VDA

6

Quality Management in the Automotive Industry

QM - Systemaudit Part 2

- Services -

Based on DIN EN ISO 9001, 9002, 9004-1 and DIN EN ISO 9004-2

2nd Edition 1999

Quality management
System audit

- Services -

Based on DIN EN ISO 9001, 9002
DIN EN ISO 9004-1 and
DIN ISO 9004-2

2nd edition 1999

Verband der Automobilindustrie e.V. (VDA)
(Association of the automotive industry)

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Preface

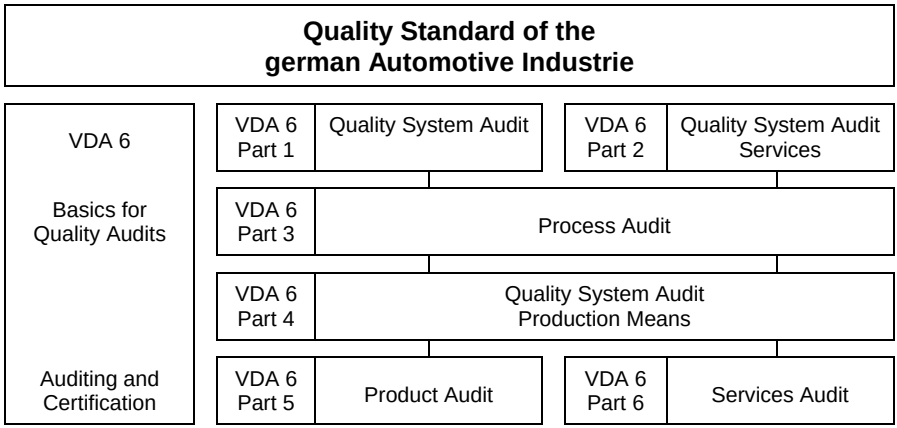
The trend towards total service provision takes place before the background of customers more and more frequently using the tougher competition on the domestic as well as on the international supplier markets for their own benefit.

This also more and more influences the person and load transport vehicle segment within the automotive branch. The cost-benefit-ratio no longer is the sole decisive factor, but the quality of the rendered services today plays a role of growing importance.

So a discussion has been started in the service providing segment of the automotive industry on how all quality aspects of the service can be integrated into a quality management system which is specific to the automotive branch and promoting.

DIN ISO 9004-1 and DIN ISO 9004-2 as a guideline as well as the textual versions of the DIN EN ISO 9001 resp 9002 have been the platform on which the working team prepared the VDA-paper volume 6, part 2.

Assuming that each company has developed its own quality management system adapted to its size, branch, and product/service, or is presently in the state of implementing it, the VDA-working team started their considerations with how to monitor the ,,Quality standard of the German automotive industry" (VDA 6) with the help of quality audits close to everyday practise. The overall audit strategy for the automotive industry as defined by the committee **QUALITYMANAGEMENT** looks as follows:



There is an agreement that this paper is going to be divided into a

Part U: Management
Part P: Product/Service and Process

while the Part U is mostly congruent with the statements of the VDA-Paper Volume 6, Part 1, ,,QM-system for material products". The element Z1 here however is a mandatory part.

The Part P is oriented along the process chain from market research to final customer services.

We very much hope that this paper of the VDA-6 series too will be able to reach the success of VDA-paper volume 6, Part 1, and would like to heartily thank the contributing companies and their employees for their efforts in the preparation of this VDA-paper.

The following companies have contributed to this paper:

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1 Introduction

1.1 Quality management and Service

The automotive industry is process-oriented. This reasons the involvement of service providers in the QM-system.

Intenal as well as external service providers might be concerned.

From any vehicle, the customer expects a constantly high product quality, and he also has great expectations concerning the service provision.

Hence an increasing quality, cost and speed competition is developing, while the subjective quality rating by the customer frequently becomes more decisive for the corporate success.

The service provider has to win the customer's trust and to maintain it permanently. Yet customers in the past have experienced a rising quality of life standard. So the requirements they raise towards services of the automotive industry are higher. If his expectations are not met, the customer will wander off towards another service provider.

In order to successfully develop services in the automotive industry further, we recommend to involve these areas into an overall quality management system.

1.2 Product quality and service quality

If a vehicle which was produced in an industrial process is understood as the product, then product quality in the first place means a certain product feature defined by construction, materials, production means and production processes.

Services are such processes in which the internal or external customers are directly or indirectly participating in the process, e.g. when a car is purchased or tyres are exchanged. In this case, the quality of the service is assessed directly by the customer.

Hence the service quality is clearly distinguished from the product quality.

While material products usually can be touched up after sales for customer's satisfaction, poor services are often also the last services for a customer as he is prone to wander off, mostly without giving reasons.

We should consider that services on principle are immaterial, but without material services, they may not be represented.

1.3 Chances and Risks

As all other systems, launching and further development of a quality management system comprises chances and risks for the company.

It depends on the overall implementation of the quality principle from the management board down to the trainee, and on the living example of the managers, if the activities and measures are designed to benefit the corporate interest or if they are just ,,fulfilling requirements".

For example: are errors damned on principle or turned into the basis for measures of improvement (e.g. learning organization)?

Does the extent of documentation satisfy the demands for stable processes, or does it merely refine bureaucracy? Do the measures only aim at the short-term good rating in the next audit to come, (or receipt of certificate/ record), or do they also aim at a ,,return on investment"?

Hence it depends on managers and employees what can be made of it.

1.4 Hints on auditing

QM-system audits for services in the automotive practise become more and more important.

A questionnaire has been developed in order to make the quality of any service provider fit for assessment. This questionnaire allows to rate a QM-System for services.

This questionnaire is structured as follows:

Part U: Management
Part P: Product/Service and Process.

It is the intention of this paper to allow the rating of a defined QM-system by an uniform procedure. So the expenses for further QM-system audits, e.g. by other customers can be reduced.

This VDA-paper volume 6, Part 2 is the document to be used for higher qualification up to the VDA 6.2-level. lt further serves as basis for customer/ supplier audits.

2 QM-system according to standard dass DIN EN ISO 9000

The standard series DIN EN ISO 9000 has normative character within the European Union (EU) and within the EFTA. The German version is identical for Austria, Germany and Switzerland.

For deliveries according to the provisions of the EU fulfilling the contents of the EN is binding in order to grant free traffic of goods under the same conditions. This applies also to the contents of the European quality management standards. So its fulfillment has to be proven upon request. The following gives a survey on the contents of the individual standards.

2.1 Explanations concerning DIN ISO 9004, part 2 (Revision 6/ 1992) quality management and elements of a quality assurance system Guideline for services

Quality and customer satisfaction are major issues to which more and more attention is drawn all over the world. This part of the ISO 9004 takes this awareness into account and wants to encourage organizations and corporations to design the quality aspects of their activities which lead to services more effectively.

Producing and maintaining satisfactory quality in any Organization depends on a systematic approach to a quality management the task of which it is to assure understanding and fulfilling customers requirements. To achieve (satisfactory) quality it is necessary to swear all organizational levels on the quality principles and also permanently review and improve the defined quality management on the basis of feedback about the customers expectations.

The successful application of quality management to a service creates special opportunities for

- improved service level of the services and customers satisfaction,
- increased productivity and effectiveness as well as cost reductions,
- and increased market shares.

This part of the ISO 9004 can be applied to a newly offered or modified service in the context of the development of a quality management system. It can also be directly referred to for implementation of a quality management system for already existing services. The quality management system encompasses all processes which are required for rendering an effective service, starting from marketing through to final delivery. It also comprises the analysis of the services delivered to customers.

The concepts and principles contained in this part of the ISO 9004 are suitable for large as well as for small organizations. Even though a small service providing organization won't have or need the complex structures required by larger corporations, the same principles apply. The difference is only in size. In most cases, the customer will be the final recipient of any service outside the organization. However the customer might also frequently be within the own organization, which is particularly so in larger corporations in which the customer can be present in a subsequent stage of the delivery process. Even though this part of the ISO 9004 has been written basically with reference to external customers, it can also be applied to fulfill completely quality requirements from internal customers, too.

2.2 Models for quality assurance/QM-specification (according to introduction to DIN EN ISO 9001)

Extent and depth of the presentation of the QM-system may depend on the kind of the products/services to be delivered, the used technologies, and the size of the corporation to be rated.

The following paragraphs have been taken from the national preface and the introduction to the DIN EN ISO 9001: 1994-08, which is very appropriately formulated as follows:

Winning trust into the suppliers' ability to fulfill defined minimum requirements to his quality management system today more and more becomes a prerequisite for the cooperation between customer and supplier. This trust can be established by specification of the quality management system

towards the customer or an authorised body. All systematic trustfunding activities according to the DIN EN ISO 8402 are denominated as quality assurance or quality management specification (in short: QM-specification).

The standards DIN EN ISO 9001, DIN EN ISO 9002 and DIN EN ISO 9003 each contain one model for quality assurance/QM-specification. Only these three standards of the DIN EN ISO 9000-class are foreseen for specification purposes. These standards show a way of how to establish trust in a supplier's ability.

lt has to be emphasised that the requirements to the quality assurance/QM-specification as defined in this international standard ISO 9001, in ISO 9002 and ISO 9003 are a supplement (and not an alternative) to the defined quality requirements (for products[1]).

lt is intended that these international standards are applied in their present form. Occasionally it could become necessary however to adjust them to certain contract situations by adding or cancelling certain requirements. ISO 9000-1 serves as a guideline both for such amendments as well as for selection of the appropriate model, either ISO 9001, ISO 9002 or ISO 9003.

The alternative models for quality assurancelQM-specification listed hereafter and described in three international standards represent three differently pronounced versions of the ,,functional or organizational quality ability" which are suitable for the application in contracts between two parties (see main section 5: Comparison matrix of section numbers).

[1] According to EN ISO 8402,1.4 product can also include service.

ISO 9001	*Quality management systems -* *Model for quality assurance/QM-specification in design, development, production, assembly and maintenance.* *To be applied if the supplier/contractor has to assure the fulfillment of defined requirements during design², development, production, assembly and maintenance.*
ISO 9003	*Quality management systems -* *Model for quality assurance/QM-specification in production, assembly and maintenance.* *To be applied if the supplier/contractor has to assure the fulfillment of defined requirements during production, assembly and maintenance.*
ISO 9002	*Quality management systems -* *Model for quality assurance/QM-specification during final testing.* *To be applied if the supplier/contractor has to fulfill defined requirements only during final testing.*

Model ISO 9003 is not referred to within the application range of the VDA.

3 QM-system audit - Services -

3.1 General remarks

A service provider's QM-system can be assessed by representatives of the customer or the contract party who has ordered the service provider's services. The auditor has to master the QM-elements to be assessed by him as well as the quality techniques to be applied. He should be qualified to evaluate the appropriateness of the applied QM-measures concerning the applied process, the state-of-the-art and the required product or service quality.

The extensive economic and organizational assessment of a corporation according to this QM-system audit raises high requirements towards the auditors. Among these requirements are - among other things - suitable technical training and service experience, integrity and the ability to handle people.

In particular the following QM-elements, contained in the DIN EN ISO 9004-1 and DIN ISO 9004-2:

- management responsibility
- quality management system
- training, personnel
- financial considerations concerning QM-systems
- product safety
- interface to the customer
- analysis and improvement of service
- corporate strategy (e.g. EFQM)

raise requirements to the qualification of many auditors which previously were unusual, as now these auditors have to be competent discussion partners for their management concerning the mentioned quality elements.

Technical questions have to be answered by the respectively responsible person and not by the quality expert who usually will answer only specific QM-system questions.

Once a system audit of a service provider's QM-system according to section 3.4 has proven that the service meets the requirements, recurring QM-system audits have to be performed in appropriate defined intervals.

lt the results of the QM-system audit do not meet the requirements, measures and deadlines for improving the system have to be defined. Their assessment is the subject of a post-audit which will consider the claimed items.

3.2 Definition of QM-elements and pertinent questions

Prior to the assessment of the QM-system of any service provider, those QM-elements which are relevant for him have to be defined together with the pertinent questions between the involved parties.

The elements of a QM-system in case of technical reasons can be adapted, cancelled (e.g. element 08 ,,Development") or amended with supplements typical for the corporation or the branch.

Additional questions to the QM-system have to be notified to the service provider in advance.

The requirements/explanations to the questions are always only examples. They should not be interpreted as a comprehensive test list. The proofs and listings shown as examples need not be provided if not usual in the concerned branch.

For the individual elements, some references are made under the header requirements/explanations, which are assessed with different intensity for the individual questions.

Additional QM-elements may also be entered.

Some questions concerning the QM-system may only be answered along the evaluation of the service to be rendered resp. of the product to be delivered and/or the applied procedures. This could require a separate assessment (service rating, service audit).

Non-applicant questions resp. supplementary questions should be marked, reasoned and considered in the assessment.

3.3 Audit process

The procedure described below refers to the focuses for the planning/execution of an audit by the auditor in order to assure the correct audit process. This also necessitates the early involvement of the audit partner.

Steps	**Focus**
Informational-/ Pre-discussion	Clarification of the audit requirements and processing. Definition of QM-elements/pertinent questions.
Review of documents	Conformity test system requirements and actual status. Adjustment of further processing (depending on results).
Audit planning	Adjustment of probable expenditures. Detail planning depends on kind and structure of the unit to be audited. The audit partner therefore should be involved quite early.
Audit execution	Introductory discussion, audit execution on the basis of the questionnaire (audit checklist). Evaluation of results and agreement on further proceedings in case discrepancies have been noticed. Informing the audited parties on the audit results and the further proceeding in a final discussion. The audit result has to be documented in an audit report. Depending on degree of fulfillment score application for VDA-record.
Control/Renewal audit	Plan subsequent audits depending on degree of fulfillment resp. on the customers requirements.

3.4 Rating and assessment

3.4.1 Assessment of individual questions and QM-elements

The auditor evaluates definition and efficiency of the QM-measures along the fulfillment of the concerned requirements by first determining:

- Is the subject in question defined in writing in the QM-system, in processes, context and responsibilities (e.g.: in the QM-manual, in processing or working instructions)?

Next he has to assess:

- Is the subject in question effectively proven in practice?

According to the scheme following hereafter, answering the questions leads to the rating of the applicant questions. This rating can score 0, 4, 6, 8 or 10 points per question. The following point rating per question applies:

Subject in question	**Rating of answers**				
Defined in the QM-system	completely	mostly*)		no	yes/no
Effectively proven in practice	yes	no	mostly*)		no
Number of points scored	10	8	6	4	0

*) „Mostly“ means that the basic requirement is defined/effectively proven, and no particular risk is given.

Rating

10 points:	Completely defined in the QM-system and also effectively proven.
8 points:	Mostly defined in the QM-system and also effectively proven.
6 points:	Mostly defined in the QM-system and mostly effective proven.
4 points:	Not/Insufficiently defined in the QM-system but mostly effectively proven in practise.
0 points:	Not effectively proven, notwithstanding the comprehensiveness of the definition in the QM-system.

In the summarising evaluation of any QM-element, each question is weighted equally.

The element rating E_E results as percentage of the total points score of all applications questions referring to the total number of possible points of all applicant questions. If all questions applicant to one QM-element are rated with 10 points, then the degree of fulfillment is E_E 100 %.

Calculation of the degree of fulfillment of any QM-element:

$$E_E = \frac{\text{Total of scored points of the applicant questions}}{\text{Total of all possible points of the applicant questions}} \times 100\ [\%]$$

3.4.2 Total audit result rating

For the two parts U (management) and P (service process) first the fulfillment degrees E_U and E_P have to be calculated. They are calculated as average values of the fulfillment degrees of the correspondingly audited QM-elements:

$$E_U \text{ resp. } E_P = \frac{\text{Total of the fulfillment degrees of the applicant QM-elements}}{\text{Number of assessed QM-elements}} \text{ in [\%]}$$

The two fulfillment degrees E_U and E_P are summarised to a fulfillment degree E_{GES}:

$$E_{GES} = \frac{C_E + E_P}{2} \text{ in [\%].}$$

The rating system can also be applied when QM-elements or questions are added or cancelled.

Remark concerning formula E_{GES}:

Different from the calculation of E_{GES} in the VDA-paper volume 6 part 1 here part U is not weighed additionally higher. Then given ratio of the QM-elements (7 to 11) here already results in a higher weighing than in the VDA-paper volume 6.

3.4.3 Classification

Total fulfillment degree in percent	Rating of the QM-systems	Marking of the rating
90 trough 100	fulfilled	A *)
80 trough < 90	mostly fulfilled	AB *)
60 trough < 80	fulfilled conditionally	B
< 60	not fulfilled	C

*) Remarks:

1. Audited companies which reach a total fulfillment degree of more than 90 % resp. 80 % but in one or several QM-elements only reach a fulfillment degree of below 75 % will be degraded from A to AB resp. from AB to B.
2. If items the non-fulfillment of which may have decisive impact on the service quality are rated with zero points, then the audited company may be degraded from A to AB resp. from AB to B.
3. Only one degradation to 1 or 2 is permitted.
4. Degradations have to be reasoned in an explanation sheet.

3.5 Survey of results

The results of the QM-system audit according to the audit parts U (management) and P (Service process) have to be represented according to the sample form sheets (main section 8). The survey of results per QM-element are entered in the sheet "Survey of results".

3.6 Final discussion and report

In a final discussion of the QM-system audit the auditor informs the management about the weaknesses requiring corrective measures. These are represented in a survey sheet „corrective measures“. The survey on the QM-system audit result is supplemented by the auditor with a report which details the observed weaknesses.

lt necessary, a date for a post-audit is scheduled which should take place within the next six months.

3.7 Corrective measures

The QM-system audit results as represented according to sections 3.5 and 3.6 will serve the management as basis for corrective measures. lt is the task of the audited company to work out an improvement program and to implement it. This is to be reported to the auditor in charge of the audit.

3.8 VDA-Audit certificate

If a total rating score of at least 90 % is achieved, a VDA 6, part 2-certificate may be awarded under condition that the auditor is registered as a lead auditor at the VDA. The corporate unit will apply for the certificate through the lead auditor.

A VDA-record may also be awarded under consideration of already granted certificates according to DIN EN ISO 9001 or 9002 with supplementing higher qualification (see main section 11).

The certificate is valid for three years as of the date of issuance.

VDA **VERBAND DER AUTOMOBILINDUSTRIE E.V.**

Urkunde

In der Firma

Bereich

wurde ein

QUALITÄTSMANAGEMENT-SYSTEMAUDIT

nach Band 6, Teil 2 der VDA-Schriftenreihe "Qualitätsmanagement in der Automobilindustrie" auf Grundlagen DIN EN ISO 9001, 9002 9004-1 und DIN ISO 9004-2 mit folgendem Ergebnis durchgeführt:

Erfüllungsgrad: **Prozemt**

Ausgestellt: **Gültig bis:**

Das Audit wurde durchgeführt von:

Registriert VDA Nr._____

_____

Firma/Unterschrift des Bevollmächtigten

(VDA-Stempel)

4 Terms

Definitions and explanations of terms concerning individual elements are given within the questionnaire. Superior terms are briefly summarised below (Numeration according to DIN EN ISO 8402/1995):

4.1 General Terms according to DIN EN ISO 8402/1995 (Excerpt)

#.1.1 Unit

A unit is what can be described and considered separately on us own.

Remark: A unit might be for example
- an activity or a process (1.2)
- a product (1.4)
- an organization (1.7), a system or a person or any combination of same.

#.1.2 Process

Set of interacting means and activities converting entries into results.

Remark: Means might be personnel, finances, systems, equipment, technologies and methods.

#.1.3 Procedure

Defined manner of completing a certain task.

Remark 1: In many cases, procedures are documented (e.g. procedure of a QM-system (3.6)).

Remark 2: If a procedure is documented, the terms „procedure defined in writing" or „processing instruction" are frequently used.

Remark 3: A procedure defined in writing or a processing instruction normally contain the purpose and application range of a task: what has to be done and by whom, when, where and how is it done. Which materials, equipment and documents have to be used. How is this controlled and recorded.

#.1.4 Product

Result of activities and processes (1.2).

Remark 1: The term product can include service (1.5), hardware, process technology products, software or combinations of those.

Remark 2: A product may be material, (e.g. assembly results, process technology products) or immaterial (e.g. knowledge or drafts) or any combination of same.

Remark 3: A product may either be intentional (e.g. product offered to customer (1.9)) or unintentional (e.g. contaminants or unwanted effects).

#.1.5 Service

Result of fulfilling customers' requirements gathered at the interface between supplier (1.10) and customer (1.9) or through internal activities of the supplier (1.10).

Remark 1: The supplier or the customer may be represented at the interface by personnel or equipment.

Remark 2: Customer activities at the interface with the supplier may be essential to the service provision (1.6).

Remark 3: Supply or use of tangible products (1.4) may form part of the service provision.

Remark 4: A service may be linked with the manufacture and supply of tangible product.

#.1.6 Service providing

Suppliers' activities required for provision of a service (1.5).

#.1.7 Organization

Company, body, plant, corporation or institution or parts of same, registered or not, public or private, with its own functions and own administration.

#.1.8 Organizational structure

Responsibilities, authorisations and interrelations by means of which any organization (1.7) fulfils its tasks.

#.1.9 Customer

Recipient of a product (1.4) supplied by a supplier (1.10).

Remark 1: In a contractual situation, the "customer" may be called "client" (1.11).

Remark 2: Customer might be e.g. end-users, users, beneficiaries or clients.

Remark 3: In relation to the organization, the customer might either be external or internal.

#.1.10 Supplier

Organization (1.7), supplying to the customer (1.9) a product (1.4).

Remark 1: In a contractual situation, the supplier may be called "contractor" (1.12).

Remark 2: Supplier might be e.g. the manufacturer, distributor, importer, an assembly house or a service organization.

Remark 3: In relation to the organization, the supplier might either be internal or external.

4.2 Quality-related terms according to DIN EN ISO 8402/1995 (Excerpt)

#.2.3 Quality Requirements

The formulation of the requirements of their implementation into a series of defined quantitative or qualitative requirements to the characteristics of a unit (1.1) to allow its implementation and testing.

Remark 1: It is decisive that quality requirement fully reflects the defined and prerequisite customer requirements (1.9).

Remark 2: The term "requirement" comprises market, contractual, and also internal requirements of a certain organization (1.7). These can be developed, detailed and upgraded in the various planning stages.

Remark 3: Defined quantitative requirements to the characteristics comprise e.g. nominal values, measurement values, limit deviations and tolerances.

Remark 4: The quality requirement should be expressed and documented in functional conditions.

#.2.15 Testing

Activity such as measuring, examining, dimensioning one or several characteristics of a unit (1.1) as well as comparing results with defined requirements in order to determine if conformity (2.9) has been achieved for each characteristic.

#.2.17 Verification

Confirming that defined requirements have been met by means of examination and providing a record (2.19).

Remark 1: In design and development, verification concerns the process (1.2) of examining the result of a considered activity in order to determine conformity (2.9) with the requirement raised to this activity (concerning its result).

Remark 2: The word "verified" is used for denomination of the concerned status.

#.2.18 Validation

Confirm by means of examination and evidence of proof (2.19) that the special requirements for a certain intended use have been met.

Remark 1: In design and development, validation concerns the process (1.2) of examining a product (1.4) to determine conformity (2.9) with the user's requirements.

Remark 2: Validation usually takes place at the finished product and under defined operating conditions. It may become necessary in earlier stage.

Remark 3: The word "validated" is used to denominate the concerned status.

Remark 4: Multiple validations are permitted if several intended uses occur.

#.2.19 Proof

Information the correctness of which can be proven and which is based on facts gathered by observing, measuring, examining or other evaluation processes.

4.3 Terms concerning quality management system according to DIN EN ISO 8402/1995 (Excerpt)

#.3.1 Quality policy

Comprehensive intentions and targets of any organization (1.7) on quality (2.1) as formally expressed by the management.

Remark: Quality policy is an element of the corporate strategy and approved by the management.

#.3.6 Quality system (Quality management system)

The necessary organizational structures (1.8), procedures (1.3), processes (1.2) and means in order to implement quality management (3.2.

Remark 1: The QM-system should have the extent that is necessary in order to archive the quality targets.

Remark 2: The QM-system of an organization (1.7) is foreseen first of all to fulfill the internal requirements of this organization. It is more extensive than the requirements of any individual customer (1.9), who will assess only that part of the QM-systems which is relevant (for him).

Remark 3: For contractual or other obliging purposes of quality assessment specification of the implementation of defined QM-system elements can be mandatory.

#.3.12 Quality management manual

Document defining the quality policy (3.1) and describing the QM-system (3.6) of an organization (1.7).

Remark 1: A quality management manual (called „QM-manual“ hereafter) may refer o the entity of an organization' activities, or only to a part of them. Title and assigned purpose of the manual reflect the application range.

Remark 2: Usually a QM-manual will at least contain or refer to the following:

a) quality policy;
b) responsibilities and authorisations (competences) as well as reciprocal interrelations of staff who are managing, executing, testing or assessing quality-oriented activities;
c) the procedures (1.3) of the QM-system (3.6) and pertinent instructions;
d) specification of testing, updating and administration of the manual.

Remark 3: Comprehensiveness and format of QM-manuals may differ in order to meet the organizations' requirements. They may contain more than one document. Depending on the purpose of the manual, a denomination may be used, e.g. „Quality Assurance Manual"/"QM-Specification Manual".

4.4 Terms concerning tools and techniques/technologies according to DIN EN ISO 8402/1995 (Excerpt)

#.4.9 Quality audit

Systematic and independent examination to determine if quality-relevant activities and related results correspond to the planned instructions and directions and if these directions are actually implemented and suitable to achieve the targets.

Remark 1: Typically, quality audits are applied to QM-systems (3.6) or to elements of them, to processes (1.2) or products (1.4) (including services (1.5)), but are not restricted to them. Such quality audits are frequently called "system audit", "procedure audit", "product audit", "service audit".

Remark 2: Quality audits are performed by persons who have no direct responsibility within the units to be audited, while it is desirable that they cooperate with the concerned staff.

Remark 3: One of the purposes of a quality audit is to determine the necessity of improvement or corrective measures (4.14). A quality audit should not be mixed up with the activities of quality control (4.7) or testing (2.15) which are performed for purposes of process control or acceptance of incoming goods.

Remark 4: Quality audits may be performed for internal or external purposes.

#.4.10 Quality audit record

A fact noticed during a quality audit (4.9) and certified by proof (2.19).

#.4.14 Corrective measure

Activity to be performed for elimination of the causes of occured errors (2.10), defectives (2.11) or other unwanted situations to prevent their recurrence.

Remark 1: Corrective measure may cause changes e.g. in procedures (1.3) and systems in order to improve quality improvements (3.8) in any status of the quality circle (4.1).

Remark 2: We distinguish between „correction“ and „corrective measure“:
- "correction" concerns a repair (4.18), touch-up work (4.19) or adjustment and refers to curing occured errors;
- "corrective measure" refers to the elimination of the causes of an error.

4.5 Additional terms (Definitions for this paper)

4.5.1 System

The structure of an organization, in which competences (responsibilities, authorisations) and interrelations, as well as procedures (#.1.3) and processes (#.1.2) are defined with the appropriate means to implement a certain task.

4.5.2 Method

A planned, purposive procedure (#.1.3) leading to technical capability for the solution of theoretical and practical tasks.

4.5.3 QM-processing instructions

QM-processing instructions are special defaults needed to fulfill the defined quality-related activity. They come into effect only if signed appropriately.

4.5.4 Working instructions/Testing instructions

Detailed description of the working steps of an activity.

Definition of individual activities/detailed instructions, both general or tied to one order.

Remark: Contains technical know-how.

5 Comparison matrix of the section numbers for corresponding subjects

Comparison of the questionnaire in main section 7 with the sections and sub-sections of the standards DIN EN ISO 9001, 9002 and DIN ISO 9004-2.

Quest-ionnaire no. According to VDA	Section header	Pertinent section or sub-section of the standards			
		DIN ISO		DIN EN ISO	
		9004-2		9001	9002
01	Management responsibility	5.2, 5.3, 6.4	4.1	•	•
02	Quality management system	5.2, 5.4	4.1 4.2 4.3	•	•
03	Internal quality audits	5.4, 6.2	4.17	•	•
04	Training, personnel	5.3, 5.4	4.18	•	•
05	Financial considerations of QM-systems	–	–	–	–
06	Product safety	–	–	–	–
Z1	Corporate strategy	–	–	–	–
07	Market research	5.5, 6.1, 6.2	4.4	•	•
08	Development	6.1, 6.2	4.4	•	-
09	Service preparation	6.2, 6.3	4.3, 4.4, 4.10	•	•
10	Promotion and marketing	6.1	–	–	–
11	Sales	5.4, 5.5, 6.1	4.3	•	•
12	Purchasing	6.2	4.6, 4.10 4.13	•	•
13	Service providing	6.2, 6.3	4.7, 4.8, 4.9, 4.10, 4.11, 4.12, 4.13, 4.15	•	•
14	Customer services	5.4, 5.5, 6.3, 6.4	4.10, 4.14, 4.19	•	•
15	Analysis and improvement of service	6.3, 6.4	4.14, 4.19, 4.20	•	•
16	Control documents and data	5.4	4.5, 4.16	•	•
17	Control quality records	5.4, 6.4	4.16	•	•

Key: • Full requirement
- QM-element, not comprised in a.m. standards

6 Structure of questions and number of questions per QM-Element

		Page	No. of questions
U	**Management**		
01	Management responsibility DIN EN ISO 9001, Section 4.1 DIN ISO 9004-2, Sections 5.2, 5.3, 6.4	41	6
02	Quality management system DIN EN ISO 9001 Sections 4.1, 4.2, 4.3 DIN ISO 9004-2, Sections 5.2, 5.4	49	4
03	Internal quality audits DIN EN ISO 9001, Section 4.17 DIN ISO 9004-2, Sections 5.4, 6.2	54	4
04	Training, personnel DIN EN ISO 9001, Section 4.18 DIN ISO 9004-2, Sections 5.3, 5.4	59	6
05	Financial considerations of QM-systems DIN EN ISO 9004-1, Sections 6.1, 6.2, 6.3	64	4
06	Product safety DIN EN ISO 9004-1, Section 19	69	5
Z1	Corporate strategy	75	5
	Total number of questions (Part U)		**34**

7 Questionnaire to the QM-system audit - Services -

Structure

For each QM-element, the general requirements are described in a preface. These general requirements are suitable to open a dialogue with the person in charge of this element. They briefly explain the subject in its context and list the questions.

Each item is structured as follows:

1. Question

2. Definition

If necessary, the terms used in the question for which no definition was given are explained for better understanding.

Explanation of terms

If necessary, those terms used in the question for which no definition was given are explained for better understanding.

3. Requirements/Explanations:

The section „Requirements/Explanations“ defines QM-system requirements and if necessary also adds an explanation.

Note: The auditor has to assess the definition and the effectiveness of the QM-measure for each applicant item.

Part U: Management

01 Management responsibility

DIN EN ISO 9001, Section 4.1
DIN ISO 9004-2, Sections 5.2, 5.3, 6.4

Each management develops the quality policy for its corporations, defines it, and obliges all units and levels to comply with it. Concrete quality targets as well as a quality management system (QM-system) have to be agreed. Quality has to be understood as an overall task.

"Management" defines the organizational unit within the corporation which is responsible for profit and loss.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
01.1	Has the quality policy been defined by the management and made known to all levels?	4.1.1	4.2
01.2	Have quality targets been in the scope of corporate planning resp. in the quality policy, are the results monitored?	4.1.1	4.3.1
01.3	Is a continuous improvement process part of the quality policy?	--	--
01.4	Have the required means been provided by the corporate management?	4.1.2.2	5.2.4
01.5	Has the management appointed a QM-manager? Are his duties, authorisation and responsibilities defined?	4.1.2.14. 1.2.3	5.2.2 5.2.3
01.6	Does management regularly assess the effectiveness of the QM-system?	4.1.3	5.5

01.1 Has the quality policy been defined by the corporate management and made known to all levels?

Definition:

Quality policy (according to DIN EN ISO 8402/3.1):

Comprehensive intentions and targets of a organization concerning quality as formally expressed by the management.

Remark: Quality policy is an element of the corporate policy and is approved by the management.

Requirements/Explanations:

The quality policy has to be formulated in a manner that can be understood, implemented and complied with by all employees on all organizational levels. The principles of quality policy have to be specified in the QM-manual or a similar documentation of equal rank. The contents of quality policy should consider the following aspects, such as:

- Classification of the service to be provided
- Customer satisfaction
- Role of employees in the implementation of quality policy
- Employee satisfaction
- Targets referring to service quality
- Zero-error-strategy, error prevention
- Continuous improvement
- Environmental matters
- Obligations towards society.

The quality policy can be made known by the following publications:

- Organizational guidelines and instructions
- Information meetings on quality policy
- Bulletins
- Brochures
- Pinboard.

Measurable quality targets have to be derived from the quality policy (see question 01.2).

01.2 Have quality targets been defined in the scope of corporate planning resp. in the quality policy, and will the results be monitored?

Term definition:

"Quality targets" are default for processes, structures/work flows and services defined for all levels. These targets are derived from customer requirements, the competitive situation, the legal environment, internal defaults and compliance with the zero-error-strategy.

Requirements/Explanations:

Target defaults in the scope of quality policy could be e.g.:

a) Targets related to the corporation

- Meet general social demands (laws, provisions, regulations)
- Improve market acceptance
- Make profits
- Assure the existence of the corporation
- Continuously improve quality (see item 01.3).

b) Targets related to product and service

- Reducing defective waste and after-sales touch-up
- Improving delivery quality
- Raising the service quality level
- Increasing reliability
- Environment friendliness
- Working safety and health protection

c) Targets related to customer

- Shortening administrative handling times for inquiries, orders, etc. (Δ days)
- Increasing customers' satisfaction (e.g. reduction of complaints Δ %)
- Reduction response times for handling of complaints (Δ days)
- Improving in-time delivery diligence

d) Superior targets

- Cost reduction not on expense of quality (%)
- Long-term advance quality planning (see question 02.5)
- Increase improvement proposal activities (methods, equipment, processes etc.)
- Calculating and assessment of all costs related to QM-elements in order to minimise quality losses
- Monitor effectiveness of corrective measures on the basis of audit results
- Quality of service and process development (time, implementation, benefits, feasibility, etc.)
- Expand QM-system towards TQM, EQA, etc.

The quality targets to be agreed should be achievable and measurable. Further they should be updated regularly and represented in a comprehensible form. Target achievement has to be monitored consequently on all management levels (Target/Actual-comparison).

The targets should be made known to the employees in a concrete, clear, and provable fashion.

Without definition of targets, efficient improvement of quality and increase of productivity in all corporate units can neither be achieved nor tracked.

(See also item Z1.1).

01.3 Is a continuous process of improvement part of quality policy?

Requirements/Explanations:

Improvement schemes for the commercial and technical functional units within the corporation should be introduced and maintained. Subjects of those schemes could be e.g.:

- Reducing non-value-adding activities
- Simplifying processes/work-flows
- Minimising losses
- Reducing unscheduled stand-times/break-down times
- Improving serviceability
- Reducing consumption of water, air and energy.

Note: Links to item 01.2 are possible. The used working methods can be chosen per corporation.

In a continuous process of improvement, the conscious handling and sparing consumption of resources have to be considered as well. To be considered e.g.:

- The logistical chain
- Buildings/facilities
- Equipment
- Environmental protection.

The strategy of continuous improvement involves all employees, service processes and business transactions of a corporation. Improvements relate e.g. to the following:

- Quality
- Price
- Service
- In-time-delivery.

01.4* Have the necessary means be provided by the corporate management?

Requirements/Explanations:

To allow the QM-system to work efficiently, the corporate management is responsible to provide the spatial, financial and personnel means in order to fulfill the requirements of the QM-elements. This means for example:

- Qualified personnel with task-related skills for supervising, executing and testing duties (also project management)
- Equipment for service development and providing
- EDP-support e.g. for data analysis, graphic representations, statistics
- Communication devices (telephone, fax).

Effectiveness and efficiency of a QM-system depend on the provision of the necessary means for implementation of quality policy and quality targets.

Note: The evaluation of this item can only be finally made once the whole QM-system has been made transparent by the audit and it has been determined that all necessary means are available.

01.5 Has the management appointed a QM-representative and have his tasks, authorities been defined?

Term definition:

As "QM-representative of the management“ we define the person who maintains the management interests concerning strategic quality management towards all management levels.

The QM-representative must be a member of the company’s management circle, but need not be a member of the board of directors. He/she however directly reports to the board of directors.

Requirements/Explanations:

Responsibilities and authorisations of the QM-representative are among other things:

- Reporting on the quality situation
- Determining, implementing and maintaining the QM-system in accordance with the requirements of this catalogue, which includes matters specific to that branch
- Monitoring the implementation of the strategic targets
- Control and coordination of QM-tasks in cross-functional cooperation
- Representing the effectiveness of the QM-system and deriving improvement schemes.

01.6 Does the board of directors regularly assess the effectiveness of the QM-system?

Definition:

QM-assessment (according to DIN EN ISO 8402/3.9):

Formal assessment of the status and appropriateness of the QM-system (quality management system) relating to quality targets by the top management level.

Requirements/Explanations:

The corporate management has to convince itself of the effectiveness of the introduced QM-system and to assess it regularly. It is the aim of this assessment to achieve a steady improvement and adjustment to changed conditions (market, technology etc.). This can be made by recording and assessing e.g. following information:

- Reports on service performance
- Regular round-table-talks on quality
- Quality key figures concerning the defaults (see item 01.2)
- Reports on internal quality audits (see item 03.2) with derived measures
- Status of the continuous improvement process (see item 01.3)
- Customer satisfaction analysis
- Analysis of the influence of new technologies, quality concepts, marketing strategies and environment requirements on the service providing or the process of service providing
- Cost/benefit-ratio.

The assessment results from the comparison of the determination with the quality policy targets and usually leads to general preventive and corrective measures.

02 Quality management system

DIN EN ISO 9001, Sections 4.1, 4.2, 4.3
DIN ISO 9004-2, Sections 5.2, 5.4

A quality management system (QM-system) consists of the structural organization, the responsibilities, procedures, processes and means for implementation of the quality management.

The QM-system shall promote continuous quality improvement.

The QM-system should be described and approved by the management. This is most suitably done in a QM-manual and supplementary processing instructions or similar documentation.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
02.1	Has the QM-system been described in a quality system manual or similar documentation?	4.2.1 4.2.2	5.4.1 5.4.2 5.4.3.1
02.2	Does the QM-system encompass all units, levels and employees of the corporation?	4.1.2	5.4.2
02.3	Have the tasks, responsibilities and authorisations for all quality-relevant activities been defined in corresponding instructions?	4.1.2.1	5.2.4
02.4	Is there a quality planning for the necessary measures and processes for fulfilling the quality requirements?	4.2.3 4.3.2a	5.4.3b

02.1 Has the QM-system been described in a quality system manual or similar documentation?

Definition:

Quality management manual (according to DIN EN ISO 8402/3.12):

Document defining the quality policy and describing the QM-system (quality management system) of any organization.

Requirements/Explanations:

A quality management manual (QM-manual) or similar document has to describe all QM-elements required for the operation of the business with reference to equally applicant internal and external instructions, standards, provisions or the like.

The documentation encompasses:

- Organizational structures
- Processes for performing all quality-relevant activities within the corporation.

The description of the quality management system should also:

- emphasise the prevention of errors rather than elimination of errors
- contain quality management planning through all stages of service provision
- pay particular attention to the quality circle for services
- represent the overall process in the main stages of Marketing, Design and Service Provision with feed back (customer feed-back).

The manual has to state the approval of the board of directors, the date of effectiveness, resp. the revision service. The responsibilities for upgrading, the revision service and distribution list have to be defined. The main purpose of the QM-manual is to define the structure of the QM-system and at the same time serve as permanent reference for its implementation and maintenance.

Besides, special processes can be defined separately in processing instructions, quality management plans, or similar documents.

02.2 Does the QM-system encompass all units, levels and employees of the corporation?

Definition:

QM-system/(quality management system) (according to DIN EN ISO 8402/3.6):

Organizational structures, procedures, processes and means required to implement the quality management.

Requirements/Explanations:

Quality management concerns all service stages. The cooperation of these stages is a prerequisite for the overall fulfillment of the requirements raised by customers, legislation, and society.

A cross-departmental understanding of quality and quality assurance should be like a „red band" rolling through the whole corporation. Understanding of quality management as the duty of all employees can become obvious e.g. in:

- cross-unit activities
- corresponding trainings, presentations, publications
- unit-specific targets for quality improvement
- competence charts.

Job descriptions and organigram charts serve - among other things -to support the employees, to provide clarity at interfaces, and to give evidence of the task. They make the organization transparent, facilitate qualification and recruitment of staff as well as promote motivation and readiness to make decisions.

02.3 Have the tasks, responsibilities and authorisations for all quality-relevant activities been defined in corresponding instructions?

Term definition:

,,Ouality related activities" concern both preventive and reactive measures during the whole lifetime of products/services.

Requirements/Explanations:

Tasks, responsibilities and authorisations have to be defined unambiguously and clearly for all units and employees having an impact on the quality of services and processes. Attention has to be paid to the interfaces between different units and tasks.

These definitions are most suitably made e.g. in:

- Function or job descriptions
- QM-processing instructions
- Competence charts
- Task descriptions which have to be approved by signature. It has to be assured that the tasks are unambiguously defined concerning the functions for fulfilling the defined requirements, and furnished with the necessary independence. Decisions have to be made such as e.g. who:

  - can block defective products/services or processes,
  - is responsible for proposing and monitoring problem solutions
  - monitors quality requirements in particular after modifications have been determined
  - is responsible for the quality-relevant documentation.

Instructions have to be approved by signature.

02.4 Is there a quality planning for the necessary measures and processes for fulfilling the quality requirements?

Definition:

Quality planning (according to DIN EN ISO 8402/3.3):

Tasks defining targets and quality requirements as well as requirements for application of the elements of the QM-system.

Remark:

Quality planning encompasses:

a) *Planning concerning product/service: Identification, classification and weighing of the quality features as well as definition of targets, quality requirements and restrictions;*

b) Planning concerning supervising and executing tasks: Preparation of application of the QM-system together with work-fiow-charts and time schedules;

c) Preparation of QM-plans as well as providing for quality improvements.

Requirements/Explanations:

Quality planning (also called advance quality planning) should be understood as a cross-functional task and should be documented in a manner suitable for the size, structure, and working method (e.g. also by means of reference to corresponding processing instructions). Application of project management supports quality planning duties. Specific quality practises, means and sequence of activities for a certain service should be described in an appropriate manner. This means e.g. the following:

- Definition and labelling of significant features
- Supplying equipment, processes and control measures
- Updating procedures and equipment
- In-time advance supply of measuring technology means
- Testing service achievement at suitable positions
- Clarification of acceptance criteria

On principle, we have to distinguish between entrepreneurial and order-related quality planning.

A good quality planning means is the quality management plan which represents and specifies the specific quality-related working methods as well as work-flows for service providing.

03 Internal quality audits

DIN EN ISO 9001 Section 4.17
DIN ISO 9004-2 Sections 5.4, 6.2

No organisational measure, also no processing instruction in the QM-system will work automatically once it has been approved. They all need further development and monitoring.

Internal quality audits carried out by trained and qualified employees serve for systematic and continuous testing if the activities and results defined in the QM-system

- actually correspond to the defaults
- are suitable for target achievement
- offer opportunities for improvement.

All elements, aspects and parts belonging to a QM-system have to be subject to regular internal survey (quality audits). The results have to be submitted to the management in a documented manner for their assessment and as far as necessary must lead to corrective measures.

Audit reports are quality records.

The internal quality audit comprises all QM-elements and hence gives objective evidence on the necessity of reduction, elimination and - most important - prevention of errors.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
03.1	Is the staff (auditors) qualified for execution of internal quality audits and independent of the units to be audited?	4.17.2	5.4.4
03.2	Will the elements belonging to the QM-system be internally audited and assessed according to an audit-plan?	4.17.1 4.17.3	5.4.4
03.3	Will the performance and process requirements be audited internally according to an audit plan?	-	–
03.4	Do discrepancies lead to corrective measures, will these be documented and their effectiveness be monitored ?	-	6.2.2

03.1 Is the staff (auditors) qualified for execution of internal quality audits and independent of the units to be audited?

Definition:

Quality auditor (according to DIN EN ISO 8402/4.11):

A person suitably qualified to carry out quality audits.

Term definition:

"Quality auditors" (see DIN ISO 10011, Part 2) have to be impartial and free of influences which might impair their objectivity.

The staff entrusted with carrying out audits have to be independent of the units on which they report.

Requirements/Explanations:

Auditors have to be qualified to carry out and supervise quality audits. Following aspects should be considered as particularly relevant:

- Qualification according to DIN ISO 10011-2
- Knowledge and understanding of the standards which form the basis for audits of quality systems (DIN EN ISO 9000-9004, VDA-Paper volume 6, Part 2)
- Methods for assessment by means of evaluation, interviews, rating and reporting (e.g. auditor training)
- Skills required for supervision of a quality audit such as planning, organization, communication and supervision
- Experiences in quality management and quality techniques
- Knowledge of the work flows and processes to be audited
- Soft skills such as integrity, judgement capability, analytic skills, impartiality
- Maintaining skills with certificates.

The requirement profile for auditors has to be defined. This profile has to be proven in acceptable manner.

03.2 Will the elements belonging to the QM-system be internally audited and assessed according to an audit-plan?

Term definition:

An „audit plan“ (according to DIN ISO 10011-1) defines the different audits with schedules and the units to be audited. This audit is the systematic review of all QM-elements concerning their effectiveness, compliance, and up-to-date-ness.

Requirements/Explanations:

System audits have to be planned under consideration of the relevant QM-elements, agreed with the units, and then carried out.

An audit plan has to contain the following Information:

- Audit target
- Reference documents (standards, QM-manual, processing instructions etc.)
- Units to be audited
- Audit process
- Questionnaire
- Schedule
- Auditors/audit team
- Reporting with distribution list
- Tracking the measures.

Compliance with the following is of special importance for internal audits:

- Specification of the service (See DIN ISO 9004-2/6.2.3)
- Specification of the service provision (see DIN ISO 9004-2/6.2.4)
- Specification for quality control (see DIN ISO 9004-2/6.2.5).

Individual QM-elements or partial processes can well be audited and assessed at different times.

03.3 Will the performance and process requirements be audited internally according to an audit plan?

Term definition:

A „service audit“ serves for rating the compliance of the service performance with the defined service quality requirements. This can necessitate the testing of products.

A „process audit“ serves for testing whether the services are up to fulfill the quality requirements and if the process is mastered and suitable.

Requirements/Explanations:

Service and process audits have to be scheduled and performed.

Audit plans have to be defined for services and processes and should contain following information:

- Audit target
- Reference documents
- Services and processes to be audited
- Audit process
- Questionnaire
- Schedule
- Auditors
- Reporting with distribution list
- Tracking the measures.

During these audits the suitability of the working conditions and environment should also be reviewed (see also item 14.6).

03.4 Do discrepancies lead to corrective measures, will these be documented and their effectiveness be monitored?

Definition:

Corrective measure (according to DIN EN ISO 8402/4.14):

Task carried out for elimination of the causes of an occured error; defective or other unwanted situation in order to prevent its recurrence.

Requirements/Explanations:

Any discrepancies noticed must lead to immediate corrective measures, i.e. the elimination of the causes of one or several errors.

Within a defined period of time, an action plan concerning the discrepancies and the proposed corrective measures has to be presented. The action plan should contain e.g.:

- Discrepancies
  - Non-fulfillment of standard requirement
  - Assembly is unsuitable to reach targets
  - Activity is not conform to the instruction
  - Instruction is not actually complied with
- Rate/weigh discrepancies
  - Image
  - Risk/product safety
  - Cost-effectiveness
- Corrective measures
- Responsibilities/Deadlines
- Testing for effectiveness
- Reporting
- Adjusting documentation (such as QM-system).

The effectiveness of the introduced measures (action plan) has to be proven and rated within an appropriate period of time (see item 01.6).

04 Training, personnel

DIN EN ISO 9001 Section 4.18
DIN ISO 9004-2 Section 5.3

Definition:

The personnel employed in the services of the corporation are an essential factor for the corporation's quality and service ability. Managers have the most influence on the qualification and motivation of their staff. Hence measures for training, qualification and motivation of managers and their staff should be planned and performed on all levels and in all units.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
04.1	Is steady improvement of the supervision for the employees achieved?	-	-
04.2	Is the required qualification for providing the service defined and known?	4.18	5.3.2.2
04.3	Are skills and knowledge of the employees evaluated, assured and developed further?	4.18	5.3.2.2
04.4	Are performance targets agreed with the employees? Are they permanently reviewed, target achievement assessed and measures derived from noticed discrepancies?	-	-
04.5	Is the employees' quality commitment promoted and continuously improved?	-	-
04.6	Is employees' satisfaction evaluated and are measures derived from this assessment?	-	5.3.2.1

04.1 Is steady improvement of the supervision for the employees achieved?

Term definition:

Up-to-date supervision of the employees in a corporation requires that all managers in all units and on all levels beside the technical competence also have the necessary skills to supervise and motivate their subordinate staff as suitable in present times.

Requirements/Explanations:

Supervision of employees can be improved e.g. by following measures:

- Orientation of personnel management along the management principles
- Target agreements concerning improvement of supervising behaviour
- Review of target agreements concerning their relevance and effectiveness.

Evidence can be given e.g. by specified improvements during the past two years, or by means of interviewing employees.

04.2 Is the required qualification for providing the service defined and known?

Term definition:

Qualification means:

- The status given to an employee once he has proven his suitability to perform defined tasks.
- The competence to carry out a task properly.

Requirements/Explanations:

All employees on all levels performing quality-related tasks have to be involved. Requirement profiles have to be defined with regards to functions.

The superior in rank is responsible for evaluation of qualifications.

The qualification of employees has to be defined, e.g. in:

- Requirement profiles
- Job descriptions
- Function descriptions.

Sufficient knowledge about the possibilities of quality techniques in managers and staff form the basis for their purposive application within the corporation.

04.3 Are skills and knowledge of the employees evaluated, assured and developed further?

Term definition:

As „skills“ and „knowledge“ we understand the actual qualification of employees.

Requirements/Explanations:

lt should be specified how the actual qualification of employees is evaluated and how it is assured that available qualifications are promoted and further developed.

The direct superior in rank is responsible for the qualification of employees.

Some very important topics in this respect are:

- Procedure for recruitment of new employees
- Initial training on the job/instruction
- Regular determination of training demands of all employees concerning personal and functional skills
- Differenciated training demands concerning knowledge and conduct
- Execution and implementation of training measures
- Planning of succession.

04.4 Are performance targets agreed with the employees? Are they permanently reviewed, target achievement assessed and measures derived from noticed discrepancies?

Requirements/Explanations:

All employees on all levels performing quality-related tasks should be involved. Between employees and superiors achievable performance targets have to be agreed and proven. These targets have to be derived from the unit targets/corporate targets. An assessment of target achievement has to take place regularly in discussions with the employees, and in case of discrepancies (both positive or negative) measures have to be defined. The contact between superior and employee is thus intensified.

Among these aspects are among others:

- Definition of performance indicators
- Derivation of departmental targets from unit targets/corporate targets
- Regular discussions with employees (at least annually).

04.5 Is the employees' quality commitment promoted and continuously improved?

Term definitions:

As „commitment" we understand the individual employees' readiness to service and his attitude towards the corporation as shown also in his motivation.

Requirements/Explanations:

Such an improvement can be achieved e.g. by:

- Promotion of overall quality consciousness
- Transparency of performance results
- lncentive systems for employees
- Proposal system for improvements proposed by employees
- Quality circle
- Trainings.

Evidence o such actions has to be rendered.

04.6 Is employees' satisfaction evaluated and are measures derived from this assessment?

Requirements/Explanations:

Surveys on employees' satisfaction have to be carried out in regular intervals in all corporate units, and appropriate measures should be derived of the results.

These might be:

- Interviews with employees
- Trend statements about the indicators (absences, illness leaves, personnel fluctuation, readiness for further training in the corporation/in private)
- Evaluation of the effectiveness of supervision
- Training activities.

Evidence of such activities has to be given (See also item Z1.5)

05 Financial considerations on quality management systems

DIN EN ISO 9004-1 Section 6

Quality-related costs are costs spent on assurance of satisfactory quality and on the creation of trust that the quality requirements will be met, as well as losses due to non-achievement of satisfactory quality.

Quality resp. non-quality have considerable impact on the profit and loss situation of a corporation and its organisational units.

Improvement of effectiveness and efficiency of work will reduce losses and increase customer satisfaction.

Hence it is important that the effectiveness of the QM-system is measured also in economical terms.

Financial reporting can be made in parallel or in context with the classic recording of operating costs. It has to be transparent and should allow for long-term comparisons/trend surveys.

Note: To the external auditor, key figures and trends have to be proven, but not absolute values/amounts.

(See also item Z1.2)

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
05.1	Is there a procedure for financial reporting on the effectiveness of the QM-system?	-	6.1
05.2	Is financial reporting issued regularly and is it assessed by the persons in charge?	(4.1.3)	6.3
05.3	Are there records of internal losses due to insufficient quality (non-conformity)	-	6.2.2
05.4	Are there records of external losses due to non-sufficient quality (non-conformity)?	-	6.2.2

05.1 Is there a procedure for financial reporting on the effectiveness of the QM-system?

Requirements/Explanations:

For collection, analysis and representation of financial data on QM-elements, there are different methods.

The applied methods of financial reporting depend on the individual structure of each corporation and its organisational units, its activities, and the maturity of the QM-system.

The known methods do not exclude others or their adjustment and/or combination.

The corresponding procedure, the method and its cost structure (See items 05.2 through 05.4) have to be represented (e.g. with instructions, distributor records, cost center and accounts plans, summarising all financial expenses for the corporate management).

Methods of financial reporting on QM-system activities are e.g. records on expenses e.g. for:

Qualitv-related costs

- error prevention
- tests
- internal and external errors

or process-related costs (costs/profits-ratio-calculation) with

- conformity costs
- non-conformity costs

or quality-related losses (calculation of quality losses) with

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

Amount, process and analysis of the expenses in relation to errors and error causes have to be reported to the corporate management.

Note: Detailed statements are the subject of internal audits only. To external auditors, only the presence of the procedure has to be proven.

The corporation has the duty of recording financial key figures indicating the efficiency of the QM-system, and to represent and analyse them in terms of cause and time, introduce corrective and preventive measures and to track its effectiveness.

05.2 Is financial reporting issued regularly and is it assessed by the persons in charge?

Term definition:

„Financial reporting“ on quality-related tasks should be made and evaluated regularly by the responsible persons. lmprovements and targets should be derived hereof.

Requirements/Explanations:

The reports have to be easy to survey and to be related to business measuring units such as sales, turnover or value added in order to achieve realistic entrepreneurial views. The key figures resp. measuring units have to be aligned to target values, trends must, and improvement potentials should be visible.

For the subsequent period quality and cost targets have to be defined. therefore, e.g. the following questions have to be answered:

- Can the top management level recognise problematic issues from the quality-related cost report?
- Are costs analysed and provable corrective measures derived?
- Does the top management derive provable corrective measures from the quality-related cost report?

05.3 Are there records of internal losses due to insufficient quality (non-conformity)?

Term definition:

„Internal losses“ are losses occurring prior to delivery due to insufficient quality. They are caused by reduced working efficiency due to touch-up, poor ergonomy, and so on. There are also error costs resulting from the non-fulfillment of quality requirements by a product/a service prior to delivery (e.g. repeated execution of a service, touch-up, repeated test, damages).

Note: Measuring units for internal effectiveness and efficiency which are decisive for permanent corporate success concerning quality costs are non-conformity costs per task unit.

Requirements/Explanations:

Concerning the costs/expenses for e.g.:

- Damages
- Repairs
- Re-acquisition
- Reduced values
- Non-scheduled tests
- Storage-/Standing costs
- Problem examinations
- Breakdown times due to errors
- Failure to meet planing defaults
- Value modifications (higher value than planned or agreed).

These cost focuses have to be specified in terms of time and process.

05.4 Are there records of external losses due to non sufficient quality (non-conformity)?

Term definition:

„External losses“ are material and immaterial losses occuring after deliver due to insufficient quality.

Material losses are costs for errors resulting from the non-fulfillment of quality requirements by a product/a service after delivery (e.g. rejects, touch-up and repairs, warranty services and return shipments, direct cost and compensations, costs for call-back actions, costs of product liability).

Typical immaterial losses are e.g. lost future sales due to unsatisfied customers.

Requirements/Explanations:

Concerns the expenses e.g. for:

- Warranty (upon delivery/ „0 km“ and after having been used by customer)
- Accomodation
- Problem examination
- Call-back actions
- Product liability
- Consequential damages/compensations

as far as possible also

- Image loss
- Loss of customers due to their dissatisfaction.

Cost focuses have to be specified in terms of causes and time resp. process.

06 Product safety

DIN EN ISO 9004-1 Section 19

Corporations are instructed to integrate preventive quality assurance measures into operational processes in order to exclude product/service errors as far as possible. It is the aim of such measures to restrict the risk for the corporation and for the employees working on all hierarchical levels in the corporation.

The safety aspects of a service should be evaluated with the intention of increasing safety.

Employees on the different management levels should be suitably aware of about the impact that faulty products and services as well as the consequences of product liability have on the corporation.

Basically the quality management system has to be outlined so that possible errors can be reliably prevented

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
06.1	Are the principles of product liability known in the corporation?	-	-
06.2	Do procedures serve for the recognition of product/service risks?	(4.8)	19 a,b
06.3	Have pertinent safety regulations been determined, made known, implemented and is their maintenance monitored?	-	-
06.4	Does the service provider meet his obligation to instruct?	-	19 c
06.5	Are people warned against possible dangers in the plant which are not evidently obvious?	-	-

06.1 Are the principles of product liability known in the corporation?

Definition:

Product liability (according to DIN EN ISO 8402/2.12)

Obligation of a producer or other persons for indemnification due to personal, material or other damage, caused by a product.

Remark: The legal and financial effects of product liability depend on the respective jurisdiction.

Hints: The paragraphs 823, 831 BGB (German Civil Code) do not expressly regulate the matters of product liability. The basis is rather the implicit safe goods traffic obligation for producers, suppliers, traders who bring goods into commercial traffic. The requirements of caution and care can be classified into following categories according to the jurisdiction:

- Development errors
- Construction errors
- Fabrication errors
- Instruction errors
- Product observance errors.

Requirements/Explanations:

Indicators of the knowledge about product liability principles could be records of e.g.:

- Information and qualification of persons in charge
- Legal counsel (internal/external)
- Product liability insurances
- Observance of science and technology.

Product safety defects could lead to liability claims against the supplier. Knowledge on the product liability principles therefore is required for all employees who give relevant instructions on product safety.

Principles are:

- Liability depending on cause (defined by the reversion of obligation to give evidence, e.g. the burden of evidence lies with the plaintiff)
- Liability not depending on cause (product liability law), liability for direct damages and consequential detective damages
- It has to be proven that the production process (construction, production and testing) is up to the state-of-the-art (Merely fulfilling the standard is not sufficient!).
- Responsibilities have to be defined
- Testing documentation with archive filing
- Trackability has to be assured (damage restriction)
- Hints to possible risks to the user during product usage/application.

06.2 Do procedures serve for the recognition of product/service risks?

Term definition:

„Product-/Service risks“ are risks pertinent to products/services with regards to fulfilling their own function.

Requirements/Explanations:

The procedures to be applied serve for recognition and estimation of the risk potentials pertinent to a service which is developed, produced and/or described improperly. If necessary, they have to lead to decisions on necessary measures.

Product-/service risks are reduced e.g. by:

- Qualified documented risk assessment of the service to be provided
- Systematic risk assessment of new developments concerning their operational handling safety
- Risk examinations considering possible abuse
- Compliance with the „state of the art“ for products, materials and processes
- Instructions and caution hints in operation manuals
- Correspondence and promotion statements to customers concerning promised features

- A call-back system warranting appropriate opportunities to tracking and call-back of unsafe products
- An early-warning-system for call-back risks.

06.3 Have pertinent safety regulations been determined made known, implemented and is their maintenance monitored?

Term definition:

Under „pertinent safety regulations“ we understand the consideration of effective DIN-Standards, VDE-/VDI-guidelines, regulations etc. concerning the provided service.

Requirements/Explanations:

Before a service is provided, it has to be checked it applicant practise regulations, standards, drawings and specifications are complied with.

Negative impacts by the service provider on society and environment have to be avoided.

Documented obligations have to be checked for compatibility with the pertinent regulations and legal provisions.

The specifications for service provision should contain all legal regulation as well as relevant working safety, health protection and environmental protection requirements.

06.4 Does the Service provider meet his obligation to instruct?

Term definition:

As wrong instructions in operation manuals/instructions we would understand for example if due to lack of or defective operating instructions or insufficient warnings against possible dangers, products could be wrongly used by the buyer, and this abuse would cause damages.

Requirements/Explanations:

Concerning the obligation to instruct, the jurisdiction requires that the products are accompanied by operating manuals and handling instructions. Besides this mere obligation to instruct, warnings have to be issued against possible dangers which might result from the product or wrong usage of the product.

The following should e.g. be considered:

- Instructions and caution hints
- Maintenance manuals
- Service literature
- Labelling and promotion material

in order to prevent erroneous interpretation, in particular with regards to the usage intended by the customer and known dangers.

06.5 Are people warned against possible dangers in the plant which are not evidently obvious?

Term definition:

All those systems/processes/events have to be classified as not evidently obvious dangers, in which it is not obviously evident that the usage/application might endanger or injure/damage persons or objects.

Requirements/Explanations:

The persons in charge resp. the employees entrusted with execution of tasks have to assure that a possible danger is mostly excluded by suitable measures such as e.g.

- Marking/delimitation of danger zones
- Installation of safety signs
- Persons in charge of supervision/safety.

Z1 Corporate strategy

This element directly addresses the responsible persons within the corporations as long-term corporate success can only be achieved by overall business activities.

Better and constant quality, due deliveries in the agreed schedules, and cost reductions at the one hand, intensified trusting customer-supplier-relationship on the other hand presently force many corporations to adjust their strategy to these requirements. The board of directors including the subsequent management level therefore has to tackle the following subjects:

- business plan
- business results
- customer satisfaction
- comparison of internal and external data
- employees satisfaction

This element is an internal part of the questionnaire and is assessed within Part U.

Note: To the external auditor, key figures and trends have to be disclosed, but not absolute values/amounts.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
Z1.1	Does the corporation have a strategic business plan containing aspects of costs, distribution, quality and do on?	-	-
Z1.2	Are methods of measuring business results installed, and are they used regularly to implement improvements?	-	-
Z1.3	Are corporate performance data compared with results from benchmarking or other methods, and are corrective measures introduced if necessary?	-	-
Z1.4	Is a procedure allowing to measure customer satisfaction and to record changes installed?	-	-
Z1.5	Is employees' satisfaction a corporate management principles, and is it continuously maintained?	-	-

Z1.1 Does the corporation have a strategic business plan containing aspects of costs, distribution, quality and do on?

Terms definition:

A "business plan" is a document with strategic projects and targets specific to the corporation which have to be fulfilled or achieved within a given deadline.

Requirements/Explanations:

Usually, a business plan contains:

a) Aspects of cost
   - Financial and costs planning (investments, personnel and material costs)
   - Cost targets.

b) Aspects of distribution
   - Market data
   - Turnover/sales targets
   - Criteria of customer satisfaction (see item Z1.4)

c) Aspects concerning the corporation as an entity
   - Growth projects
   - Plans of operation design
   - Personnel planning
   - Comparison with other corporations (benchmarking)

d) Aspects of development
   - Development projects
   - Analyses of competition performance

e) Aspects of process and quality
   - Important key figures of process performances
   - Important quality-related figures (see item 01.2)

All aspects should be:

- furnished with dates
- based on project-related knowledge
- consider present and future customers' expectations
-- be traceable and monitored as well as adjustable to changes
- serve to improve process and quality

Business activities have to be carried out across functional borders.

Note: To the external auditors, key figures, time schedules, trends, trend analyses have to be disclosed, but not absolute values/ amounts, and not for all aspects. The corporation's interests have to be considered.

(See also items 01.1 and 01.2)

Z1.2 Are methods of measuring business results installed, and are they used regularly to implement improvements?

Term definition:

"Business results" represent what the corporation achieves in relation to its planned operational performance.

Requirements/Explanations:

Indicators for financial measuring units could be e.g.:

- Profit
- Cash flow
- Turnover
- Value added
- Capital of the corporation
- Liquidity
- Dividends
- Long-term shareholder value.

These figures in practice are stated partially in absolute figures, partially as the ration per capital unit, or per headcount.

Indicators for non-financial measuring units could be e.g.:

- Market shares
- Exploitation of the plant
- Touch-ups and repairs
- Variability of products/services
- Achieved customer satisfaction
- Image key data
- Due and on time deliveries
- Order processing time

The measured units are outlined along the corporate strategies and the entrepreneurial targets and defaults. They contain measuring units indicating the company's efficiency and cost-effectiveness and decisive for the long-term, lasting corporate success.

The data have to be analysed/evaluated and the results must lead to corrective measures (e.g. action plans).

Note: Only the installed system, not the result has to be audited.

(See also item 05.1 trough 05.4)

Z1.3 Are corporate performance data compared with results from benchmarking or other methods, and are corrective measures introduced if necessary?

Requirements/Explanations:

Evaluation, analysis and benefit of corporate performance with data of competitions or other companies by means of benchmarking should given hints as to e.g.:

- Productivity
- Cost-effectiveness
- Quality status
- Performance.

Trends in data and information should be compared with the progress concerning the overall targets, and converted into suitable information to be used for:

- Development of priorities for fast solutions of customer-related problems
- Determining of essential customer-related trends and interrelationships in order to allow auditing the corporate status, decision making, and more long-term planning.

Note: Only the installed system is to be audited, not the result.

(See also item 07.4 and 15.1 through 15.5)

Z1.4 Is a procedure allowing to measure customer satisfaction and to record changes installed?

Requirements/Explanations:

The procedure has to consider the following criteria such as:

- Method application
- Recognition frequency
- Data evaluation and representation
- Interpretation of trends
- Competences
- Distribution list

Comparisons with competitors and benchmarking-methods are useful.

As far as possible, not only the direct customer, but also the final user should be involved.

From the gathered recognitions, measures which can improve customer satisfaction should be derived.

Note: Only the installed procedure has to be audited, not the result.

(See also item 14.4)

Z1.5 Is employees' satisfaction a corporate management principles, and is it continuously maintained?

Term definition:

"Employee satisfaction" the employees' attitude towards the corporation. Demands and expectations of employees should be satisfied by comprehensive quality approach.

Requirements/Explanations:

The sensations and feelings of employees are indicators of their satisfaction. These are expressed e.g. in the following:

-- Working conditions, work place, room, equipment
- Health protection and working safety provisions
- Communication on the employee and workshop levels
- Employee assessments, target agreements, career plans
- Awareness of requirements of their work
- Awareness of quality policy and corporate strategy
- Participation in quality activities
- System for recognition and rewarding of performance
- Management and supervision style
- Work place safety

Further indicators might be e.g.:

- Absence and illness quota
- Personnel fluctuation
- Junior staff is easy to be hired
- Corporate services/facilities are made use of.

The gathered recognitions should lead to measures which will increase employees' satisfaction.

Note: Only the installed system has to be audited, not the result.

(See also 04.6)

Part P: Product/Service and Process

07 Market research

DIN EN ISO 9001, Section 4.4
DIN ISO 9004-1, Sections 5.5, 6.1, 6.2

This QM-element addresses market research quality.

Market research should exactly determine the requirements to a service, the market demands and customer expectations.

Requirements to the service have to be documented and made known to all concerned bodies within the corporation in an easy-to-understand manner.

		Reference DIN EN ISO 9001	DIN ISO 9004-2
07.1	Have responsibilities and competences for market research, survey and analysis been defined?	4.4	6.1.1
07.2	Have responsibilities and competences for market research, survey and analysis been defined?	-	5.5.2
07.3	Are customer requirements to products/ services systematically researched and converted to actions?	-	6.1.1
07.4	Are benchmarks (system, process and product comparisons) and competition analyses carried out?	-	6.1.1
07.5	Are additional products/services derived from market analyses and offered on the market?	-	6.2.1 6.1.3

07.1 Have responsibilities and competences for market research, survey and analysis been defined?

Requirements/Explanations:

The function market research, survey and analysis has to determine the requirements and expectations towards the offered services. To this end, a flow chart has to be defined in which all involved functional and organizational units are involved with their overall or partial responsibilities.

07.2 Have responsibilities and competences for market research, survey and analysis been defined?

Requirements/Explanations:

Demands can consist of different requirements such as e.g.:

- Requirements by superior corporate unit/legal provisions
- Customer demands
- Market research
- Innovation or adjustment to the latest state-of-the-art.

07.3 Are customer requirements to products/services systematically researched and converted to actions?

Requirements/Explanations:

For this purpose, a system has to be installed which in regular intervals systematically research the customer demands and expectations related to the offered products/services (consumer's taste, demand class, expected reliability, availability) and then analyses and documents the results. It is the task of the management to drive corrective measure on basis of the results, implement these measures and monitor their effectiveness.

Exemplary tasks are:

- Planning how, who and by whom interviews are held, the kind of questions to be asked, time, place, number of interviewees, etc.
- Results of the survey such as specific customer requirements/ customer expectations have to be made known to the management and the concerned bodies.

07.4 Are benchmarks (system, process and product comparisons) and competition analyses carried out?

Term definition:

Benchmarking is the systematic search for best practise by means of direct comparison with a benchmarking partner. This comparison leads to standard „benchmarks“, along which the own performance can be rated resp. audited. The aim is improving the own products/services and practises.

Benchmarking can be carried out internally as comparison between corporate units, or externally as competition benchmarking, function benchmarking (Comparison with similar functions within the branch) or as a comparison between specific business processes.

Requirements/Explanations:

Execution and evaluation of benchmarking and competitive analyses have to be specified as well as the process of deriving measures from their results.

(See also item Z1.3)

07.5 Are additional products/services derived from market analyses and offered on the market?

Requirements/Explanations:

It has to be specified how the information gathered from analyses are

- edited
- made known to the concerned bodies
- leading to specification of new or additional products/services
- implemented and introduced
- reviewed concerning their effectiveness
- and in CASE defaults are not met, corresponding actions are taken.

08 Development

DIN EN ISO 9001 Section 4.4
DIN ISO 9004-2 Sections 6.1, 6.2

The QM-element development describes the quality assurance tasks in the range of services development. For conversion of customer requirements into service specifications, they should consider preparation and specification for due and customer conform achievement.

The provision of means e.g.: personnel, equipment, pilot application is a prerequisite for service development.

Note: This element only has to be audited if the service provider is responsible for development. Not applicant if a ready-developed service is taken over.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
08.1	Have responsibilities and competences for service development been defined?	4.4.1 4.4.2 4.4.3	6.1.4 6.2.1 6.2.2
08.2	Are procedures and regulations for creation of requirement catalogues installed?	4.4.4	6.1.3 6.2.1
08.3	Are the results of services development documented in specifications/processing instructions?	4.4.5	6.2.3
08.4	Is service development checked against the requirement catalogue for fulfillment of requirements at the end of each stage (including release)?	4.4.6 4.4.7	6.2.6 6.2.7
08.5	Is it assured that modifications during development activities are documented in uniform and traceable manner?	4.4.9	6.2.8

08.1 Have responsibilities and competences for service development been defined?

Requirements/Explanations:

For the development plan, current milestone-plans, flow charts etc. have to be presented with detailed plans representing all activities from conception/ order through to introduction. The systematic tackling of planned tasks (project planning) has to be assured. A responsible project manager and all involved units with their tasks have to be stated. A central monitoring of project progress has to be assured (target-actual-comparison). Monitoring has to comprise compliance with all defined targets, such as:

- tasks
- competences
- responsibilities
- deadlines
- means.

Evidence has to be given by means of examples.

08.2 Are procedures and regulations for creation of requirement catalogues installed?

Definition:

Requirement catalogues can be specifications/delineations of services and performance.

Specification (according to DIN 69905):

Entity of all the customers requirements to services and deliveries of a contractor.

According to VDI/VDE 3694: The specification has to describe the requirements from the user's point of view; including all marginal conditions. These should be quantifiable and verifiable.

*The specification defines **HOW** and **WHAT FOR** a task has to be solved.*

Delineafion *(DIN 69905):*

Details to be carried out for implementation of the specification, defined by the contractor.

According to VDI/VDE 3694: The delineation contains the specification The delineation details the user's specifications and further the requirements to be fulfilled under consideration of concrete approaches to solutions.

The delineation defines **HOW** and **WITH WHICH MEANS** the requirements shall be fulfilled.

Requirements/Explanations:

A procedure has to be proven which assures that the customers requirements are fulfilled in a generally comprehensible manner.

The following aspects have to be considered among others:

- Legal and governmental requirements
- Market research results
- Agreed contractor's obligations
- Exact description of requirement profiles and
- Development requirements have to contain the results of contract review.

08.3 Are the results of services development documented in specifications/processing instructions?

Definition:

Specification (according to DIN EN ISO 8402/3.14):

A document defining requirements:

Remark 1: A determinative word should be used to indicate the type of the specification, such as product specification, test specification.

Remark 2: A specification should refer to drawings, patterns or other pertinent documents, or contain same, and should also state means and criteria with which conformity can be tested (2.9).

Requirements/Explanations:

The results of development work concerning the service have to be appropriately documented in specifications or processing instructions. These documents for implementation of quality requirements have to be complete and unambiguously.

These could be for example:

- Description of requirement profile and safety criteria
- Comprehensible and complete description of service features
- Acceptance criteria for each service feature
- Involvement of sub-contractors
- Service provision/delivery
- Operation and service manuals.

08.4 Is service development checked against the requirement catalogue for fulfilment of requirements at the end of each stage (including release)?

Requirements/Explanations:

Already during project planning, a service audit (development review) is to be foreseen at the end of each stage (milestone-plan). Comparison against the requirements of the delineation/specification can be made by applying different methods. Concerning the assessments the meaning of the terms has to be defined, and also how the results have to be documented, such as in particular:

- Review — Assessment of individual steps
- Verification — Comparison of results with requirements of the delineation
- Validation — Review of suitability for application or comparison against the specification, often with participation of customer: acceptance test.

08.5 Is it assured that modifications during development activities are documented in a uniform and traceable manner?

Requirements/Explanations:

Processes and competences have to be defined, such as:

- Planning, documentation and recording of modifications
- Evaluation of the impact of modifications
- Notification of all parties involved in the process
- Determination of how customers have to be notified about modifications.

Introduction and implementation of modifications has to be documented i.e. has to be traceable and provable.

For a complete survey of all modifications, suitable summarises have to be edited. lt has to be defined who is in charge of this task.

The system must be able to exclude abuse.

Determinations of the release and distribution system have to state the process flow which assures that the proper documents are available at the right time and place, and that they can not be mixed up with invalid documents.

09 Service preparation

DIN EN ISO 9001 Sections 4.3, 4.4, 4.10
DIN ISO 9004-2, Sections 6.2, 6.3

The service development stage has to be followed by all necessary preparations for assuring safe launching of the service.

The QM-element service preparation describes all quality-assurance measures during the stage of launching the service.

These should assure that all requirements specified in the deline-ation and all monitoring criteria are implemented in practise.

After the service preparation is finished, further development and optimation have to take place.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
09.1	Is implementation of the requirement catalogue into the service process assured?	4.3.2c	6.2.6
09.2	Are there regulations for the launching of new products/services?	4.4.4	6.1.3 6.2.1
09.3	Are there regulations for testing, recording and monitoring for auditing the quality of the product/service?	4.4.5	6.2.3
09.4	After the product/service preparation is over, do review and release take place?	4.4.6 4.4.7	6.2.6 6.2.7

09.1 Is implementation of the requirement catalogue into the service process assured?

Definition:

Specification an delineation (according to DIN 69905):

(See item 08.2)

Requirements/Explanations:

Compliance with all requirements specified in the specification for provision of the service has to be assured.

Cyclic reviews shall check if the defined requirements are actually complied with.

The representatives of all functions that have an impact on the service quality should participate in these reviews.

The following should be considered among others:

- Work place design
- Legal regulations
- Description of how the service is to be provided
- Description of how the processes are controlled
- Determination of training demand and extent.

09.2 Are there regulations for the launching of new products/ services?

Requirements/Explanations:

Launching new products/services requires that all activities from the planning through to launching are described in detailed plans and milestone plans as far as concerning the service provider.

All those criteria which lead to acceptance of the products/services have to be described unambiguously.

Monitoring of the compliance with all defined targets is mandatory.

Definitions of following aspects have to be considered among others:

- Processes in manuals
- Quality criteria
- Acceptance criteria for the services
- Time schedule for the launching stage
- Purchasing of products, materials, elements, services, tools and equipments.

09.3 Are there regulations for testing, recording and **monitoring for auditing** the quality of the **product/service?**

Requirements/Explanations:

The procedures for testing, recording and monitoring for audit purposes of the product/service quality have to be defined in processing instructions.

The following have to be considered among others:

- Test procedures
- Product-/Service specifications
- Checklists
- Documentation of results
- Verification by spot-checks.

09.4 After the product/service preparation is over, do review and release take place?

Requirements/Explanations:

Procedures for release and implementation have to be defined together with the competences of the individual functional and organisational units.

Prior to the first provision of a service, the following items have to be checked for confirmation:

- Documents being always up-to-date by means of appropriate revision service
- Competence of the employees
- Suitability of the means
- Procedures for standard cases and discrepancies
- Agreements for discrepancies from the standards.

10 Promotion and marketing

DIN ISO 9004-2 Section 6.1

Promotion always is an important factor for the marketing of products/services and therefore always has to be applied (directly or indirectly).

The QM-element describes the quality assurances measures which may considerably contribute to successful promotion and hence are to be understood as minimum requirements. Depending on size/structure of a corporation, promotion can be made by corporate staff (departments/units) or with external support.

DIN ISO 9004-2 in section 5.5 describes the Interface to the customers which mainly addresses the analysis of demands. This can be classified as limit range for launching promotion activities, but is also addressed in the marketing unit.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
10.1	Are there regulations for responsibilities/ competences, planning and execution of promotion actions?	-	-
10.2	Do type and contents of promotion and marketing consider the results of surveys, market analyses etc.?	-	-
10.3	Have requirements to the corporate image been defined and are they applied?	-	-
10.4	Does promotion assure that the promised services are achievable and conform with the legal regulations, the requirements of the contractual partners or the customers expectations?	-	6.1.5
10.5	Is the success of the chosen promotion appropriately reviewed?	-	-
10.6	Is the competence of the service provider part of the promotion actions?	-	-

10.1 Are there regulations for responsibilities/competences, planning and execution of promotion actions?

Requirements/Explanations:

The methods, responsibility for execution and competence for decision making have to be defined appropriately. This also has to consider release of funds.

In the focus should be objective customer information, i.e. a corresponding presentation/marketing of the products/services with the aim of sales promotion.

10.2 Do type and contents of promotion and marketing consider the results of surveys, market analyses etc.?

Requirements/Explanations:

Depending on the kind of products/services, an appropriate survey of the need of explanation for the products/services has to be defined based on the market situation.

The results of market analyses, benchmarking, interviews etc. have to be considered in the type of promotion and marketing (see item 07.5). Depending on the products/services, promotion can be made by means of adverts, sales rooms, mailings, displays/showrooms, or information presentations.

Based on marketing plans, systematic marketing has to be assured.

For promotion purposes, indirect factors have to be considered, such as:

- Cleanliness of the site
- Display of certificates, awards, records and so on.
- Dress code, appearance, conduct.

Active customer contact also is to be considered. This means for example:

- Exhibitions on fairs (expert or general fairs)
- Reference examples
- Sponsoring
- Public media.

10.3 Have requirements to the corporate image been defined, and are they applied?

Requirements/Explanations:

These requirements refer to the „Corporate Identity" (CI) and also comprise communication with existing and potential customers. Depending on the kind of products/services, availability, design of the environment orderliness/cleanliness and appearance of the employees also have to be considered.

10.4 Does promotion assure that the promised services are achievable and conform with the legal regulations, the requirements of the contractual partners or the customers expectations?

Requirements/Explanations:

The employee who is in charge before release, meaning prior to launching/ execution of promotion actions, has to review if all a.m. requirements are fulfilled. Execution of the review has to be documented appropriately.

In any case it has to be assured that the promoted/promised features can be granted, and are not in contradiction to legal regulations (fair trade law) or partnership agreements (customer/supplier).

This measure shall positively influence the quality of promotion and should prevent the possible errors listed hereafter, such as:

- Missing the target group
- lmprecise statements
- Untrue promises.

The correct application of promotion measures should become visible for example in the following:

- lncreased product/service acceptance
- Creation of trust
- lncreased corporate identity/customer interest
- Rising popularity
- Sales growth.

10.5 Is the success of the chosen promotion appropriately reviewed?

Requirements/Explanations:

In an appropriate manner it has to be audited if the promotion actions bring the desired success.

Review can be made by means of:

- Purposive questions in case of customer interest/contract negotiations or similar occasions
- Sales statistics
- Surveys/Degree of getting through to customers

or similar measures.

The information have to be evaluated accordingly and considered in future promotion actions (costs/benefits).

10.6 Is the competence of the service provider part of the promotion actions?

Requirements/Explanations:

Depending on the type of products/services to be marketed, creation of trust is an essential factor. By evidence of corresponding expertise (certificates, awards, credentials) and suitable application of these records in promotion activities can decisively influence creation of customers trust.

Therefore such records should be a fix part of mailings, or be on show in rooms visited by customers.

11 Sales/Service agreement

DIN EN ISO 9001 Section 4.3
DIN ISO 9004-2 Sections 5.4, 5.5, 6.1

This QM-element describes the quality assurance measures which the supplier has to comply with during preparation of proposals and contract review.

The qualitative and quantitative features (and as far as applicant also costs) of the service and the process of providing the service should be unambiguously defined as basis of an agreement in order to prevent errors at the interface between customer and service provider.

The supplier of products/services should state in an appropriate manner his capability to complete the service order.

The description of the interface between service provider and service recipient/partner as well as its contents have to be stated unambiguously. A joint agreement has to be defined.

The agreement should contain in particular the unambiguous acceptance criteria in order to avoid problems and to create trust.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
11.1	Are there definitions and procedures defining the methods and responsibilities for proposal and contract review (for all types of contracts)?	4.3.1	6.1.2 6.1.3
11.2	Are the demands and expected customer services evaluated and documented appropriately?	-	5.4.3.1 5.5.2 6.1.3
11.3	Are inquiries proposals, contracts checked for completeness and feasibility and then released?	4.3.2b 4.3.2c	6.1.4
11.4	Is the agreed scope of delivery acknowledged accordingly?	4.3.4	5.5.2
11.5	Have procedures and responsibilities for contract reviews been defined?	4.3.4	5.5.2

11.1 Are there definitions and procedures defining the methods and responsibilities for proposal and contract review (for all types of contracts)?

Requirements/Explanations:

The service provider has to define the procedure and responsibilities for all kinds of possible contracts (sales, rental, leasing, service agreements and so on) in a proper manner. This definition, or a similar document, must show the competences of the employees entrusted with the execution.

The focus is on an unambiguous feasibility check, i.e. the procedure has to assure that possible weaknesses (being unable to fulfill requirements etc.) are recognised before a contract is agreed. lt also has to be considered whether further departments within the corporation or at the customer's have to be contacted.

11.2 Are the demands and expected customer services evaluated and documented appropriately?

Requirements/Explanations:

Prior to execution of an agreement, the scope of the services to be provided has to be clarified unambiguously. lt also has to be considered that possibly the customers knowledge/experience are not sufficient to estimate the scope of the service. lt this is the case, the customer has to be notified about possible problems by the service provider.

This might concern e.g. the further procedure after a hidden defective has been found in the process of providing the service. the following focuses need special attention:

- Clarification of the extent of product/service
- Definition of the scope of delivery
- Delimitation of costs to be expected for providing the service
- Definition of expenses in terms of deadline/time requirements for providing the service
- Definition of quality requirements
- Consideration of EU-directives, provisions and laws.

The applicant requirements should be stated in writing while the form of the documentation should be adjusted to the value and scope of the service to be provided.

11.3 Are inquiries, proposals, contracts checked for completeness and feasibility and then released?

Requirements/Explanations:

All inquiries, proposals and contracts have to be reviewed by authorised employees concerning the feasibility of the requirements. If the competence/ expertise of the entrusted employees is not sufficient to review the feasibility of all the requirements, accordingly competent employees have to be involved in the review process.

As far as required, the documentation also has to consider the interface to the customer (employee/contact person). The documentation has to give evidence that suitable review of the feasibility has been performed.

In case discrepancies between proposal and contract are noticed, the customer has to be notified. In each case it has to be assured that modified requirements are feasible before an agreement is executed.

When preparing an agreement the handling of possible non-fulfillment of customer requirements has to be considered (see also explanations to item 11.2/Hidden expectations).

11.4 Is the agreed scope of delivery acknowledged accordingly?

Requirements/Explanations:

On principle, the product to be delivered or the service to be provided has to be acknowledged. Depending on type and extent of the services, this might be done with a simple order acknowledgement (e.g. delivery note, requirement check), or by signing signature of complex agreements.

11.5 Have procedures and responsibilities for contract reviews been defined?

Requirements/Explanations:

When providing a service, unforeseeable events, or events which are hardly foreseeable, can necessitate modification of the defined scope of delivery. This can be caused by the service provider or by the customer. In order to prevent problems, this opportunity and the related proceedings should already be considered during preparation of the agreement. In any case, there have to be regulations for the further proceedings.

The focuses listed hereafter need special attention:

- Sufficient documentation/registration of noticed problems/discrepancies
- Notification of customer if problems are noticed by contractor
- Working out possible solutions/alternatives
- Feasibility study
- Agreement on further proceedings with the customer
- Modification/expansion of the scope of deliveries
- Adjustment of the agreement (in writing or as a phone memo)
- Confirmation of the contract amendment
- Make sure that all concerned/involved employees are informed.

The QM-system has to define the proceedings and the responsibility for execution of contract amendments. Recording of evidence has to be adjusted to the value/extent of the service, and can be made in form of a memo or if necessary by a new contract text or alternatively as an amendment to the existing contract.

12 Purchasing

DIN EN ISO 9001 Sections 4.6, 4.10, 4.13
DIN ISO 9004-2 Section 6.2

This QM-element describes the quality assurance measures which the service provider has to take for the purchasing of products/services from his suppliers/subcontractors.

So the products/services purchased from suppliers/subcontractors become direct or indirect parts of the finished product and so influence the quality of the product.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
12.1	Is there a regulation of competences and an audit process for suppliers/subcontractors of products/services?	4.6.2	6.2.4.3
12.2	Is there a survey of approved suppliers/ subcontractors?	4.6.2a	-
12.3	Are the purchasing process, competences and handling of modifications defined?	4.6.1 4.6.3	-
12.4	Do the purchasing documents contain all quality requirements to the products/ services?	4.6.3	-
12.5	Are the purchased products/services subject to tests?	4.6.4 4.10.2	-
12.6	Is the handling of complaints about services from suppliers/subcontractors defined?	4.13	-
12.7	Are the services provided by suppliers/ subcontractors systematically audited and have the results influence on the survey of approved suppliers/subcontractors?	4.6.2b 4.6.2c	-

12.1 Is there a regulation of competences and an audit process for suppliers/subcontractors of products/services?

Requirements/Explanations:

Depending on the size/structure and type of the corporation, the procedures/ work flows have to be defined in appropriate manner, such as in:

- QM-manuals
- Processing instructions
- Organisation instructions or similar documents.

This determination has to show the proceeding and the responsibility for the execution as well as the decision making competences.

For the first qualification and the current audit, appropriate procedures/ records such as e.g.:

- Checklists
- Requirement profiles
- Simple rating procedures.

which allow for sufficient objectivity have to be applied.

Depending on the values of the products/services to be purchased it has to be considered that the supplier/subcontractor is sufficiently qualified. This can be proven e.g. by:

- Certification by registered certification agencies
- System audit results of other customers of the supplier/ subcontractor
- Quality achieved so far
- Image within the branch.

These factors have to be considered when checklists are applied.

If the suppliers/subcontractors ability to deliver quality should be in doubt, performance of a QM-system audit should be considered.

12.2 Is there a survey of approved suppliers/subcontractors?

Requirements/Explanations:

The corporation must have installed a systematic which assures that purchases can only be made from approved, sufficiently qualified suppliers/ subcontractors.

Fulfillment of these requirements can be made by means of a list or comparable actual presentation (EDP). This list must only contain approved suppliers/subcontractors, resp. the status (qualification, approved or blocked) has to be evident unambiguously. The list must be made available (be visible) to all bodies involved in the purchasing process.

12.3 Are the purchasing process, competences and handling of modifications defined?

Requirements/Explanations:

The proceedings for purchasing products/services have to be defined in a manner that shows the main processes including responsibilities/competences. In particular the possible internal and external interfaces have to be considered.

The definition can be made e.g. as:

- Flow-Charts (under consideration of responsibilities/interfaces)
- Work flow descriptions
- Organisational instructions or similar.

For the edition of default documentation, size/structure of the corporation have to be considered appropriately

Concerning eventually necessary modifications of the purchasing process, such as modifications of specifications or changes of the scope of delivery the competences for coordination/handling have to be defined under consideration of feasibility. If necessary, also internal/external interface regulations have to be considered.

12.4 Do the purchasing documents contain all quality requirements to the products/services?

Requirements/Explanations:

Complete and easily comprehensible specification have to be contained in the orders (drawings, standards, quality agreements/design quality, laws/regulations to be considered, etc.).

Together with the supplier/subcontractor all those details have to be agreed which are relevant for purchasing products/services. Among these are, besides the technical specification, also:

- Tests to be carried out
- Acceptance criteria
- Processing if service is not or not sufficiently provided (alternative regulations)
- Compliance with legal requirements in context with staff leasing.

12.5 Are the purchased products/services subject to tests?

Requirements/Explanations:

All the products/services from the supplier/subcontractor have to be properly tested by qualified employees prior resp. during usage concerning compliance with agreed scope of delivery.

The proceedings have to be adjusted to the purchased products/services.

This can be done by means of e.g.

- lncoming goods inspections
- Interim inspections
- or by certified characteristics.

Execution of inspection/monitoring has to be documented. Record of the execution should be given on delivery notes checklists or similar test records. These records have to allow sufficient traceability concerning testing persons/employees, date and extent of inspection/monitoring, as well as state the test results. Further, this documentation must be assignable to the concerned supplier/subcontractor.

These proceedings have to assure that the requirements raised under item 12.4 are fulfilled/complied with.

12.6 Is the handling of complaints about services from suppliers/ subcontractors defined?

Definition:

Complaint (according to DIN 8402/2.10, 2.11):

Complaints have to be initialled if defectives or errors are determined.

Requirements/Explanations:

The supplier must have a procedure for how to handle defectives or non-conformities.

Discrepancies against target values/expectations can be noticed during incoming, interim or final inspection, but also during assembly or during application/usage.

The defined procedure must exclude further errors/defectives within the value adding chain, which means immediate measures have to be taken if necessary.

The subcontractor has to be contacted quickly and elimination measures (short, medium and Iong-term) in the sense of corrective measures have to be taken.

The complaints have to be considered accordingly for supplier audits (see also item 12.7).

12.7 Are the services provided by suppliers/subcontractors systematically audited and have the results influence on the survey of approved suppliers/subcontractors?

Term definition:

A „systematic audit“ encompasses or contains the assessment of the products/services supplied by the supplier/subcontractor by means of expressive key figures or similar criteria on the basis of the agreed scope of delivery.

Requirements/Explanations:

The audit of suppliers/subcontractors has to take place after delivery of products or provision of services. The assessment should be made regularly.

For the audit, also field complaints and subsequent complaints have to be considered accordingly. If necessary, suitable measures have to be implemented and documented following the audit criteria (see also element 15).

The results of the audit should further cause deletion from the survey of approved suppliers/subcontractors if supplier/subcontractor fails the audit.

13 Service providing

DIN EN ISO 9001	Sections	4.7, 4.8, 4.9, 4.0, 4.11, 4.12, 4.13, 4.15
DIN ISO 9004-2	Sections	6.2, 6.3

This element summarises all quality-relevant tasks which are required for providing the service starting from acceptance of order through to delivery to the customer.

Among these are the following:

- Accepting product to be treated and/or order from customer
- Application of suitable processing and testing instructions
- Assurance of labelling and trackability
- Recording completed tasks and tests
- Method and recognition of resting resp. release status
- Handling of and proceeding with faulty products/services
- Handling of products/services during the completion of the order
- Storage, packaging and shipment measures for product protection
- Assurance of serviceability and precision of operating and testing means.

		Reference DIN EN ISO 9001	DIN ISO 9004-2
13.1	Upon acceptance of the order is it determined if the customer supplies any own products and thus special measures are required?	4.7	-
13.2	Have procedures and responsibilities for the order processing been defined, covering also the required means, methods as well as tests, and are methods for determination of testing status defined ?	4.9 4.10 4.112	6.2.4.2 6.2.5 6.3.1/4
13.3	Are marking and trackability defined and traceable in each stage of order completion?	4.8	6.2.4.5
13.4	Have procedures and competences for final inspections and delivery to customer been defined?	4.10	6.3.2 6.3.3 6.2.4.4
13.5	Is it warranted that faulty products/services are marked, measures decided upon, and records filed?	4.13	6.3.5
13.6	Have procedures for handling, storage, packaging and shipment of products as well as protection of customers possessions during the order completion been defined?	4.15	6.2.4.6
13.7	Are the used operating and testing means (including test software) registered, are they regularly inspected for functionality and precision, and are records thereof filed?	4.9 4.11	6.3.6

13.1 Upon acceptance of the order is it determined if the customer supplies any own products and thus special measures are required?

Term definitions:

„Customer-supplied products“ are products supplied by the customer himself free of charge and which have no direct value added during the service providing (assembly, further processing).

Requirements/Explanations:

Concerning customer-supplied products care has to be taken that it is noted already during the contract review or upon acceptance of the order whether the customer supplies anything. For definition of the procedure, the following has to be considered:

- Can the customer-supplied product be treated just like self-supplied products? If not, are special measures necessary or are such agreed with the customer?
- In any case, a proper acceptance review has to take place
- In case products/services are faulty, damaged or lost, the customer has to be notified
- Determinations, agreement and execution of special measures have to be documented
- Careful handling and storage of products/services has to be warranted (see item 13.6).

13.2 Have procedures and responsibilities for the order processing been defined, covering also the required means, methods as well as tests, and are methods for determination of testing status defined?

Requirements/Explanations:

Internal processing instructions have to be edited in writing, defining how to proceed for providing a service starting from the acceptance of the order through to delivery to the customer.

The processing instructions have to contain all information, responsibilities, means, interfaces and processes required for proper control and processing of the order. Concerning repairs or adjustments of products or services, instructions of the manufacturer or producer may be relied upon. The used instructions must be up-to-date, which means a revision service has to be defined for updating. The instructions for order processing also have to contain e.g. the following aspects or statements:

- Acceptance of customer possessions (possibly together with customer) to be able to execute the service
- Performance of all tasks and their review, if applicant with supplementary instructions such as assembly, usage or operating manuals as well as test instructions.
- Reference to brand-conform spare parts and auxiliaries (product liability reasons)
- Current records on the execution of performed measures and/or inspections
- Preparation of „document“, while measures and results have to be recorded.

13.3 Are marking and trackability defined and traceable in each stage of order completion?

Term definitions:

„Marking and trackability“ means that during the whole process of providing a service it is at all times obvious which order is concerned and activities, test results, measures and documentation can at all times be assigned to the proper product/service.

This should enable delimitation of faulty products/services, damage restriction in case of errors, as well as trackability of customer complaints and liability claims.

Requirements/Explanations:

Therefore, the processing instructions have to consider the following, and in some cases also further aspects specific to the product or service

- Marking for acceptance from customer, in case of spare parts for release on stock, as well as during all stages of providing the service up to delivery to customer
- Trackability of products/services back to their origin, meaning as far as necessary to the external producer or manufacturer and internally to the performing employee(s)
- corresponding records on the concerned documents (see also item 13.2>.

13.4 Have procedures and competences for final inspections and delivery to customer been defined?

Term definitions:

„Final inspection“ means the internal final inspection through an authorised employee prior to delivery to the customer. This inspection can also be made together with the customer. Such inspections may also be called shipment tests or acceptance tests.

Requirements/Explanations:

For final, shipment or acceptance tests, there have to be unambiguous testing instructions in order to warrant their repeatability. These instructions can be either general or specific to a product or service, and have to contain - among other things - the following statements:

- Check for completeness, function, condition, correctness and cleanliness
- Completeness and flawlessness of the product or customer possession supplied by the customer
- Final assessment or in some cases order-specific special tests (e.g. test drives, expertises etc.)
- Records on voluntary and mandatory inspections (product liability, environmental protection etc.).
- Warrant proper application and usage by means of complete hand-over and if necessary hints and instructions
- Regulations for observance and auditing of the quality features not covered by the final inspection, such as e.g. billing, explanations, or hand-out to customer.

13.5 Is it warranted that faulty products/services are marked, measures decided upon, and records filed?

Term definitions:

„Errors“ (non-fulfillment of defined requirement) in products/services are extra-ordinary events which can occur upon acceptance of the product and/ or order completion through to the final inspection resp. acceptance by the customer, and therefore have to be recognised and eliminated.

Requirements/Explanations:

Concerning the control of faulty products/services, written definitions have to be available, describing how to proceed in such cases, how the decision-making competence is defined, and how the records of elimination are filed. For these definitions, the following aspects have to be considered among other items:

- Marking, documentation and rating of faulty products/services
- Separation of those so that they can by no means be used further, processed further, or used without corrections
- Competences for deciding what to do (including environmental-friendly disposal)
- Determinations concerning suppliers have to be integrated into the supplier audit
- Re-checks for touched-up products/services
- Special releases under involvement of competent persons and/or the customer
- Record of evidence of definitions, decisions, measures and reviews.

13.6 Have procedures for handling, storage, packaging and shipment of products as well as protection of customers' possessions during the order completion been defined?

Requirements/Explanations:

These procedures concern products/services which have to be treated, processed, cared for or performed by the corporation from acceptance of products/services through to delivery or hand-over to customer. So this mainly concerns the obligation of caution and care in the scope of order completion (marking and trackability see item 13.3).

Procedures and instructions have to be defined in writing, considering among other things the following measures:

- Effective control of storage and handling for protection against damages, impair, and concerning environmental aspects
- Methods and means for the handling of products/services during order completion (including for example test drives)
- Protection of customer-supplied products/services, even during difficult tasks/works
- Protection/packaging of products/services prior to shipment (including obligation of caution and care for shipment agents).

13.7 Are the used operating and testing means (including test software) registered, are they regularly inspected for functionality and precision, and are records thereof filed?

Requirements/Explanations:

Operating and testing means have to be suited for their application in the continuous providing of services, functional and precise.

For the performance of inspection and maintenance of operating and testing means in regular intervals (including testing systems and software), written regulations have to be defined with description of tasks to be performed, intervals and necessary records to be complied with. For the definitions, the following aspects have to be considered among other aspects:

- Influence of the means on working safety during the order completion
- Required precision of operating means and gauging of the testing means
- Definition of test intervals on the basis of risk estimations.
- Unambiguous marking or operating and testing means
- Trackability of testing means to national/international standards and their records
- Possibly performance of monitoring of (critical) testing means through external registered bodies
- Measures against occurence of errors or damages of testing means, also with reference to already tested products/services

14 Customer services (After-sales service, product observance)

DIN EN ISO 9001 Sections 4.10, 5.14, 1.19
DIN ISO 9004-2 Sections 5.1, 5.5, 6.3, 6.4

This element summarises all quality-relevant activities which are required after a service has been provided or handed over, delivered, or a product has been repaired, in order to observe the results of the service as well as the product in its usage, and to increase customer satisfaction.

This means e.g.:

- Offer additional services (e.g. help to stay mobile, trouble-shooting service, substitute service)
- Handle and evaluate customer information, complaints and warranty cases
- active customer services.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
14.1	Have procedures, processes, responsibilities and competences been defined for customer services/after sales services?	4.19	5.5
14.2	Are there procedures for product observance during the stage of usage?	4.14.2	6.3
14.3	Are there procedures for observing the acceptance and the effects of the provided service?	-	6.3.3 6.3.5.2
14.4	Are customers involved in the service and product quality audit (customer satisfaction)?	4.1.4	5.4.2 6.3.3 6.4.1

14.1 Have procedures, processes, responsibilities and competences been defined for customer services/after sales services?

Term definition:

„Customer services/after sales services“ in the sense of this QM-element means the part of customer services dealing with the handling of material and immaterial products as well as service recipients after the service has been provided or after hand-over or delivery of a product.

Requirements/Explanations:

Customer services/after sales services encompass all methods for the promotion of customer contacts and become obvious for example in:

- Technical advice for assembly, usage and operation Disclosure of risks
- Proposal of problem solutions should problems occur
- Visits, correspondence
- Information material with service offers, also for upgrades/ modifications
- Invitations for events organised by the service provider Training and instruction for customers
- Continuous service communication (seasonal offers, birthday greetings etc.)
- Supplying substitute car/device.

External customer complaints have to be processed at once.

14.2 Are there procedures for product observance during the stage of usage?

Requirements/Explanations:

The internal proceeding has to be defined.

Not only the warranty period, but the whole duration of usage should considered (e.g. also long-term evaluations).

Each manufacturer should know how his products/services will behave and recommend themselves during the period of usage.

This can be recorded by activities performed by the service provider on behalf of the manufacturer in order to gather information on the quality of the products during the period of usage.

This covers e.g. the following:

- Regular market surveillance
- Registration and evaluation of customer complaints, field service reports, external customer complaints, warranty cases, touch-up orders, return shipments and lost customers
- early warning system.

These information have to be made available to the concerned organisational and functional units.

14.3 Are there procedures for observing the acceptance and the effects of the provided service?

Requirements/Explanations:

Rating by the customer is the final measure for the quality of a service. Immediate or delayed responses to occuring errors should not only be observed shortly after the service has been provided, but also during the warranty period and the whole life-time.

Each service provider has to define procedures for observing the acceptance and determining the proof of the results of his products/services starting from delivery to the customer.

Corresponding information can be gathered by means of own activities such as:

- Discussions with customers during resp. after hand-over
- Regular market surveillance
- Registration of complaints, customer claims touch-up orders and
- lost customers

and then be evaluated and made available to the concerned organisational units.

14.4 Are customers involved in the service and product quality audit (customer satisfaction)?

Requirements/Explanations:

The quality of a product or service must not only be audited by the producer or service provider alone.

Rather procedures have to be defined how the assessment of customers of used products and the provided services are systematically registered and evaluated. Comparison of internal and external ratings as well as a comparison of possible differing quality scales has to be performed.

The customers sensation/impression can not only be registered by the service provider during his communication with the user of the products and services in discussion notes or minutes of meeting, but also acquired by e.g.

- purposive questionnaire actions
- technical interviews and
- (by phone or personal) survey of the measure of customer satisfaction. (See also item Z1.4)

15 Analysis and improvement of services

DIN EN ISO 9001 Sections 4.14, 4.19, 4.20
DIN ISO 9004-2 Sections 6.3, 6.4

This QM-element concerns the analysis, evaluation and improvement of service quality, including necessary statistical methods.

Therefore, an information system for gathering and distributing data from all relevant sources, an analysis and assessment procedure for the service processes and weaknesses as well as procedures for permanent improvement of services themselves have to be installed.

This also comprises the analysis of product breakdowns and the introduction of corresponding measures.

The necessity of launching, executing and monitoring a measure for elimination of an error root cause or for error prevention purposes can be recognised e.g. from:

- Field service reports
- Customer claims/customer complaints
- Internal audits
- Internal and external assessment of the service quality.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
15.1	Have procedures and competences for gathering, distributing and analysing data and for the direction and monitoring of measures for improving service and product quality been defined ?	4.14.1 4.14.2 4.19	6.3.5 6.4.1 6.4.4
15.2	Are there procedures and processes for analysing error root causes of products and services?	4.14.2b	6.3.5 6.4.2
15.3	Are statistical methods used for planning, data collection and analysis?	4.20	6.4.3
15.4	Are error prevention procedures installed?	4.14.3	6.3.5 6.4.2
15.5	Is there a program for continuous improvement of service quality and customer satisfaction?	-	6.4.4

15.1 Have procedures and competences for gathering, distributing and analysing data and for the direction and monitoring of measures for improving service and product quality been defined?

Requirements/Explanations:

Collection, evaluation and distribution of all quality-relevant records as well as the implementation of corrective measures for internally and externally occured errors should be organised so that fast and complete problem elimination is warranted, e.g. by means of:

- Identification of systematic faults and relevant data
- Analysis of errors and data
- Definition of measures and responsibilities
- Notification of concerned and responsible bodies
- Determination of monitoring mechanisms.

The responsibilities for the information system and the authorisations for direction of improvement and monitoring have to be proven.

15.2 Are there procedures and processes for analysing error root causes of products and services?

Requirements/Explanations:

The analysis of data from internal and external audits (including customer responses and complaints) and quality audits has to be a purposive and planned process. It is the aim to identify non-fulfillment of defined quality requirements, in particular systematic errors and their root causes, and to derive and implement suitable error prevention measures.

In case problems occur concerning quality and customer satisfaction, the actual, deeper causes have to be determined. As far as applicant, the product suppliers, service providers and/or customers/service recipients have to be involved in the processes, documentation and records have to be considered.

Procedures for analysis of error causes could be e.g.:

- Cause-effect -diagram (Fishbone-/Ishikawa-diagram)
- Process flow analysis
- Stratification (separate data and classify by categories)
- other statistical methods.

15.3 Are there procedures and processes for analysing error root causes of products and services?

Requirements/Explanations:

The application of statistical methods during all stages of the quality circle is of particular importance. The method to be chosen further depends on the products, production processes, services, kind and quantities of data as well as the purpose of the statistical examination.

The most important methods are:

- Spot check testing
- Error collection index cards
- Pareto- and ABC-analysis
- Presentation of frequencies (bar and pie diagram)
- Ability examination.

15.4 Are there statistical methods used for planning, data collection and analysis?

Term definition:

„Error prevention“ means „get it right first time“. Therefore, all processes in the planning, implementation and usage stages have to be designed and controlled so that errors do not occur.

Requirement/Explanations:

Processes have to be defined with the aim of promoting customer-oriented thinking and acting, preventively assuring the processes and exclude error recurrence.

This also applies to product breakdowns and malfunctions claimed to be the error of the personnel of the service provider or customer, for which however the actual error cause are defectives in the service providing process, complex processes, products and processes which are difficult to maintain or operate or poor instruction manuals or lack of training and instructions.

Error prevention is only possible if the introduced management methods are consequently implemented and quality and auxiliary technologies are applied systematically.

Examples:

- working in regulated circles (Plan-do-check-act)
- working according to flow charts or checklists
- Risk-analyses (e.g. FMEA)

15.5 Is there a program for continuous improvement of service quality and customer satisfaction?

Requirements/Explanations:

The principle of continuous improvement is a central pillar of corporate quality (see item 01.3).

Implementation of this principle requires corresponding attitude of all employees as well as a program/system which starts and accompanies such improvement processes.

This particularly concerns measures for

- Improving the quality level of products and services,
- Optimation of processes,
- Increasing efficiency (cost-reduction for processes, increased
- customer benefit) and
- Improving customer services and customer relations.

Steps and activities in this program might be e.g.:

- Organisation of improvement management (with responsibilities and authorisations),
- Selection of projects to be improved, selection criteria for operational and customer data, priorities,
- Organisation of the different projects for improvement (targets, processes, methods),
- Systematic diagnosis and implementation of the gathered recognitions (involvement of concerned bodies, optimation),
- Result evaluation (customer benefit, cost-effectiveness, comparison with targets),
- Regular monitoring (feedback-system, benchmarks, audits customer reports).

Continuous improvement of the service and ability to deliver quality-hence customer satisfaction - is the aim of all measures and activities.

16 Control documents and data (definitions)

DIN EN ISO 9001 Sections 4.5, 4.16
DIN ISO 9004-2, Section 5.4

Quality management needs documents describing the structure and procedures of QM-elements. Therefore, their identification, collection, order, distribution, filing and maintenance has to be considered. Documents and data can be available on carrier media such as paper, magnetic data carriers or optical data carriers. Within the filing period, legibility has to be provided.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
16.1	Have responsibilities and procedures for identification, maintenance approval and release of quality-relevant documents and data been defined?	4.5.1 4.5.2	5.4.3.2
16.2	Is there a release and distribution system with revision service for quality-relevant documents and data?	4.5.2 4.5.3	5.4.3.2
16.3	Is it defined where, how, and for how long quality-relevant documents and data have to be filed?	4.16	5.4.3.1
16.4	Are purposive introduction and control of external documents and data warranted?	4.5.2	5.4.3.2

16.1 Have responsibilities and procedures for identification, maintenance, approval and release of quality-relevant documents and data been defined?

Term definition:

„Identification“ is the unambiguous assignment of own to customer-specific index data.

„Edition“ is preparing and compiling defaults in a document.

„Approval“ contains - among other things - the comparison and implementation between own and customer specification as well as formal and contentual approval of documents and records.

„Release“ is the approval/permission by the responsible bodies.

Requirements/Explanations:

The processes have to be overall concepts from the customer through to the supplier, involving all relevant internal bodies. For quality-relevant documents and data, procedures and responsibilities have to be defined.

Examples:

- Documents for contract review
- Specifications
- Drawings
- Workshop manuals
- Standards, laws
- Testing instructions
- Working instructions
- Procedures for providing the service
- QM-processing instructions
- QM-manual
- Procedure for QM-records
- Test procedures.

The above mentioned documents must be available in all involved organisational units in the latest revision status. Special marking instructions given by the customer have to be observed.

A survey of all kinds of quality-relevant documents is required.

16.2 Is there a release and distribution system with revision service for quality-relevant documents and data?

Term definition:

„Maintenance“ comprises revision services and filing while trackability has to be warranted.

Requirements/Explanations:

Processes and competences for the following matters have to be defined:

- Distribution, availability
- Release of revisions
- Provision of latest revision (valid revision status)
- Type of highlighting revisions in the documents
- Cancellation/invalidation.

Introduction and implementation of modifications have to be documented meaning they are provable and traceable.

For complete survey of all modifications, summarising overview sheets have to be edited. Responsibility for this edition has to be defined.

The system has to exclude abuse.

Definition of distribution and maintenance system has to specify the structure which warrants that the proper documents and data are available at the right time and place, mistakes are excluded, and invalid documents and data are no longer used.

16.3 Is it defined where, how, and for how long quality-relevant documents and data have to be filed?

Requirements/Explanations:

Definitions of e.g. the followings are mandatory:

- Filing period
- Filing order
- Filing place.

The following has to be considered for this purpose:

- Protection against fire, water, etc.
- Archive media (files, microfiches, EDP-memory)
- if necessary additional safekeeping archive (double archives, safety back-ups etc.)

Filing of quality-relevant documents and data - even of those which are no longer valid - has to be regulated to be able to prove at a later data that the QM-system and the products/services have fulfilled the quality requirements at a certain date.

The filing period (archiving) has to be adapted to legal regulations, general guidelines, customers and product liability aspects.

16.4 Are purposive introduction and control of external documents and data warranted?

Requirements/Explanations:

The service provider must have a working procedure assuring that all documents, standards, specifications, processing instructions and their revisions received from manufacturers, suppliers and customers are duly checked, distributed resp. introduced. This has to be recorded in a fashion similar to the recording of own documents.

17 Control quality records (proofs)

DIN EN ISO 9001 Section 4.16
DIN ISO 9004-2 Sections 5.4, 6.4

Quality management needs records of quality-relevant data in order to specify fulfillment of defined quality requirements. Therefore, identification, collection, order, distribution and filing have to be considered. Trackability of the records has to be warranted at all times.

Quality records have to be filed in order to document fulfillment of defined quality requirements by services, and the effective working of the QM-system. Pertinent quality records from suppliers must be a part of these data.

All quality record must be legible and kept in facilities under suitable archive conditions protected against damages or perishing or loss, and kept in order so that they are easily recovered. This also applies to records on electronic data carrier, for which also system upgrades/changes and overaging have to be considered.

		Reference DIN EN ISO 9001	**DIN ISO 9004-2**
17.1	Have responsibilities and procedures for collection and review of quality-relevant records been defined ?	4.16	5.4.3.2
17.2	Are there procedures and responsibilities for evaluation and distribution of quality-relevant records?	4.16	6.4.3
17.3	Is it defined how where, and for how long quality-relevant records will be filed?	4.16	5.4.3.1
17.4	Is it defined how quality-relevant documents are made available to the customer if agreed by contract?	4.16	(5.4.3.1)

17.1 Have responsibilities and procedures for collection and review of quality-relevant records been defined?

Term definition:

„Review“ comprises plausibility control as well as formal and contentual control of records.

Requirements/Explanations:

Processes have to be an overall concept from the customer through to the supplier involving all relevant internal bodies of the service provider. For quality-relevant records, procedures and responsibilities have to be defined.

Examples are e.g.:

- Records of contract review
- Acceptance reports
- Field service reports/Defective reports
- Quality audits (System, process, service)
- Function tests
- Calibrations
- Records of performed preventive and corrective measures
- Error elimination
- Quality-related costs
- -Management-Review
- Documentation for preventive maintenance
- Complaints/customer claims resp. pertinent evaluations.

A comprehensible survey of all regularly edited records is useful.

17.2 Are there procedures and responsibilities for evaluation and distribution of quality-relevant records?

Term definition:

„Procedure“ describes what is evaluated, when, and in which extent.

„Responsibilities“ are those functions within the corporation which evaluate and distribute quality-relevant records.

Requirements/Explanations:

For quality control in the different regulation circles, sensible evaluations of quality data have to be available to the concerned bodies. This applies to individual reports, periodic regular reports and status reports.

Quality records received from customers/subcontractors or customers have to be integrated into this procedure.

Procedures and responsibilities have to be regulated concerning evaluation and distribution.

17.3 Is it defined how, where, and for how long quality-relevant records will be filed?

Requirements/Explanations:

Defaults for the following are required e.g.:

- Filing period
- Filing order
- Filing place.

For this purpose, following has to be considered:

- Protection against fire, water, etc.
- Archive means (files, microfiches, EDP-memory)
- If necessary additional safety archives (double archive, safety back-ups etc.)

Filing of quality-relevant records is necessary to be able to prove at a later data that the QM-system and the products/services have fulfilled quality requirements at a certain date.

The filing period (archiving) and data backups have to be adapted to legal regulations, general guidelines, customers and product liability aspects.

Determinations could be e.g.:

Two years: Records of performance results (certificates, test results, etc.)

Three years: Management reports, internal quality audit reports, QM-audits.

17.4 Is it defined how quality-relevant documents are made available to the customer if agreed by contract?

Requirements/Explanations:

As far as agreed by contract, quality-relevant documents have to be made available to the customer. The pertinent procedure has to be defined.

Direct assignment and labelling of the corresponding records to the defined products/services and the related processes have to be described a process.

In many cases, certain features are no longer provable at the result of the service. So it is necessary to be able to rely on the service providers' quality records.

8 Form sheets for the QM-system audit

For orderly execution of QM-system audits it is helpful to use form sheets for fast and rational collection of results comprehensible for all involved bodies. The form sheets following hereafter show exemplary models.

Form sheets available from:

Druckerei Henrich
D-60528 Frankfurt am Main, Schwanheimer Str. 110
(0 69) 9 67 77 - 0
(0 69) 9 67 77 - 111

VDA	QM-Systemaudit	Auftrag: Datum:

VDA Qualitätsmanagement in der Automobilindustrie

6

QM-Systemaudit

Teil 2

Dienstleistung

Grundlagen DIN EN ISO 9001, 9002, 9004-1 und DIN ISO 9004-2

Systemaudit-bericht

VDA	QM-Systemaudit **Gesamteinstufung**	Auftrag: Seite: 2

Lief.-Nr.:	Zeitraum des Audits:
Firma:	Auftragsgrund:
	Auftraggeber: 0

Letzte Auditergebnisse / Zertifikate

Zertifikat-/Auditbasis-Nr.	Datum	durchgeführt von	Ergebnis/Stand Maßnahmen

Einstufungsergebnis:

Erfüllungsgrad (%) EU ☐ EP ☐ EGES ☐

Einstufung Auditor ☐ (bei Abstufung gem. Abs. 3.4.3 Anmerkung 1 u. 2

Bemerkungen zur Einstufung (Auditor):

Systemfreigabe / Datum:	Termin Verbesserungsprogramm:

Systemeinstufung:

Gesamterfüllungsgrad in Prozent	Beurteilung des QM-Systems	Bezeichnung der Beurteilung
90 bis 100	erfüllt	A*)
80 bis unter 90	überwiegend erfüllt	AB*)
60 bis unter 80	bedingt erfüllt	B
unter 60	nicht erfüllt	C

*) siehe Anmerkung unter Abschnitt 3.4.3

Unterschriften: Auditor/in: _____

Firma: _____ _____

Leitung Qualitätsaudit Lieferanten

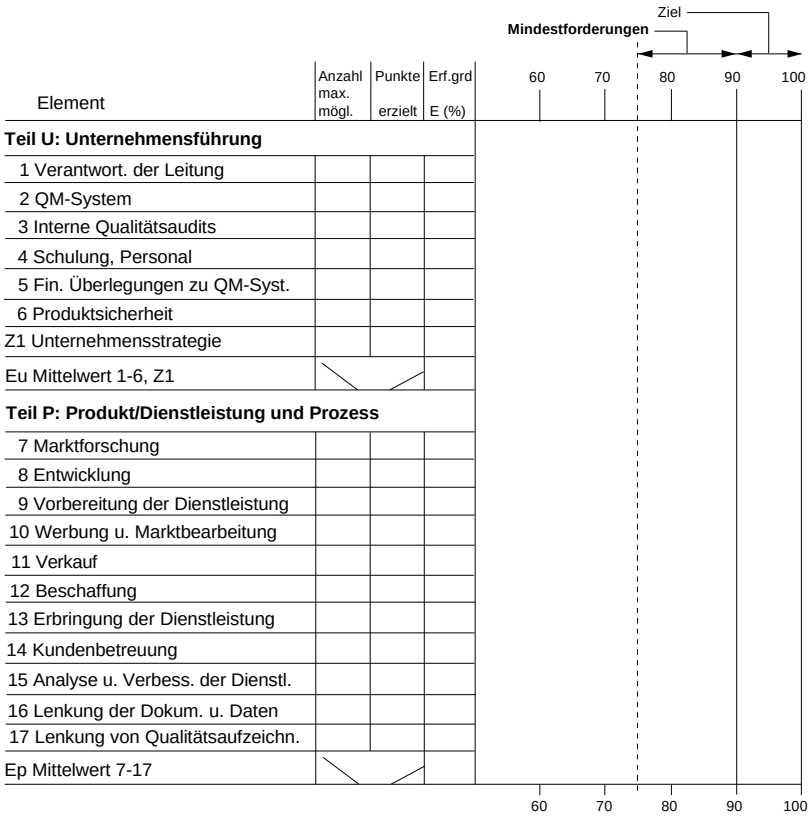
Firma:						

VDA

QM-Systemaudit
Ergebnisübersicht

Auftrag: 0

Seite: 3



Element	Anzahl max. mögl.	Punkte erzielt	Erf.grd E (%)
Teil U: Unternehmensführung			
1 Verantwort. der Leitung			
2 QM-System			
3 Interne Qualitätsaudits			
4 Schulung, Personal			
5 Fin. Überlegungen zu QM-Syst.			
6 Produktsicherheit			
Z1 Unternehmensstrategie			
Eu Mittelwert 1-6, Z1			
Teil P: Produkt/Dienstleistung und Prozess			
7 Marktforschung			
8 Entwicklung			
9 Vorbereitung der Dienstleistung			
10 Werbung u. Marktbearbeitung			
11 Verkauf			
12 Beschaffung			
13 Erbringung der Dienstleistung			
14 Kundenbetreuung			
15 Analyse u. Verbess. der Dienstl.			
16 Lenkung der Dokum. u. Daten			
17 Lenkung von Qualitätsaufzeichn.			
Ep Mittelwert 7-17			

Erfüllungsgrad Eges = 1/2 Eu + 1/2 Ep

VDA	**QM-Systemaudit** **Übersicht der bewerteten Fragen**	Auftrag: 0 Seite: 4
Firma:		Lief.-Nr.:

Auditfrage

	.01	.02	.03	.04	.05	.06	.07
01							
02							
03							
04							
05							
06							
Z1							
07							
08							
09							
10							
11							
12							
13							
14							
15							
16							
17							

Anmerkung: nb = Frage ist nicht bewertet

* = übernommene Ergebnisse von: _____
Firma / Auditor / Datum

Begründung für nicht bewertete Fragen:

VDA	**QM-Systemaudit** Übersicht der bewerteten Fragen	Auftrag: 0 Seite: 5
Firma:		Lief.-Nr.:

☐ QM-Systemaudit

☐ Prozessaudit

☐ Qualitätsaudit Nachweisführung

☐ Beanstandung

Frage	**Feststellungen**	**Maßnahmen des Lieferanten**	**Termin**	**Verantwortl.**

9 Literature

9.1 Series of VDA-papers

Volume 1 Parts from automobile manufacturers and their suppliers which require mandatory documentation
- How to issue documentation -, 1973

Volume 2 Quality assurance for deliveries in the automotive industry
- Selection of suppliers/Sampling - Quality serial production, 2. Edition 1995

Volume 3 Reliability assurance for vehicle manufacturers and suppliers
- Procedures and examples -, 2. edition 1994

Volume 4 Quality assurance prior to serial usage
- new edition in two parts

Volume 5 Product audits for vehicle manufacturers and suppliers
- Introduction/execution/audits -, 1983

Volume 6 Part 1: Quality management system audit
- Material products -, 3. edition completely revised 1996

Volume 7 Principles for the exchange of quality data
- Handling of quality data messages- ,1994

Volume 8 Guideline for quality assurance for manufacturers of trailers, trucks and containers, 1994

Volume 9 Quality assurance
- Emission and consumption -,1995

9.2 Masing, Walter (Ed.)

Handbuch des Qualitätsmanagements (Quality management manual) 3. edition, 1994

9.3 Manfred Bruhn

Qualitätsmanagement für Dienstleistungen (Ouality management for services), 1996

9.4 DGO-Paper 11 - 04 (Revision 1995)

Begriffe zum Qualitätsmanagement (Quality management terms)

9.5 DGQ-Paper 12 - 62 (Revision 1991)

Qualitätssicherungshandbuch (Quality assurance manual)

9.6 DGO-paper 12 - 63 (Revision 1993)

Systemaudit (System audit)

9.7 DGO-Paper 14 - 18 (Revision 95)

Wirtschaftlichkeit durch Qualitätsmanagement (Cost-effectiveness through quality management)

9.8 DGQ-Paper 30 - 01 (Revision 95)

Qualitätsmanagement bei Dienstleistungen (Quality management for services)

9.9 DGO-Paper 30 - 11 (W. Junghans)

Qualitätsmanagementsystem in Vertriebsorganisationen für technische Serienprodukte (Quality management system for distributors of technical serial products)

9.10 DIN EN ISO 8402 (1995)

Qualitätsmanagement und Qualitätssicherung - Begriffe
(Quality management and quality assurance - terms)

9.11 DIN EN ISO 9000, Part 1 (08/94)

Qualitätsmanagement und Qualitätssicherungsnormen, Leitfaden zur Auswahl und Anwendung
(Quality management and quality assurance standards; guideline for selection and application)

9.12 DIN EN ISO 9000, Part 2 (03/92)

Qualitätsmanagement und Qualitätssicherungsnormen;
Allgemeiner Leitfaden zur Auswahl und Anwendung von ISO 9001, ISO 9002 und ISO 9003
(Quality management and quality assurance standards; general guideline for selection and application of ISO 9001, ISO 9002 and ISO 9003)

9.13 DIN EN ISO 9001 (08/94)

Qualitätsmanagementsysteme, Modell zur Qualitätssicherung/QM-Darlegung in Design/Entwicklung, Produktion, Montage und Wartung
(Quality management systems; Model for quality assurance/QM-specification in design/development, production, assembly and maintenance)

9.14 DIN EN ISO 9002 (08/94)

Qualitätsmanagementsysteme, Modell zur Qualitätssicherung/QM-Darlegung in Produktion, Montage und Wartung
(Quality management systems, model for quality assurance/QM-specification in production, assembly and maintenance)

9.15 DIN EN ISO 9004, Part 1(08/94)

Qualitätsmanagement- und Elemente eines Qualitätssicherungssystems-Leitfaden
Quality management guideline and elements of a quality assurance system guideline

9.16 DIN EN ISO 9004, Part 2 (08/94)

Qualitätsmanagement- und Elemente eines Qualitätssicherungssystems-
Leitfaden für Dienstleistungen
Quality management guideline and elements of a quality assurance system
- Guideline for services

9.17 DIN ISO 10011 Part 1 (06/92)

Leitfaden für das Audit von Qualitätssicherungssystemen, Auditdurchführung
(Guideline for the audit of quality assurance systems, audit performance)

9.18 DIN ISO 10011 Part 2 (06/92)

Qualifikationskriterien für Qualitätsauditoren
(Qualification criteria for quality auditors)

9.19 DIN ISO10011 Part 3 (06/92)

Management von Auditprogrammen
(Audit program management)

Reference sources

9.1 Verband der Automobilindustrie e. V (VDA)
Lindenstraße 5, 60325 Frankfurt

9.2 Carl Hansen Verlag, München

9.3 Springer-Verlag, Berlin, Heidelberg, New York

9.4 Beuth-Verlag GmbH, Berlin

Literature - company specific

(served only as reference for this paper, not available)

- FORD Motor Comp. USA
  QSA - W
  Ouality System Assessment
  for Warehouses and Distribution Facilities
  Edition 1995

- Volkswagen AG, Wolfsburg
  Volkswagen AUDI Vertriebszentrum
  Systemaudit und die Prüfkriterien nach DIN EN ISO 9002
  Edition 1996

- BMW AG, München
  Qualitätsaudit für den Händlerbetrieb
  Edition 1994

- Mercedes-Benz Vertriebsorganisation Deutschland
  Auditfragenkatalog der MBVD nach DIN EN ISO 9001
  Edition 1995

- MAN AG, München
  Servicesaudit für MAN-Serviceniederlassungen
  Edition 1994

- DQS / ÖQS / SQS
  Interpretation ISO 9000ff
  Speditionsdienstleistungen/Dienstleistungen
  Edition 1993

10 Agreements with associations

(not proven at the time being)

11 Hints for awarding the VDA 6.2-certificate

11.1 VDA 6.2-certificate

The VDA 6.2-certificate serves as proof for a performed audit.

The criteria defined in the EN 45012 concerning independence and impartiality have to be complied with.

It is the aim of this certificate to document higher qualification of the quality management system and to create reciprocal trust in the service area.

11.2 Auditing according to VDA 6.2 with award of a certificate

The certificate can be awarded if:

1. A lead auditor, approved by the VDA, has carried out a complete audit according to VDA 6.2 (answering all applicant questions) and a fulfillment degree of at least 90 % has been reached.

2. A certificate according to DIN EN ISO 9001/2 had been awarded and at least 10 spot checks of different QM-elements have been taken by the lead auditor.

In general, following elements have to be tested additionally

05 Financial considerations concerning the quality management system
06 Product safety
Z1 Corporate strategy
09 Preparation of the service
10 Promotion and marketing
14 Customer services
15 Analysis and improvement of the service.

11.3 Procedure for applying for VDA-certificate

The certificate can be applied for at the VDA by a representative of corporation that contracted the VDA lead auditor. A prerequisite of registration of the audit at the VDA is registration of the lead auditor in VDA auditor register.

The complete audit report has to be attached to the application for award the certificate.

The certificate has to be signed by the lead auditor.

After review at the VDA, the certificate is stamped with a registration number and signed by a Managing Director or legal representative of VDA.

To the
Verband der Automobilindustrie e. V. (VDA)
Lindenstraße 5

D-60325 Frankfurt am Main

Application for award of a VDA-6.2 certificate

Company:

Location:

Fulfillment degree:

The completed form sheets VDA 6.2, Main selection 8, have to be attached in copy.

Lead auditor:

Company:

Co-auditor:

Company:

Audit date: from to

ð Complete audit
ð Supplement for already awarded certificate

Place/date	Signature Lead-Auditor	Place/date	Signature Audited corporation

12 Appendix

12.1 Modifications

(not applicant at the time being)

12.2 Comparison table sheets

Comparison table sheets for comparison with DIN EN ISO 9001 are illustrated below.

12.2.1 Comparison matrix VDA 6.2/DIN EN ISO 9001_{94}

VDA 6.2	Subject of the item	DIN EN ISO 9001
Part U:	**Board of directors/Management**	
01.	Management Responsibility	4.1
01.1	Quality policy	4.1.1
01.2	Quality targets	4.1.1
01.3	Continual improvement	--
01.4	Required means	4.1.2.2
01.5	Representative of the board of directors	4.1.2.1, 4.1.2.3
01.6	Quality management audit	4.1.3
02.	Quality management system	4.1, 4.2
02.1	QM-manual	4.2.1, 4.2.2
02.2	Application range for the QM-system	4.1.2
02.3	Tasks, responsibility, authorisation	4.1.2.1
02.5	Project management	(4.4.3)
02.4	Quality planning	4.2.3, 4.3.2a
03.	Internal quality audits	4.17
03.1	Qualification and independence of the auditors	4.17
03.2	Audit-planning	4.17
03.3	Service and process audits	--
03.4	Corrective measures and their documentation	--

VDA 6.2	Subject of the item	DIN EN ISO 9001
04.	Training, personnel	4.18
04.1	Employee supervision	--
04.2	Qualification of employees	4.18
04.3	Further development of employees	4.18
04.4	Target agreements and target achievement	--
04.5	Employee motivation	--
04.6	Survey on employee satisfaction	--
05.	Financial considerations on QM-systems	
05.1	Procedures for reporting	--
05.2	Regular intervals of reporting	(4.1.3)
05.3	Error costs internal	--
05.4	Error costs external	--
06.	Product safety	
06.1	Product liability principles	--
06.2	Procedures for risk determination	(4.8)
06.3	Definition and implementation of safety regulations	--
06.4	Completeness of operation instructions/manuals	--
06.5	Recognition of dangers of putting into operation and usage	--
Z1.	Corporate strategy	
Z1.1	Business plan for costs, distribution, quality etc.	--
Z1.2	Measuring methods for business results and KVP-usage	--
Z1.3	Performance data, corporate/comparison	--
Z1.4	Customer satisfaction, measuring and modification	--
Z1.5	Promotion of employee satisfaction	--

VDA 6.2	Subject of the item	DIN EN ISO 9001
Part P:	**Product and Process**	
07.	Market research	4.4
07.1	Responsibilities and competences	--
07.2	Evaluation of demands for new products/services	4.4.4
07.3	Customer requirements to products/services	--
07.4	Benchmarks and competition analyses	--
07.5	Expansion of offer range due to market analyses	--
08.	Development	4.4
08.1	Responsibilities and competences	4.4.1, 4.4.2, 4.4.3
08.2	Preparation of specification and delineation	4.4.4
08.3	Development resultsProduct/process trial	4.4.5
08.4	Review of fulfillment of requirements/expectations	4.4.6, 4.4.7
08.5	Handling of development modifications	4.4.9
09	Service preparation	4.3, 4.4, 4.10
09.1	Implementation of specification and delineation	4.3.2c
09.2	Procedure for launching of new products/services	4.4.5
09.3	Procedure for monitoring/auditing	4.10.1
09.4	Review and release of new products/services	4.4.8
10.	Promotion and marketing	--
10.1	Responsibilities for planning and performance	--
10.2	Consideration of survey and market analyses	--
10.3	Requirement to the appearance of the service provider	--
10.4	Does the promotion comply with laws and customer expectations	--
10.5	Evaluation of promotion success	--
10.6	Competence of the service provider as a advertiser	--

VDA 6.2	Subject of the item	DIN EN ISO 9001
11.	Sales	4.3
11.1	Procedures and competences for contract reviews	4.3.1
11.2	Determination of customer demands and expectations	--
11.3	Review of feasibility	4.3.2b, 4.3.2c
11.4	Order acknowledgements	4.3.4
11.5	Procedures for contract amendments	4.3.4
12.	Purchasing	4.6, 13
12.1	Procedures and competences for supplier audits	4.6.2
12.2	Survey of approved suppliers	4.6.2a
12.3	Purchasing process and responsibilities	4.6.1, 4.6.3
12.4	Purchasing documents/quality requirements	4.6.3
12.5	Inspection of purchased products/services	4.6.4, 4.10.2
12.6	Handling of delivery complaints	4.13
12.7	Current supplier audits and records	4.6.2b, 4.6.2c
13.	Service providing	4.7,4.8,4.10,4.11, 4.12, 4.13, 4.15
13.1	Customer supplied products/services	4.7
13.2	Procedures and competences for order completion	4.9, 4.10, 4.12
13.3	Marketing and trackability	4.8
13.4	Final inspection and hand-over to customer	4.10.4
13.5	Handling of faulty products/services	4.13
13.6	Handling, storage, packaging/protection, shipment etc.	4.15
13.7	Functionality/precision of operating and testing means	4.9, 4.11

VDA 6.2	Subject of the item	DIN EN ISO 9001
14.	Customer services	4.10, 4.14, 4.19
14.1	Procedures and competences for customer services	4.19
14.2	Production observance during stage of usage	4.14.2
14.3	Acceptance and effects of provided services	--
14.4	Customer involvement for service audit	4.10.4
15.	Analysis and improvement of service	4.14, 4.19, 4.20
15.1	Procedures and competences for determination and execution	4.14.1, 4.14.2, 4.19
15.2	Error causes, analyses	4.14.2b
15.3	Application of statistical methods	4.20
15.4	Procedure for error prevention	4.14.3
15.5	Improvement programs	--
16.	Control of documents and data (defaults)	4.5, 4.16
16.1	Procedures and competences	4.5.1, 4.5.2
16.2	Releases, distribution and revision	4.5.2, 4.5.3
16.3	Filing of default documents	4.16
16.4	Integration of external documents	4.5.2
17.	Control of quality records (proofs)	4.16
17.1	Procedures and competences	4.16
17.2	Evaluation and distribution of records	4.16
17.3	Filing of record documents	4.16
17.4	Responsibility for customers	4.16

12.2.2 Comparison matrix DIN EN ISO 9001_{94} /VDA 6.2

DIN EN ISO 9001	Element according to DIN EN ISO 9001	VDA 6.2
4.1	Management responsibility	01, 02, (05)
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