realization;
- clarification of acceptance criteria
- change control, incl. verification and validation.

It is necessary to fundamentally differentiate between organizational and contract-related quality planning.

The quality management plan provides a suitable means towards quality planning by presenting specific quality-relevant working methods, operational flows and the resources for the provision and inspection of a service.

7.2 Customer-related processes

Customer-related processes for service providers are significantly different from those of manufacturing operations/suppliers. The requirements of "the customer/market" are decisive in determining the organization of a service provider, e.g. a workshop or a distribution center. The development of new workshop services is very rarely provided for only "one customer". Normally, services are made available for the benefit of a number of different customers.

In the service provision process, individual implementation of the following "customer-related processes" appears in the widest variety of places and process stages. However, what they have in common is that they affect external customers.

7.2.1 Determination of requirements related to the service

ISO 9001:2000, Quality management systems — Requirements

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

This requirement includes both the demands of the marketplace/customers (see also sub-clause 7.2.1.1 – Market research) and the direct requirements of the customer ordering a service.

The requirements include recycling, environmental impact and characteristics identified as a result of the organization's knowledge of the product and of production and service processes. Detrimental effects caused by the service organization on society and the environment shall be avoided.

Compliance to item c) includes all applicable government, safety and environmental regulations, norms and VDE/VDI-guidelines applied to acquisition, storage, handling, recycling, elimination or disposal of materials.

The examination of which applicable standards, norms, drawings and specifications are to be followed shall be undertaken prior to providing a service.

Documentation requirements shall be checked against compatibility with relevant statutory and regulatory requirements.

7.2.1.1 Market research

Market research is a necessary process in advance of the development of new services and service provision processes.

Market research involves creating a solid foundation of systematic and comprehensible market and customer analyses, leading to the selection of services to be developed and offered. These measures secure early recognition of market changes and protect from erroneous decisions and/or investments.

A process shall be established in the organization to address at regular intervals the requirements and expectations (consumer preferences, level of expectation, expected reliability, availability) regarding the products/ services on offer, and analyze and document results.

It is a management responsibility to coordinate this process, derive and implement improvement actions, and check their effectiveness. This is especially important in the case of outsourced market research.

The instigation for converting market and customer expectations into new and/or additional services shall be demonstrated, including the extent to which competitor analysis has been used for this purpose.

The requirements apply also to changes to services and service provision processes.

7.2.2 Review of requirements related to the service

ISO 9001:2000, Quality management systems — Requirements

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.2.1 Advance consultation with the customer

In order to avoid errors at the customer/service provider interface, the scope of the service to be provided shall be fully clarified prior to contract finalization. The possibility of the customer's knowledge/experience being insufficient to estimate the scope of the service is to be taken into account. Where this is the case, the customer shall be informed of possible problems by the service provider.

This could be e.g. further procedures following identification of an invisible defect in the course of the service delivery. Particular attention shall be paid to the following key points, among others:

- clarification of the scope of product/service provision and its feasibility;

- determination of performance requirements;
- limitation of expected costs during the service provision;
- determination of deadlines/time requirement for the service provision;
- definition of quality requirements;
- consideration of statutory regulations, guidelines, directives and business terms and conditions.

Applicable requirements shall be defined in writing, whereby the documentation format shall be appropriate to the value and scope of the service to be provided.

During contract review, the organization shall investigate, confirm and document the feasibility of realizing the proposed service, including in special cases a risk analysis, e.g. for design and development contracts.

Confirmation of the product to be delivered or service to be provided is mandatory. Depending on the type and scope of the service, this can be in the form of a simple order confirmation (e.g. delivery note, call-up memo), or the sign-off of more complex contracts.

7.2.3 Customer communication

ISO 9001:2000, Quality management systems — Requirements

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

During service provision, only difficult or unpredictable events can lead to a change in the defined performance requirements. These may be initiated either by the service provider or the customer. In order to prevent problems, this possibility and any related procedure should be addressed already during contract definition. In all cases, the further procedure shall be regulated.

The following shall be considered:

- sufficient documentation/recording of the identified problem or deviation;
- customer information following identification by the supplier;
- preparation of solution proposals/alternatives;
- feasibility testing;
- agreeing the further procedure with the customer;
- alteration/extension of the performance requirements;
- adjustment of the contract (in writing or as a communication memo);
- confirmation of contract change, where necessary;
- ensuring information to all affected/involved personnel.

The procedure and responsibility for carrying out contract changes shall be defined in the quality management system. The recording of evidence shall be appropriate to the value/scope of the service and may be dealt with by means of memoranda or, if need be, a new contract or, alternatively, via an annex to an existing contract.

Customer support/after-sales includes the responsibility to provide instruct-tion and all methods of promoting customer contact. It may be recognized by, e.g.:

- technical consultation during assembly, utilization and operation;
- education of risks;
- proposals for solutions to problems;
- visits, written communication;
- informative material regarding service offers, including equipment upgrades;
- invitations to events for service providers;
- customer training;
- continual service communication (seasonal offers, birthday cards, etc.);
- availability of a replacement vehicle/equipment.

Customer complaints shall be recorded in a complaints management system with suitable measures to restore lasting customer satisfaction (see also 7.5.1.8).

7.2.3.1 Marketing

The aim of the marketing activity is to fully analyze and describe the market and to permanently strengthen customer loyalty. Marketing is therefore an important factor in the placement of products/services and is always (directly or indirectly) applied. Depending on the size/structure of an organization, marketing may be conducted within its own sphere (department/area) or with the use of external support.

Market coverage:

The systematic coverage of the market shall be ensured on the basis of marketing plans.

Knowledge from market analyses, distribution, benchmarks, surveys, etc. creates the basis for the definition of marketing activities. This can take place, among others, in the form of advertisements, billboards, leaflets, showrooms, internet, events or direct marketing.

Compliance of advertised statements:

It shall be ensured that advertised/promised services are capable of being realized and are not contrary to regulations (unfair competition) or cooperative agreements (customer/supplier). This is to positively influence advertising quality and prevent possible errors, such as:

- missing the target group,
- imprecise statements,
- false promises.

Building trust:

Trust building is an essential factor, which depends on the type of product/service to be put onto the market. Customer trust and, consequently, long-term loyalty can be greatly influenced by the availability of evidence of relevant professional competence (certificates, awards, references) and its appropriate use in advertising.

This evidence should therefore be a permanent element in communication, and/or be available and prudently placed in areas frequented by customers.

Effectiveness of marketing activities:

Suitable means shall be used to determine whether marketing activities lead to the anticipated success. Experience gained shall be taken into account in future activities. A cost/benefit analysis shall be performed.

An evaluation of effectiveness may take place by means of, e.g.:

- a targeted question during customer enquiries/contract finalization;
- conducting sales statistics;
- determination of loyalty rates;
- determination of market awareness;
- surveys to establish the level of availability to customers.

The benefit of marketing activities may be seen in, e.g.:

- sales increase;
- building trust;
- increase in product/service acceptance;
- increase in market awareness;
- a rise in company image/customer interest;
- quality of the customer portfolio;
- expanding list of prospective customers.

Corporate Identity:

Where "corporate identity" (CI) requirements exist, these shall be respected during communication with existing and potential customers. Depending on the type of product/service, this includes availability, design of the premises, order/cleanliness and employee appearance.

7.2.3.2 Acceptance and impact of provided services

Assessment by the customer is the ultimate measure of service quality. Not only the direct or delayed reaction of the customer to detected defects immediately following service delivery should be considered here, but also those arising during the warranty period and the entire duration of operational use.

Each service provider shall determine how to observe the acceptance and results of their product/service in operational use. Methods of collecting and recording this information are described in sub-clause 8.2.1.

7.3 Service development

This clause describes the quality assurance tasks in the area of service development. The development department is responsible for:

1. converting customer requirements from the requirements specification into specifications for new services, and
2. the preparation of a timely, customer-conform realization (= service provision preparation).

The provision of resources for e.g. personnel, equipment or pilot operations is a precondition for service development. This is ensured by respecting project organization requirements.

This clause is mandatory in the case of applying this standard to design and development areas of the automotive industry, where corresponding production areas are bound to comply with ISO/TS 16949:2002.

7.3.1 Design and development planning

ISO 9001:2000, Quality management systems — Requirements

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,
b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

The development plan shall present current milestone plans, network plans etc. with detailed plans, which demonstrate all activities from conception/ order through to implementation. The systematic processing of planned tasks (project planning) shall be ensured. A person responsible for the project and all involved areas shall be nominated and their tasks, competencies and responsibilities assigned. Central monitoring of the project's progress shall be ensured (ongoing comparison of actual to specified). Monitoring shall cover compliance with all prescribed objectives, such as:

- task fulfillment
- quality, costs, deadlines
- means.

Evidence shall be provided by means of examples.

The project manager is responsible for, e.g.:

- building an inter-disciplinary project team;
- establishing and implementing project targets;
- planning of the project as a whole;
- monitoring project progress;
- representation of project results in front of the customer and management;
- definition of communication channels, content and means;
- documentation (type, location and scope);
- development and updating of the Design-FMEA, including actions in design and development offices.

7.3.2 Design and development input

ISO 9001:2000, Quality management systems — Requirements

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4).

These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.2.1 Service development input

The organization shall identify, document and review the service development input requirements, including the following:

- customer requirements, customer-specific requirements, requirements specifications (contract review);
- agreed supplier commitments;
- use of information: the organization shall have a process, by which knowledge gained from previous development projects, results of market research, competitor analyses, supplier feedback, internal data, field data (long-term quality) and other suitable sources is used for similar, current and future projects;
- objectives for service quality, reliability, preservation, schedule and cost.

7.3.2.2 Special characteristics

The organization shall identify special characteristics (see 7.3.3 d) and

- include all special characteristics in the control plan,
- comply with customer-specified definitions and symbols, and
- identify service provision process control documents including drawings, sketches, control plans, and operator instructions with the customer's special characteristic symbol or the organization's equivalent symbol or notation to include those process steps that affect special characteristics.

7.3.3 Design and development outputs

ISO 9001:2000, Quality management systems — Requirements

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.3.1 Service development outputs

Development output relating to a service shall be appropriately documented with specifications and/or process instructions/procedures. Such documents for the realization of quality requirements shall be complete and unambiguous.

These may be, e.g.:

- description of the requirements profile and safety criteria;
- complete and comprehensible description of service characteristics;
- acceptance criteria for each service characteristic;
- description of supplier involvement;
- a process description: "service provision";
- operating and service manuals.

7.3.4 Design and development review

ISO 9001:2000, Quality management systems — Requirements

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

NOTE: These reviews are normally coordinated with the development phases and include service provision process development.

7.3.4.1 Monitoring

At defined stages of development, indicators shall be defined, analyzed and reported in overview as input to the management review (e.g. as quality gates).

Comparison with requirements from the requirements/performance specification can take place by application of various methods. For the purposes of the review, terminology and the way of documenting results shall be defined, in particular:

- review: evaluation of individual stages;
- verification: comparison of results with requirements from the performance specification;
- validation: confirmation of fitness for a specific intended use and/or comparison with the requirements specification, often with customer involvement: confirmation for release.

7.3.5 Design and development verification

ISO 9001:2000, Quality management systems — Requirements

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

ISO 9001:2000, Quality management systems — Requirements

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

NOTE 1: The validation process normally includes an analysis of field reports for similar products and services.

NOTE 2: The requirements of 7.3.5 and 7.3.6 above apply to both service development and service provision processes.

7.3.7 Control of design and development changes

ISO 9001:2000, Quality management systems — Requirements

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

NOTE: Design and development changes include all changes during the provision of similar services.

Procedures and responsibilities shall be established for, e.g.:

- planning, documentation and recording of changes;
- evaluation of the impact of changes;
- information to all involved in the process;
- definition of how the customer shall be informed of changes.

The introduction and realization of changes shall be documented, i.e. for evidence and traceability.

Suitable overviews shall be developed to fully summarize all changes. Responsibilities for this shall be defined.

The system shall be able to prevent misuse.

The procedure shall establish a release and distribution system that ensures the correct documents are available at the right place and time, and excludes the possibility of confusion with obsolete documents.

7.3.8 Review and release following conclusion of service provision preparation

Procedures for release and realization shall be defined for the individual functional and organizational units.

Prior to the first provision of a service, the following points shall be examined and confirmed:

- up-to-date documents, downstream change management;
- authorization of employees;
- suitability of resources;
- procedures for regular operation and under deviation;
- agreement in the case of deviation from regular operation.

7.4 Purchasing

7.4.1 Purchasing process

ISO 9001:2000, Quality management systems — Requirements

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply products in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4)

The above mentioned products include all purchased products and services that affect customer requirements. They are directly or indirectly constituent elements of the final product and influence as such the quality of the product/service.

7.4.1.1 Regulatory conformity

All purchased products, materials and services shall conform to regulatory requirements applicable to the country concerned.

7.4.1.2 Supplier quality management system

The supplier shall have in place a functioning and effective quality management system that fulfils the requirements of ISO 9001:2000. In the case of concern regarding the quality capability of the supplier, appropriate improvement measures shall be initiated and monitored by the organization. Evidence shall be provided according to the organization's request.

7.4.1.3 Customer-approved sources

Where specified by the contract (e.g. customer specification/order), the organization shall purchase products, materials and services from customer-approved sources.

The use of customer-designated sources, including tool/gauge suppliers, does not relieve the organization of the responsibility for ensuring the quality of purchased products.

7.4.2 Purchasing information

ISO 9001:2000, Quality management systems — Requirements

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Complete and easily comprehensible specifications or references shall be a constituent part of orders (drawings, standards, quality agreements regarding quality of service realization, statutory/regulatory requirements to be observed, etc.).

All details relevant to the purchasing of products/services shall be confirmed with suppliers/sub-contractors. In addition to technical specifications, this includes, e.g.:

- tests to be performed;
- acceptance criteria;
- procedure in the case of a service being not at all or not sufficiently provided (alternative plans);
- respect of statutory requirements in connection with the leasing of personnel;
- continual improvement;
- definition of measurable objectives;
- cost optimization.

7.4.3 Verification of purchased product

ISO 9001:2000, Quality management systems — Requirements

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.4.3.1 Incoming product quality

The organization shall have a process to assure the quality of purchased product/service (see 7.4.3) utilizing one or more of the following methods:

- receipt of, and evaluation of, statistical data by the organization;
- receiving inspection (mainly plausibility or identity checks);
- second- or third-party assessments or audits of suppliers, when coupled with records of acceptable delivered product and service quality;
- another method agreed with the customer.

7.4.3.2 Supplier monitoring

Supplier performance shall be monitored through the following indicators:

- delivered product/service quality
- claims, including field returns
- delivery and schedule performance (including incidents causing additional costs).

7.5 Service provision

7.5.1 Control of service provision

ISO 9001:2000, Quality management systems — Requirements

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery and post-delivery activities.

7.5.1.1 Service provision control plan

For all stages of service provision, the organization shall define procedures for inspecting, recording and monitoring of product/service quality.

The control plan shall include:

- all measurements for the control of quality;
- required inspections and handling of customer property;
- methods of monitoring and control of pre-defined characteristics;
- information required by the customer, where applicable;
- immediate reaction plan in the case of quality problems.

Control plans shall be reviewed and updated in each time a change is made to the service.

7.5.1.2 Procedures and process instructions for service realization

The organization shall prepare and maintain documented procedures and process instructions for all employees having responsibilities for the operation of processes that impact product/service quality.

These instructions shall be up-to-date and accessible for use at the work station (exception: field and emergency services).

They shall contain all information, responsibilities, means, interfaces and processes required for the orderly control and completion of an order.

In some cases, supplementary instructions may be included, such as those for assembly, utilization and operation.

In the case of repairs to or adaptation of products and/or services, the manufacturer's/producer's instructions may be used.

7.5.1.3 Work instructions for service realization

The organization shall prepare appropriate documented work instructions for all employees having responsibilities for the completion of tasks that impact product/service quality. These instructions shall be up-to-date and accessible for use at the work station (exception: field and emergency services).

7.5.1.4 Preventive maintenance

The organization shall identify process, test and inspection equipment for key processes, provide resources for its maintenance and develop an effective planned total preventive monitoring and maintenance system. As a minimum, this system shall include the following:

- planned maintenance activities;
- packaging, storage and preservation of process equipment, tooling, and test and inspection equipment;
- availability of replacement parts for maintaining the service;
- documenting, evaluating and improving maintenance objectives.

The following aspects should be taken into account:

- influence of production, test and inspection equipment on occupational safety during completion of orders;
- requirements for the accuracy of production equipment and the uncertainty of test and inspection equipment;
- definition of monitoring and maintenance intervals on the basis of risk estimation.

7.5.1.5 Coordination and scheduling of service provision

The organization shall provide evidence of scheduling the progress and completion of service provision to fulfill agreements with the customer.

7.5.1.6 Final inspection and handover to the customer

For final, delivery or acceptance inspections, clear rules and inspection instructions shall exist, in order to ensure repeatability. These instructions may be prepared generally or product-/service-specific and shall include, among others, the following:

- examination of completeness, function, condition, correctness and cleanliness;
- confirmation that customer-supplied product or customer property is complete and undamaged;
- concluding assessment or in some cases supplementary tests specific to the contract (e.g. test drive, expert opinion, etc.);
- providing evidence of mandatory and statutory tests (product liability, environmental protection);
- ensuring correct application and operational use through a comprehensive handover and any necessary guidance and instructions;
- procedures for the observation and evaluation of quality characteristics not recorded during the final inspection, such as invoicing, explanations or handover to the customer.

Internal final inspections performed by authorized personnel may, where needed, be conducted together with the customer.

7.5.1.7 Customer feedback

A process shall be available, which actively registers customer feedback regarding product and service and forwards the information to the respective positions within the organization or, if need be, to further applicable areas (e.g. customer service of the manufacturer, design and development, headquarters).

This is to ensure that all involved parties are aware of defects arising at the customer and take action to permanently eliminate them. The method of collecting and recording this information is described in clause 8.3.

7.5.1.8 Service and customer support

"Service and customer support/after-sales" is the part of a service provision process that deals with the direct attention paid to the customer, i.e. people and their needs and expectations of an organization.

Particularly following the delivery of a service or product, the continued support of the individual customer is important to achieve trust, a personalized relationship and loyalty to the organization. The treatment of claims and complaints within the organization has an especially high potential value as it can convert an initially negative experience for the customer into a positive, exceptional experience leading to increased customer satisfaction (see also 7.2.3).

7.5.2 Validation of processes for service provision

ISO 9001:2000, Quality management systems — Requirements

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4.2.4), and

e) revalidation.

7.5.3 Identification and traceability

ISO 9001:2000, Quality management systems — Requirements

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.

During the entire process of service provision, the identity of the order shall be readily recognizable. Activities, results of inspections, various measures and their documentation shall be able to be assigned to the service at all times.

The traceability of services to personnel/teams providing them shall be ensured.

This shall enable containment of non-conform products/services, damage limitation in the case of defects, follow-up of customer complaints and liability cases as well as relevant training and instruction of personnel.

7.5.4 Customer property

ISO 9001:2000, Quality management systems — Requirements

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE: Customer property can include intellectual property.

NOTE: Customer-owned returnable packaging is included in this clause.

7.5.4.1 Customer-Supplied Product

"Customer-supplied products" are products which are provided free of charge to the organization and do not directly add any value to the service being provided (e.g. installation of a customer-supplied radio, customer-supplied oil, etc.).

For customer-supplied products, care shall be taken already at the time of contract review or acceptance in determining whether the customer is supplying anything. For the procedure definition, the following shall be observed, e.g.:

- can the customer-supplied product be immediately processed as in the case of purchased products? If not, are additional measures (e.g. identification) necessary and are these agreed with the customer?
- in all cases, performance of appropriate receiving inspection;
- informing the customer of defective, damaged or misplaced products/services;
- documentation of observations, agreements and the execution of special procedures;
- ensuring due care in handling and storage.

7.5.5 Preservation of product

ISO 9001:2000, Quality management systems — Requirements

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.5.5.1 Storage and inventory

Written procedures and instructions shall include measures that enable an effective protection of products/services against damage and environmental deterioration. This applies during order completion (including e.g. test drive), storage and transport (including special cautionary measures for carriers).

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals.

The organization should use an inventory management system that includes "first-in-first-out" (FIFO) with the aim of optimizing stock rotation times and especially avoiding over-storage of product subject to limited storage periods.

Obsolete product shall be controlled in a similar manner to nonconforming product.

7.6 Control of monitoring and measuring devices

ISO 9001:2000, Quality management systems — Requirements

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE: See ISO 10012-1 and ISO 10012-2 for guidance.

7.6.1 Calibration/verification records

Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity to determined requirements, shall include:

- equipment identification, including the measurement standard against which the equipment is calibrated,
- revisions following engineering changes,
- any out-of-specification readings as received for calibration/verify-cation,
- an assessment of the impact of out-of-specification condition,
- statements of conformity to specification after calibration/verify-cation, and
- notification to the customer if suspect product or material has been shipped and/or installed, and/or in the case of delivery of a possibly defective service.

8 Measurement, analysis and improvement

8.1 General

ISO 9001:2000, Quality management systems — Requirements

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measure-ment, analysis and improvement processes needed

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statis-tical techniques, and the extent of their use.

8.1.1 Identification of service criteria

Appropriate criteria for measurement/evaluation shall be defined for each process. These are to be checked during development and operation of the processes. Where appropriate, criteria shall be evaluated using statistical methods.

8.1.2 Knowledge of basic statistical concepts

Basic statistical concepts shall be understood and utilized by management and planning functions. These include, e.g., variation, capability and trend.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

ISO 9001:2000, Quality management systems — Requirements

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE: Consideration should be given to both internal and external customers.

Customer satisfaction with the organization shall be monitored through continual evaluation of the performance of relevant processes. Not only the direct or delayed reaction of the customer to detected defects immediately following service provision should be considered here, but also those arising during the warranty period and the entire duration of the customer relationship. Customer acceptance shall be described via indicators based on objective data and including as a minimum:

- service quality performance
- customer feedback (positive and negative)
- schedule performance
- availability
- customer notifications related to quality or delivery issues

Relevant information can be collected by means of activities such as:

- customer surveys
- consultation with the customer during or after handover
- regular market observation
- recording of claims, customer complaints, correction orders and lost customers (see also sub-clause 7.2.3.2).

The knowledge gained should be subject to a trend analysis and initiate measures leading to an improvement of the service and, consequently, increased customer satisfaction.

8.2.2 Internal audit

ISO 9001:2000, Quality management systems — Requirements

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE: See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.2.1 QM system audit

The organization shall audit its quality management system to monitor and evaluate the fulfillment of the requirements of this standard and any additional internal and external requirements of the quality management system.

Note: In smaller organizations internal audits may be performed by external contractors.

8.2.2.2 Process audit

The organization shall audit each service provision process listed in its quality manual in order to determine its effectiveness.

8.2.2.3 Internal audit plans

Internal audits shall cover all processes listed in the quality manual and shall be performed according to an annual plan.

The individual audit planning and preparation shall include the following information:

- subject of audit
- reference documents
- processes to be audited
- audit plan
- scheme of questions
- scheduled dates
- audit team
- report compilation and distribution.

8.2.2.4 Internal auditor qualification

The organization shall qualify internal auditors.

Internal auditors shall be trained in quality techniques, methods and standards relevant to the requirements of the audited area.

This should include the following:

- methods of evaluation by means of investigation, interview, assessment and reporting (e.g. auditor training);
- skills that are essential for the management of a quality audit, such as planning, organization, communication and leadership;
- experience in quality management and quality techniques;
- knowledge of the operations and processes to be audited;
- personal characteristics, such as, e.g. integrity, good judgment, analytical ability, open-mindedness;
- continued professional development to maintain authorization.

8.2.3 Monitoring and measurement of processes

ISO 9001:2000, Quality management systems — Requirements

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Repairs to or adaptation of products/services shall be checked in terms of whether internal instructions, and/or those of the manufacturer/producer, have been adhered to.

The following aspects or particulars shall be observed:

- performance and inspection of all operations, where applicable according to supplementary instructions, such as those for assembly, utilization and operation, or test and inspection instructtions;
- reference to approved/released replacement parts or aids (for reasons of product liability and warranty);
- records of completed actions and/or inspections;
- documentation of effective dates of process changes.

8.2.4 Monitoring and measurement of services

ISO 9001:2000, Quality management systems — Requirements

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

The organization shall ensure that quality requirements defined by the customer are met. The interaction of processes (see 8.2.3) shall correspond to customer requirements. Indicators shall be defined that reflect the demands on the service. Results shall be available for customer review.

Inspections encompass the complete measurement of all defined criteria (see 7.5.1.6).

At defined intervals, the organization shall check whether the required results were actually achieved. These are, for example:

- trial purchase
- workshop test
- trial enquiries
- trial calls
- internal tests.

8.3 Treatment of nonconforming services

ISO 9001:2000, Quality management systems — Requirements

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

"Nonconformity“ (= non-fulfillment of a requirement) in products/services are exceptional events that can occur during acceptance of a product and/or the completion of an order up until final inspection or customer acceptance, and therefore need to be identified and corrected.

In order to control nonconforming products/services, written directions shall be made available, which describe how to proceed in such cases, how authority for decision-making is defined and how evidence of rework/

repair is ensured. These directions shall address, among others, the following aspects:

- identification, documentation and assessment of nonconforming products/services;
- selection, so that nonconforming products/services cannot be further used or processed without correction;
- decision-making criteria for further action (including environmentally responsible disposal);
- findings affecting a supplier, which shall become input to the supplier evaluation;
- re-inspection in the case of corrected products/services;
- special concessions with involvement of a competent person and/or the customer;
- recording of evidence of findings, decisions, actions and inspections.

8.4 Analysis of data

ISO 9001:2000, Quality management systems — Requirements

8.4 Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),

b) conformity to product requirements (see 7.2.1),

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

8.4.1 Analysis and use of data

Trends in quality and operational performance shall be compared with progress toward objectives. Action shall be initiated, including the following:

- determination of priorities for corrective action according to urgency and risk;
- determination of key customer-related trends and correlation for status review, decision-making and longer term planning;
- an information system for timely reporting of the impact of the provided service.

8.4.2 Benchmarking

Company-wide performance data shall be compared to information from benchmarking or similar methods, and resulting improvement measures initiated.

The evaluation, analysis and use of company-wide performance data in comparison with the data of competitors or other organizations through benchmarking shall provide information on, e.g.:

- productivity
- prices/costs = economic efficiency
- customer satisfaction
- market shares
- range of services on offer.

Note: For the purposes of audit evaluation, the existing system should be demonstrated, but not the results.

8.5 Improvement

8.5.1 Continual improvement

ISO 9001:2000, Quality management systems — Requirements

8.5 Improvement

8.5 1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The organization shall define a process for continual improvement (see examples in annex B of ISO 9004:2000).

8.5.1.1 Improvement of the service provision process

Service improvement shall be continually directed towards the reduction of variation in quality.

The following actions are required as a minimum:

- improving the quality level of services;
- optimization of work-flow;
- risk analysis for service provision;
- increase in efficiency (cost reduction of processes, increase in customer benefit);
- improvement of customer support and the customer relationship.

Activities and steps in this process may be, e.g.:

- a systematic diagnosis and implementation of knowledge gained (involvement of users, optimization);
- definition of responsibilities and authorities;
- selection of improvement projects according to defined criteria;
- monitoring of individual improvement projects;
- output review (customer benefit, economic efficiency, comparison to targets);
- application of feedback systems, benchmarks, audits, customer reports.

8.5.2 Corrective action

ISO 9001:2000, Quality management systems — Requirements

8.5.2 Corrective action

The organization shall take action to eliminate the cause of noncomformities in order to prevent recurrence.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken (see 4.2.4), and

f) reviewing corrective action taken.

8.5.2.1 Problem solving

The organization shall have a defined process for problem solving leading to root cause identification and elimination.

In the case of problems with quality and customer satisfaction, the real root causes shall be determined. This means, where appropriate, the involvement of product suppliers, service providers and/or customers/service receivers, as well as the inclusion of processes, documents and records.

Nonconformity root cause analysis procedures may be, e.g.:

- 8-D report
- cause-effect diagram (fish bone/Ishikawa diagram)
- progression analysis
- ordered and structured information.

If a customer-prescribed problem-solving format exists, the organization shall use the prescribed format.

8.5.2.2 Error-proofing

The organization shall use error-proofing methods in their corrective and preventive action process. Corrective action and applied control mechanisms shall be extended to similar processes and services, in order to eliminate the root causes of a nonconformity.

"Error-proofing" means "right first time". All processes shall be conceived and controlled in such a way as to exclude the possibility of nonconformities arising.

Operational flows shall be defined with the aim of promoting a customer-oriented mindset and actions that secure processes by preventive means (if need be following a risk estimation) and exclude the possibility of repeated failure.

This is especially applicable to product failures and breakdowns, where the actual root cause is to be found in deficiencies in service operations, complex operations, maintenance- and user-unfriendly products and processes or poor instructions and/or omitted training and introduction.

Error-proofing is only possible with consistent realization of the introduced management methods and systematic application of quality and supporting techniques.

Examples are:

- working in control-loop mode (Plan-Do-Check-Act);
- operating according to flow-charts or checklists;
- risk analyses (e.g. FMEA).

8.5.2.3 Services under claim

The organization shall analyze services claimed by the customer. Processing time for this shall be kept to a minimum. Records shall be maintained and made available upon request. Analyses shall be performed leading to corrective action to prevent recurrence.

Analysis of data from internal and external claims shall follow a purpose-oriented and planned course of action. This aims to identify noncompliance with defined requirements, root causes and above all systematic errors, in order to derive and implement error-proofing measures.

Note: The time allowed for analysis should be appropriate to the determination of root cause, the corrective action and the monitoring of its implementation effectiveness.

8.5.3 Preventive action

ISO 9001:2000, Quality management systems — Requirements

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of results of action taken (see 4.2.4), and

e) reviewing preventive action taken.

Annex A The VDA 6.2:2004 evaluation system

The VDA 6.2:2004 evaluation system is a development of the hitherto existing system, proven and accepted by auditors and auditees alike. It is oriented towards the actually existing processes of an organization, its management functions and main value-adding processes.

The well-known point score evaluation system has been clarified and modernized. The first aspect of the evaluation, "effectiveness in practice", has been augmented by a risk estimation, the second aspect, "documentation of requirements and evidence", remains unchanged.

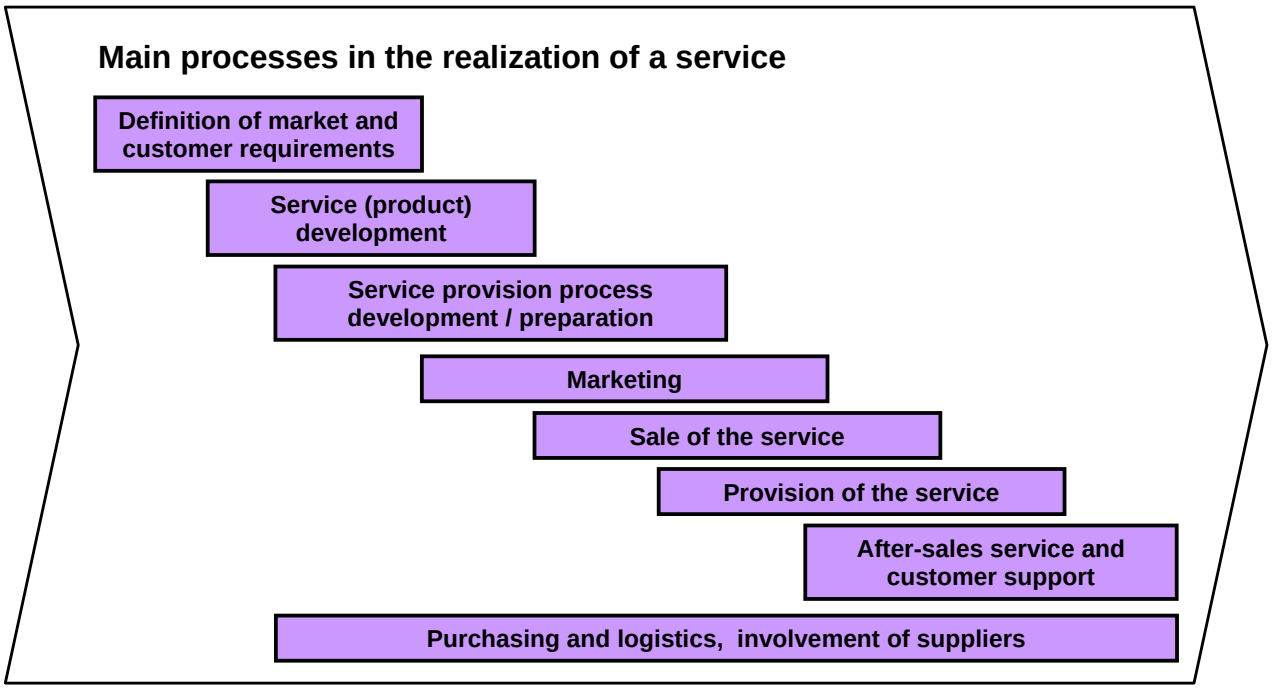
The evaluation logic (degree of fulfillment of requirements) with a corresponding point score remains as before. Experience from evaluations performed in organizations and by certification bodies has been integrated.

However, a distinction consists in the fact that there is no longer a questionnaire in the previous sense to follow, but **one** process-oriented list of topics, which is applied to each management and main realization process.

Management functions consist of the following functions:

- Corporate strategy
- Leadership, including corporate culture, personnel and safety
- Process mapping (responsibility for structural and procedural organization)
- Management systems (including the QM system)
- Financial controlling (including financial analysis of the cost of non-quality).

The traditional service provision process is arranged in the following main realization processes:

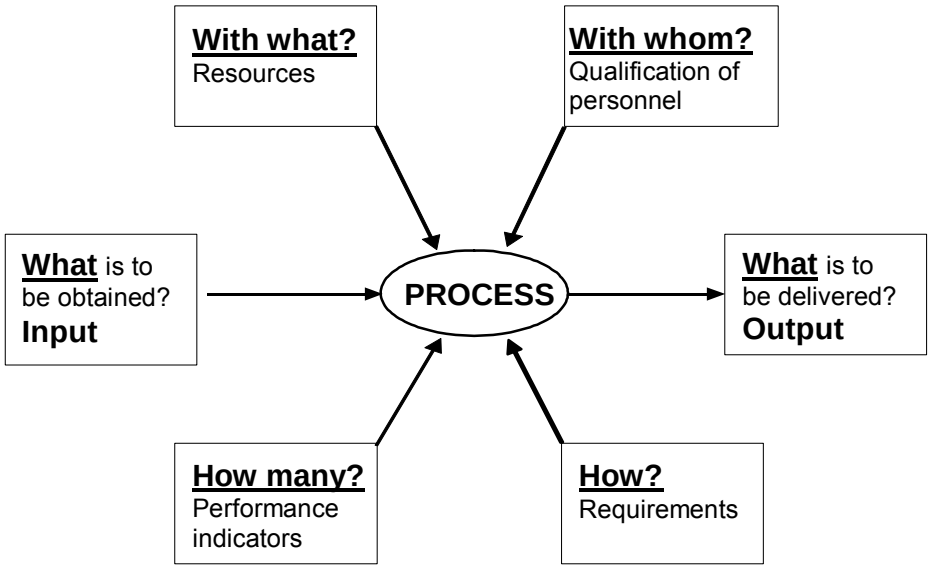


These main realization processes exist for every service provider (in special cases, however, without internal service development).

These main realization processes are the central focus of the audit and the VDA 6.2:2004 evaluation system.

Each of the 13 processes (5 management and 8 main realization processes) can be effectively audited according to the following model:

The scheme of 6 questions for each process:



In order to enhance clarity and transparency for auditors and auditees alike, each of the 13 pre-defined processes (see previous page) is evaluated only once and as a whole according to the following point score system.

The VDA 6.2:2004 evaluation system

Risk estimation, effectiveness in practice	no risk, effectiveness proven	low risk, effectiveness mostly proven	significant risk, effectiveness mostly proven	high risk, effectiveness partly proven	high risk, effectiveness not proven
Documentation of requirements and evidence	Full compliance	mostly available	mostly available	partly available	fragmented availability
VDA Point score	**10**	**8**	**6**	**4**	**0**
Status	**GREEN**	**YELLOW**	**RED**	**RED**	**RED**
Certification	**O.K.**	**conditional**	**Minor non-conformity**	**Major non-conformity**	
	VDA Certificate or Upgrade		**Neither VDA Certificate nor Upgrade**		

To achieve a Certificate Upgrade, no process may be evaluated with 6, 4 or 0 points!

The evaluation of main realization processes and management processes may be combined.

Annex B Comparison matrix VDA 6.2:2004/VDA 6.2:1997/2000

Clause VDA 6.2: 2004	Title	Element VDA 6.2 1997/2000
4	Quality management system	
4.1	General requirements	02
4.1.1	Outsourced service processes	not included
4.2	Documentation requirements	
4.2.1	General	02.3
4.2.2	Quality manual	02.1
4.2.3	Control of documents	16, 16.2
4.2.3.1	Service requirements	11.1
4.2.4	Control of records	16.1, 17
4.2.4.1	Storage of records	17.3
5	Management responsibility	
5.1	Management commitment	01, Z1
5.1.1	Business plan	Z1.1
5.1.2	Process efficiency	03.3, Z1.2
5.2	Customer focus	01.2, Z1.4, 07.2, 07.3
5.3	Quality policy	01.1, 01.2, 01.6
5.4	Planning	
5.4.1	Quality objectives	01.1, 01.2, 04.4, Z1.1
5.4.2	Quality management system planning	02, 02.4
5.5	Responsibility, authority and communication	
5.5.1	Responsibility and authority	02.3
5.5.1.1	Responsibility for quality	not included
5.5.2	Management representative	01.5
5.5.2.1	Customer representative	not included
5.5.3	Internal communication	not included
5.6	Management review	
5.6.1	General	01.6
5.6.1.1	Review of customer satisfaction	Z1.4, 14.3
5.6.1.2	Review of employee satisfaction	Z1.5, 04.6
5.6.1.3	Review of processes	Z1.3, 03.3
5.6.1.4	Financial review	Z1.2
5.6.2	Review input	01.6, Z1.3
5.6.3	Review output	01.6, 05
5.6.4	Financial reporting and evaluation	05.1, 05.2
5.6.4.1	Internal losses as a result of unacceptable quality	05.3
5.6.4.2	External losses as a result of unacceptable quality	05.4

Clause VDA 6.2: 2004	Title	Element VDA 6.2 1997/2000
5.7	Product safety	06
5.7.1	Principles of product liability	06.1
5.7.2	Recognition of product/service risks	06.2
5.7.3	Operational hazards	06.5
6	Resource management	
6.1	Provision of resources	01.4
6.2	Human resources	
6.2.1	General	04, 04.2
6.2.1.1	Employee leadership improvement	04.1
6.2.2	Competence, awareness and training	04.2, 04.3, 04.5
6.2.2.1	Training on the job	not included
6.2.2.2	Employee motivation	not included
6.2.2.3	Measurement of employee satisfaction	04.6
6.3	Infrastructure	01.4, 09.2
6.3.1	Contingency plans	09.4
6.4	Work environment	09.1
6.4.1	Safety, order and cleanliness	06.3
7	Service realization	
7.1	Planning of service realization	02.4
7.2	Customer-related processes	not included
7.2.1	Determination of requirements related to the service	08.2
7.2.1.1	Market research	07
7.2.2	Review of requirements related to the service	11
7.2.2.1	Advance consultation with the customer	11.2
7.2.3	Customer communication	06.4, 11, 14
7.2.3.1	Marketing	10.1 - 10.6
7.2.3.2	Acceptance and impact of provided services	14.3
7.3	Service development	08
7.3.1	Design and development planning	08.1
7.3.2	Design and development input	08.2
7.3.2.1	Service development input	08.2
7.3.2.2	Special characteristics	not included
7.3.3	Design and development outputs	08.4
7.3.3.1	Service development outputs	08.3
7.3.4	Design and development review	08.4
7.3.4.1	Monitoring	08.4
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