VDA

6

Quality Management in the Automotive Industry

Process Audit

Part 3

Product Development Process / Serial Production
Service Development Process /
Providing the Service

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1st Edition 1998

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Preface

Increasing demands of the customer market present the quality management of companies with constantly new and complex tasks.

In many industry sectors a „comprehensive„ quality system is part of the company strategy and provides the organizational preconditions to comply with high quality requirements for products and processes. System audits are used to review the effectiveness of quality systems at regular scheduled intervals.

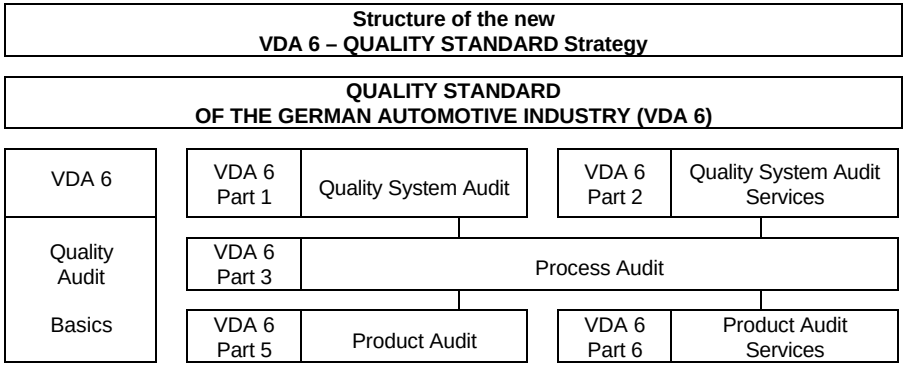
The constantly decreasing time span between the concept of a product/service to it‘s production/provision requires an ever increasing parallelism of the operations of varying company areas. This results in continuously increasing requirements on the process.

With increasing quality requirements, self assessment and reduction of inspection and testing expenditure can also only be realized through capable and controlled processes.

Naturally, this applies to the product development process/serial production, as well as the service development process/provision of the service.

Company processes have to be constantly monitored to ensure their reliability, and be able to implement timely, appropriate corrective actions in case of nonconformities.

An important instrument for process monitoring is the process audit. It is an integral part of the VDA strategy „Quality standard of the German Automotive Industry (VDA 6) as shown in the following diagram.



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1 Aim and Purpose of the Publication

This publication provides information on the significance and application scope of a process audit and clarifies the relationships between system, process and product audit. Thereby, mutual understanding and coordinated procedures for the use of this management tool within the automotive industry and it‘s suppliers are to be achieved.

Within the framework of this process audit, aspects of environmental protection are taken into appropriate account, which are mainly orientated to customer requirements. Hereby, it is not claimed that the compliance with the state specific legislative requirements is audited, the supplier often has to provide a separate evidence for this.

This publication is a guideline for performing internal and external process audits. Special process specifications and details are included only as examples, as these have to be established on a case to case basis by the auditor with the help of process experts.

The aim of this publication is to enable a widespread comparability of the process audit procedure of differing companies based on the present questionnaires targeted to reduce audit time.

The recognition of an audit result by a third party depends, however, on the result of a detailed analysis of the audit report and, if applicable, further documents, and lies at the discretion of the third party.

Lastly, this publication shall serve as a training document as well as a work instruction for process auditors and companies (who have no previous experience with process audits).

2 Relationship between System, Process and Product Audit

System, process and product audits represent a selection of the audit types available, however, this listing does not claim to be exhaustive.

Comparison of the audit types :

Audit Type	Audit Subject	Purpose
System Audit	Quality System	Assessment of the completeness and effectiveness of the basic requirements
Process Audit	Product development process/ Serial production Service development process/ Providing the service	Assessment of the quality capability for specific products/ product groups and their processes
Product Audit	Products or services	Assessment of quality characteristics

The otherwise independent and separate audit types show similarities, to some extent.

A comparison matrix of process and system questions is shown in chapter 13.

Further information on the types of audit and related comments, explanations, definitions and principles for the auditor qualifications, literature etc. are presented in the VDA Volume 6, Part A.

Company processes can also be audited, using this publication.

3 Definitions for a Process Audit

3.1 Task

Process audits serve the assessment of quality capability. They are intended to lead to capable and controlled processes which are robust against disturbing factors.

This is achieved through:

3.1.1 Prevention

Prevention refers to the realization, identification and implementation of actions to prevent the initial occurrence of a nonconformity.

3.1.2 Correction

Correction includes the analysis of known nonconformities and the implementation of corrective actions to eliminate and prevent their reoccurrence.

3.1.3 Continual Improvement Process (CIP)

According to CIP, detail improvements serve the optimization of the entire system. Implemented actions derived from the process audit improve the process and make it more capable and robust.

3.1.4 Management Review

Process audits enable the company management to draw conclusions on the effectiveness of sections of the quality system.

3.2 Reason for the Audit

Process audits can be scheduled (system- or project-orientated) or unscheduled (event-orientated).

3.2.1 Scheduled Process Audits

System-orientated

Process audits are carried out to an audit plan as part of a company‘s quality system.

Established series and potential suppliers that have certified quality systems, are audited according to specified requirements, i.e. only those processes directly relevant or designated to the delivery scope (expenditure minimization), or designated therefore.

Project-orientated

Process audits are carried out early on at set project milestones during development and planning processes, in order to identify nonconformities and introduce appropriate measures.

3.2.2 Unscheduled Process Audits

Event/Problem Orientation

For processes showing problems, process audits are performed at every project phase to eliminate nonconformities or to review whether sufficient consideration is given to critical process characteristics.

They are also useful to define causes of nonconformities and to introduce corrective actions.

Process audits may be initiated, e.g., for the following reasons:

- decreasing process quality
- customer complaints
- changes in the production sequence
- process insecurities
- cost reductions
- internal request.

3.3 Application

Process audits can be applied internally and externally across the full quality cycle in the following areas

Marketing
Development
Purchasing (Product/Service)
Production/Service Provision
Sales/Commissioning
Customer Service/Services
Recycling

This is illustrated, with examples, in the following table:

Type	**Organizational or Functional Unit**	**Actual process**
Product-related:	Mechanical production Paint shop Assembly	Turning Drying Pane gluing
Service-related:	Planning of inspections, measurement and tests Personnel Logistics Plant safety	First sampling Personnel recruitment Provision of parts Company safety

3.4 Conditions for Performance

3.4.1 Basic Conditions in the Company

The performance of a process audit requires a precise preparation to the company and process conditions.

This requires targeted planning and realization of primary conditions, as well as their continual optimization.

Such primary conditions are e.g.:

- DIN EN ISO 9000ff requirements
- Organizational/Company structure
- Company/Department details
  (Product and service range, references, etc.)
- Questionnaire
- Audit plan
- Quality manual, procedures, work and inspection instructions
  (depending on internal/external)
- VDA regulation requirements (e.g. VDA 6.1/VDA 6.2)
- Legal and contractual requirements
- Customer requirements
- Important product characteristics
- Important process parameters
- Quality history.

3.4.2 Auditor's Work Experience (Process Experience)

An essential prerequisite for a process auditor is at least two years practical experience in process management in the automotive industry (manufacturer and supplier).

In addition, the process auditor must have performed at least three process audits, if necessary, with the support of a technical expert (process technician, specialist) from the typical process area.

3.4.3 Responsibility

3.4.3.1 Auditing Body/Organizational/Functional Unit

- Selection of suitable auditors according to their work experience and qualification
- Audit initiation

3.4.3.2 Auditor

- Performance of a process audit according to audit plan or event-orientated:
  - Coordination with the organizational/functional area (definition of the process, interfaces etc.)
  - Audit preparation (Document review, questionnaire preparation, inclusion of specialists or know how)
  - Audit performance
  - Evaluation
  - Closing Meeting and Report
  - Initiation of corrective actions
  - Verification of the effectiveness of corrective actions
  - Confidentiality agreement.

- Maintaining his qualification
  - Knowledge of current standards and regulations
  - Auditor expertise
  - Process knowledge.

3.4.3.3 Audited Company/Organizational/Functional Unit

- Provision of all necessary information
- Inclusion of the personnel responsible for the process
- Provision of expert employees
- Determination of corrective actions
- Implementation of corrective actions
- Verification of the effectiveness of corrective actions.

4 Audit Process

The audit process is always based on the same systematic.

- Preparation
- Performance
- Finalization with a report
- Corrective actions and their follow up until effectiveness is verified.

The following flow chart (Fig. 1) illustrates this procedure.

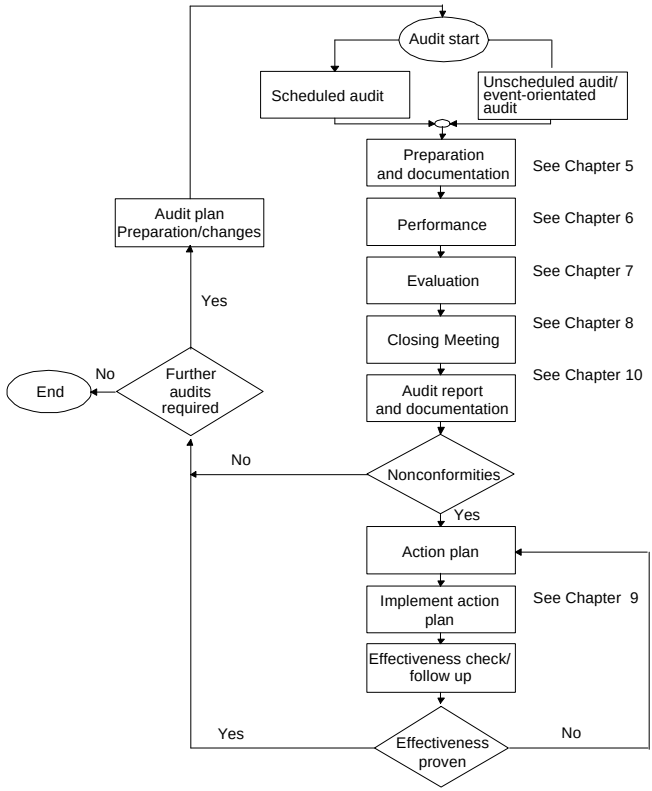


Fig. 1: Flow Chart Audit Process

5 Audit Preparation

5.1 General

Thorough preparation is especially important, as it is the basis for a successful audit, at the same time, the department to be audited must be notified of the reason and audit date.

Irrespective of the type of process audit, whether

- scheduled or unscheduled,
- internal order external,
- product or service,

the preparation procedure is the same as illustrated in Fig. 2.

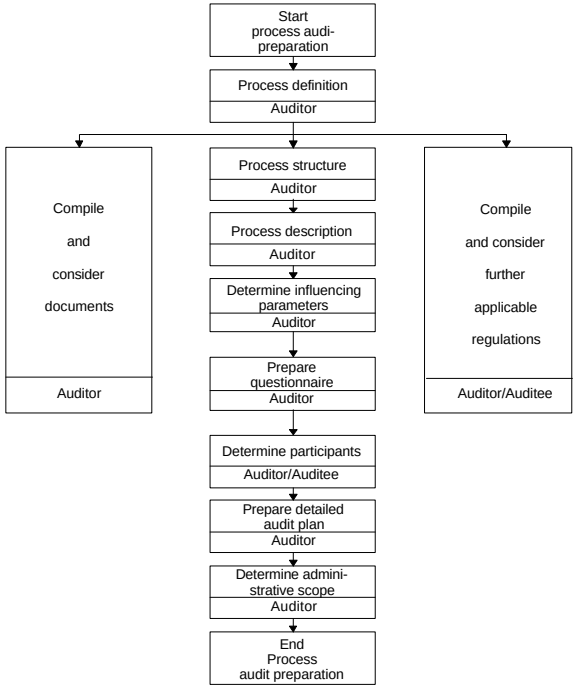


Fig. 2: Flow Chart for the Audit Preparation

5.2 Process Definition, Structure and Documents

The first audit preparation step is the **process definition**.

The auditor or audit team must define, which process is to be examined. Thereby, the external interfaces are to be determined (Fig. 3 and 4).

The auditor has the competence to define the process to be audited, however, he should coordinate with the relevant organizational units and the process responsible and, if necessary carry out pre-audit.

The next step is the **process structure** (determining the individual process steps) and considering interfaces (Fig. 3 and 4).

At this point, at the latest, the auditor or audit team have to target the **process documents**.

A sensible **process structure**, a comprehensive **process description** as well as **determining the influencing parameters,** can only be established with the appropriate documents, i.e. the auditor describes the process to be audited from his point of view and determines the influencing parameters. The influencing parameters result, initially, from the „6M's„ (Man, Method, Means/Environment, Material, Machine, Management), as well as from planning scopes.

With the help of a systematic, methodical procedure (e.g. cause-effect-diagram) the main influences, as far as possible and sensible, are further detailed. Thereby, the auditor can investigate the process during the audit at site with the help of a questionnaire.

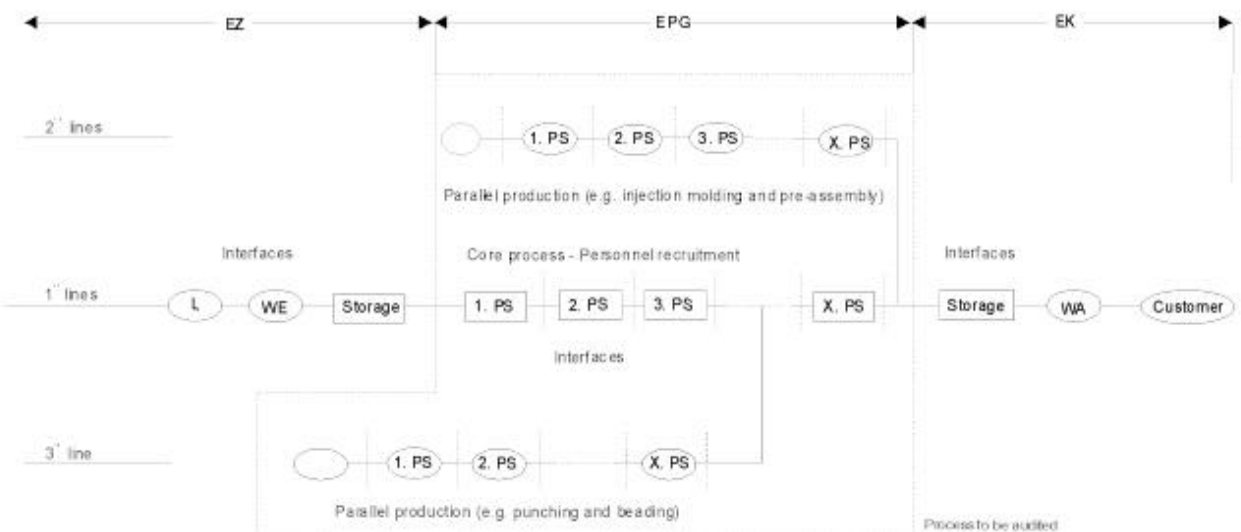
When external process audits are concerned, the documents required for preparation are often not available to the necessary extent, for competitive reasons. Thus, audit preparation has to be carried out with the documents provided.

The auditor/audit team has to consider the review of further documents during the audit process.

The process description results from the available process documents such as:

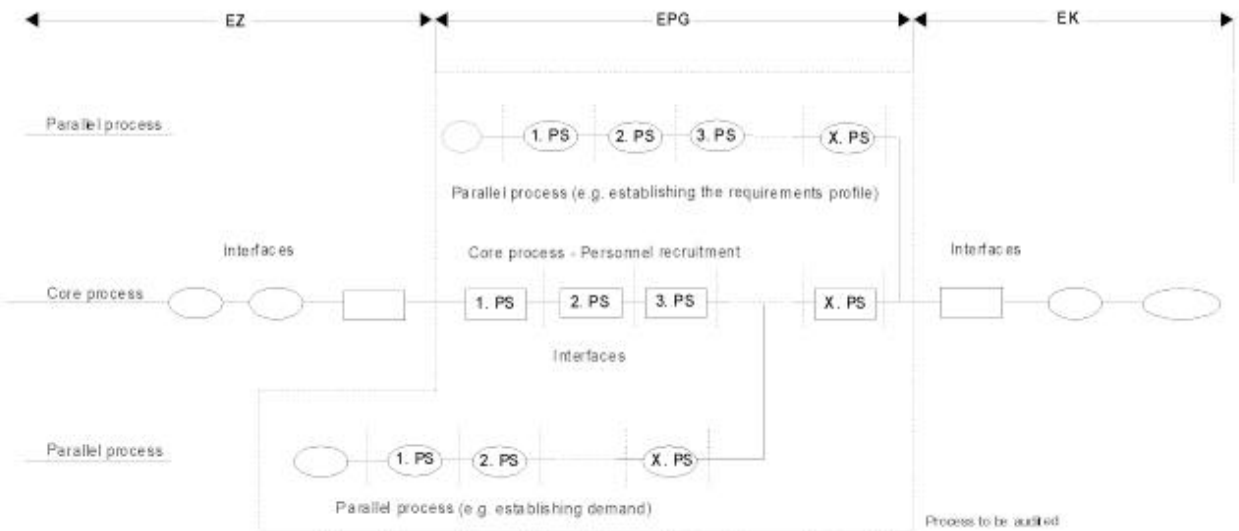
- work and inspection procedures
- process instructions
- work and inspection and testing plans.

Fig. 3:: Process Definition, Structure and Interfaces



E_e = Input material/purchased parts
E_v = Mean process steps
E_k = Customer service/satisfaction
PS = Process step
L = Supplier
WE = Material receiving
WA = Outgoing Material

Fig. 4: Process Definition, Structure, and Interfaces



E = Input material
E = Mean process steps
E = Customer service/satisfaction
PS = Process step

Further sources of information can be:

Standards, specifications, objectives (e.g. PPM), procedures, FMEA, non-conformity catalog, repair book, quality control charts, audit results, action plan from last audit, external: results of the receiving inspection and supplier conduct, layouts, VDA performance date comparison (internal/ external), employee surveys, project plans, customer surveys, statements about the quality of the service, service quality.

This preparation work is an essential basis for setting up a questionnaire.

Furthermore, the auditors and the company to be audited have to obtain information on other applicable documents which determine the framework of a process audit, e.g.:

- organizational regulations
- responsibilities.

Such framework conditions are, for example, established in:

- quality manuals
- procedures
- VDA publications
- standards
- customer requirements.

5.3 Process Specific Audit Questionnaire/Detailed Audit Plan

Based on the results of this preparation, the auditor (audit team) compiles the process specific questionnaire.

This has to be handed to the company to be audited prior to the audit and, if necessary, explanations have to be provided.

When drawing up the detailed audit plan by the auditor or audit team, the participants (auditors and auditees) are determined in agreement:

- Number and names of the auditors (if more than one auditor present, a Lead Auditor has to be determined; normally: external 2/internal 1 auditor)

- Representative of the audited organizational/functional unit e.g.:

  - personnel responsible for the process
  - specialists
  - interface representatives

- If necessary, involve specialists (for external audits in coordination with the company to be audited).

- Participants of the closing meeting.

The auditors and company to be audited agree the final detailed audit plan. It is recommended, to establish an outline showing the organizational/functional units, time/location, participants and reference to the questionnaire.

The following points amongst others are to be considered:

- Production standstills (Lunch breaks etc.)
- Shift changes.

Changes at site can be made.

The process audit preparation is completed with agreement about administrative details, such as:

- Conference rooms
- Overhead projector or other devices
- Availability of documents at site etc.

Sometimes, for this a separate checklist can be helpful.

6 Auditing

6.1 Opening Meeting

Prior to audit start, an opening meeting is to be carried out. Duration and content of the opening meeting are determined as deemed necessary for the requirements.

Criteria for this are, amongst others:
- External Audit
- Internal Audit
- Event-orientated audit
- Scheduled audit.

During the opening meeting the audit participants should firstly be introduced. For external audits company/organizational units also, if applicable, should be introduced.

The purpose and reason for the audit are again to be explained, so that all participants are equally well informed and can better identify themselves with the audit.

To ensure smooth running of the audit, the audit process (process definition, questionnaire, evaluation scheme, etc.) and the boundary conditions (responsibilities, performance at site, release of employees during questioning, etc.) are to be clarified.

Finally, every participant should have the opportunity to clarify any open questions.

6.2 Audit Process

The audit is carried out using the previously raised questionnaire. Thereby, the questions can be asked following the numbering or at random.

The type of questioning, e.g. open questions (why, when, who, how etc.) and other interview techniques are basics of the auditor training and are not included here.

The repeated application of „Why…„ questions has proven to be advantageous for the intense analysis of procedures.

During the audit, further questions may arise which should then be included in the questionnaire.

The employees at site are to be involved in the audit by questioning. It is recommended, that both positive and negative findings be recorded during the audit.

To avoid conflicts during the closing meeting, target has to be, to clear all uncertainties at site and to find a consensus.

When major nonconformities are identified, immediate actions are to be initiated together with the personnel responsible for the process.

7 Evaluation

The quantitative evaluation of scheduled process audits makes it possible for audit results in connection with the analysis of the audit report to be comparable, thus changes to previous audits in the sense of CIP can be established.

Due to differing evaluation limits and targets of individual companies, it may become necessary to adjust the percentage classification of the overall degree of conformity and the evaluation terms used. A qualitative evaluation may also be applied. Individual process elements may also be weighted. A different evaluation method (such as qualitative evaluation) must be agreed between supplier and customer and has to be stated in the audit report.

7.1 Individual Evaluation of the Questions and Process Elements

Each question is evaluated with regard to the respective requirements and their consistent achievement in the product development process (service process) and the serial production (service). The evaluation can result in 0, 4, 8, 10 points for each question, whereby the proven compliance with the requirements is the measure for awarding points. For a grading under 10 points corrective actions with deadlines have to be determined.

Points	Evaluation of compliance with individual requirements
10	Full compliance with requirements
8	Predominant compliance with requirements; minor nonconformities *
6	Partial compliance with requirements; more severe nonconformities
4	Unsatisfactory compliance with requirements, major nonconformities
0	No compliance with requirements

*) **Predominant** means, that more than ¾ of all requirements have proven to be effective and no special risk is given.

The degree of conformity E_E of a process element is calculated from:

$$E_E\,[\%] = \frac{\text{Sum of all points awarded for the respective questions}}{\text{Sum of all possible points of the respective questions}} \times 100\%$$

7.2 Overall Evaluation of the Audit Result

The following elements are evaluated individually:

Products		Services	
- Product design	E_{DE}	- Planning	E_{DE}
- Product development	E_{PE}		
- Input material/Purchased parts	E_Z	- Contract services	E_Z
- Mean of all process steps	E_{PG}	- Mean of the process steps	E_{PG}
- Customer service/satisfaction	E_K	- Customer service/satisfaction	E_K

Note: When talking about auditing services, the term „service“ is to be used instead of product and „service process“ instead of production, in the following descriptions.

Due to the differing process steps for each of the product groups in the element „Production„, a summary of the process steps (Mean E_{PG}) for each product group has to be established, before the overall degree of conformity is calculated.

This is also necessary to ensure an even weighting of the elements.

Here, differing degrees of conformity may be calculated for individual product groups, due to the selected process steps within the element „Production„.

The mean of all process steps E_{PG} of each product group can be calculated from:

$$E_{PG}\,[\%] = \frac{E_1 + E_2 + \ldots\ldots E_n}{\text{Number of evaluated process steps}} \quad [\%]$$

The overall degree of conformity E_P for the process audit is calculated as follows:

$$E_P\,[\%] = \frac{E_{DE} + E_{PE} + E_Z + E_{PG} + E_K}{\text{Number of evaluated process elements}} \quad [\%]$$

Additionally to this process evaluation, sub-elements relevant to the system can also be stated separately and evaluated in the element „Production„.

For products these are:

E_{U1} [%]	Personnel/Qualification
E_{U2} [%]	Production material /Equipment
E_{U3} [%]	Transport/Parts handling/Storage/Packaging
E_{U4} [%]	Fault Analysis/Corrective actions/Continual improvement

For services these are:

E_{U1} [%]	Personnel/Qualification
E_{U2} [%]	Providing the service
E_{U3} [%]	Communication/Identification/Information/Data flow
E_{U4} [%]	Elimination of nonconformities/ Continual improvement

Through the evaluation across several process steps, interfaces to the quality system are realized and nonconformities identified. They are also important for the overall evaluation (see downgrading criteria).

7.3 Grading

Overall degree of conformity in %	Grading of the processes	Description of the grading
90 to 100	full compliance	A *
80 to less than 90	predominant compliance	AB*
60 to less than 80	partial compliance	B*
less than 60	no compliance	C

* Notes:

1. Audited companies, which achieve a degree of compliance of 90 % or more than 80%, but only achieve a degree of compliance of less than 75 % in one or more elements, are downgraded from A to AB or AB to B.

2. For questions graded with zero points, which have a significant influence on the product/process quality when not achieved, the auditee can be downgraded from A to AB or AB to B. In special cases, a downgrading to C is possible.

3. Downgradings are to be justified on a separate explanation sheet.

8 Closing Meeting

The closing meeting, held with a set circle of participants, is the summary of all points raised during the audit (negative/positive).

The auditor explains the audit result and identifies nonconformities and improvement potential. The results are justified and, if necessary, immediate actions are recorded in writing.

All nonconformities identified by the auditor and the required corresponding actions, are to be included in an action plan. A deadline for the completion of the action plan is to be determined. Through the establishment of agreed further proceedings, support by the auditor is possible, but is not normally of a technical nature.

During the closing meeting, the auditor can determine the necessity and a date for a verification visit and record this in the final report, irrespective of nonconformities.

The audit report (see chapter 10) is signed by the auditor and auditee during the closing meeting of external audits (for internal audits this depends on the requirement).

The auditee confirms with his signature, that the recorded results have been discussed with him; he is free to make comments of his own.

9 Corrective Actions and Verification of the Effectiveness

9.1 Corrective Actions

When nonconformities are found, an action plan is to be established with a set time frame.

One generally differentiates between

- technical/organizational actions
  (e.g. changes in the production processes/provision of the service, logistics, design/software modifications)

and

- administrative actions
  (e.g. employee instructions, revision of documents),

whereby technical/organizational actions, in the sense of capable and controlled process are preferable.

Often administrative actions take precedence as they are generally easier to implement.

The action plan (see Chapter 14) includes all activities, stating responsible personnel and deadlines, suitable to eliminate nonconformities in the process.

Actions can also imply process audits in areas preceding or following the defined process.

The action plan can include a verification visit as part of the verification of the implemented actions.

Generally, the auditee is responsible for the preparation of the action plan, and for measures required in neighboring areas. Support can be provided in an adequate manner, in agreement with the auditor. However, this support must not have any effect on the impartiality of the auditor, in the case of an eventual verification visit.

9.2 Verification of the Effectiveness

The effectiveness of the agreed actions has to be verified through, e.g.

- random sample inspection
- product audit
- process audit (Partial processes)
- machine and process capability analyses
- intermediate status /degree of completion.

The relevant process manager is responsible for the completion and monitoring of the effectiveness of the actions.

If the effectiveness of corrective actions cannot be sufficiently proven, the action plan has to be revised and, if necessary, a verification visit scheduled.

A verification visit can be understood as:-

- a full audit with a complete new evaluation or
- an examination of the actually affected (partial) processes,

however, as a minimum, the identified nonconformities have to be subject to assessment.

10 Audit Report and Documentation

The documentation includes all documents from audit preparation through to the final audit report and action plan.

The type of documentation is determined in the quality system.

The audit report (see chapter 14) includes:

- Process Manager/Audit participants
- Process description (Definition) e.g. plant, procedure, product/service
- Reason for the audit
- Presentation of the result (to what extent is the product/service produced/provided in accordance with the quality requirements?)
- K.O.-criteria with justification
- Completion deadline for the action plan
- If applicable, first actions with (approximate) completion deadlines and responsibilities
- Evaluation scheme (Grading and evaluation matrix)
- Audit questions, which could not be evaluated or were taken up in addition
- Justifications for each audit (questions not asked, questions awarded less than 10 points and, when sensible, questions with 10 points)
- Reference is to be made to applicable documents when nonconformities are found (if possibly with examples).

It is important, that only points discussed during the audit and closing meeting are described in the audit report, which have been (if report is written at a later date).

Every nonconformity is to be described with reference to the questionnaire as follows:

- Problem description
- Findings (e.g. type of nonconformity, location of nonconformity).

Special positive findings should also be mentioned in the audit report.

The questionnaire forms part of the audit report (as an attachment).

All information that comes to the attention of the auditor, is to be treated as confidential.

The audited company is authorized to forward the results of the audit to other customers.

The distribution of audit reports or condensed management information from them (e.g. monthly or quarterly information on internal/external process audits) is to be dealt with internally.

The archiving, in terms of location and duration, is part of the quality system.

11 Process Audit Questionnaire

Product development process/Serial production

11.1 Application

The presented questionnaire is a basis for the auditor. He can make use of parts for his own special audit and select or supplement questions from it. The given structure is, however, to be retained.

For the general questions in VDA 6.3, it is recommendable to raise „Know-How„ or corresponding knowledge records.

With the process audit, the effect on the product is of special significance, therefore the examination from the product perspective has priority.

The questionnaire is divided into two parts:

Part A Product Development Process

1: Planning Product Development
2: Realizing Product Development
3: Planning Process Development
4: Realizing Process Development

Part B Serial Production

5: Suppliers/Input Material
6: Production
6.1: Personnel/Qualification
6.2: Production Material/Equipment
6.3: Transport/ Parts Handling/Storage/Packaging
6.4: Fault Analysis/Corrective Actions/ Continual Improvement
7 Customer Services/ Satisfaction

11.2 Structure

The questionnaire is divided into:

- An introduction to the two main processes and to each element
- Questions
  - Requirements/Explanations
  - Lists

The lists give indications to aspects which, amongst others, are of special significance, depending on the product or process. The relevant points are to be assessed.

When evaluating the different process phases according to Part B Serial Production - each process phase is to be named.

11.3 Questions/Requirements/Explanations

Part A: Product Development Process

Product/process design in the product development process is orientated to the four phases of the planning cycle of product quality (planning, realizing, analyzing, improving). Interdisciplinary cooperation and consistent action at all phases of product development are the precondition for the realization of all requirements for the series start of a product.

At the start of the product development process, all customer requirements, market trends, standards and legislation must be known and, under consideration of changes during the product development period, consistently included in the main and supporting processes.

Within the framework of reviews, the compliance and maintenance of established processes and targets are to be monitored at set regular intervals. Nonconformities and required changes often also result in changed targets.

The correct and consistent use of risk analyses and evaluation methods in the product development process gives timely knowledge of nonconformities and necessary corrective actions. They represent an essential factor in cost optimization and limitation.

All employees involved in the project are subject to high qualification and performance requirements. Their consistent performance at all phases of the product development is the precondition for fulfilling all customer requirements and for a high quality niveau at series start.

Product Development (Design)

Element 1: Product Development Planning

The internal planning objectives of a new product, based on the customer requirements and legislation to be considered, must already be raised at the quotation phase, which are then to be put into precise terms and included in a product development plan, after receipt of contract.

All necessary tasks with achievable goals and deadlines must be named in the product development plan.

The requirements on the product are often higher than the customer requirements and must be analyzed and specified in detail by the supplier. Through continual reexamination of all requirements, changes can become necessary during course of the planning phase.

Questions

1.1: Are the customer requirements available?

1.2: Is a product development plan available and are the targets maintained?

1.3: Are the resources for the realization of the product development planned?

1.4: Have the product requirements been determined and considered?

1.5: Has the feasibility been determined based on the available requirements?

1.6: Are the necessary personnel and technical conditions for the project process planned/available?

1.1 Are the customer requirements available?

Requirements/Explanations:

All customer requirements for the product to be developed must be known and included in the development.

The following points, for example, are to be considered:

- Drawings, standards, specifications, performance specification
- Logistic concepts
- Technical specifications, test specifications
- Quality agreements, target agreements
- Important product/process characteristics
- Purchase order documents with parts lists and delivery dates
- Legislation/Directives
- Waste management plans, environmental aspects.

1.2 Is a product development plan available and are the targets maintained?

Requirements/Explanations

The product development plan is an integral part of the project plan and stands in correlation with the process development plan. All activities, including those for suppliers, are to be established until start of series. The targets must be derived from the requirements and maintained at the established project phases.

The following points, for example, are to be considered:

- Customer requirements
- Costs
- Deadlines: Planning/Purchasing release, modification stoppages
- Prototype/Pilot production, start of serial production
- Resources studies
- Setting and monitoring the target
- Regular information to the company management
- Simultaneous Engineering Teams (SET).

1.3 Are the resources for the realization of the product development planned?

Requirements/Explanations:

The resources required are already to be determined and considered in the quotation phase. After award of contract, the details are to be precisely stated. When requirements are altered, an update of the resources study is to be carried out, if necessary. The required means to be planned and made available.

The following points, for example, are to be considered:

- Customer requirements
- Qualified personnel
- Lost time through absenteeism
- Through put/Processing times
- Buildings, premises (for trial/prototype construction)
- Tools/Equipment
- Test/Inspection/Laboratory equipment
- CAD, CAM, CAE.

1.4 Have the product requirements been determined and considered?

Requirements/Explanations:

The requirements on the product are to be determined, through interdisciplinary cooperation/benchmarking, for which QFD and DOE are exemplary methods. Previous experiences and future expectations must be included in the consideration. The product requirements must meet the market requirements and customer expectations, the product must be competitive.

The following points, for example, are to be considered:

- Customer requirements
- Company objectives
- Simultaneous Engineering
- Robust design/safe process
- Regular customer/supplier meetings
- Important characteristics, legislation requirements
- Functional measurements
- Fitting measurements
- Material.

1.5 Has the feasibility been determined based on the available requirements?

Requirements/Explanations

The known requirements must be checked for feasibility through interdisciplinary cooperation, here the customer requirements have special significance.

Requirements to the following points, for example, are to be considered:

- Design/Engineering
- Quality
- Process equipment, resources
- Special characteristics
- Company objectives
- Directives, standards, legislation
- Environmental aspects
- Delivery dates/Time frames
- Cost frame.

1.6 Are the necessary personnel and technical conditions for the project process planned/available?

Requirements/Explanations:

The required personnel qualifications and means are to be determined prior to the start of the project and to be included in the project plan.

The following points, for example, are to be considered:

- Project management, project planning team/responsibilities
- Qualified personnel
- Communication means (Electronic data transfer)
- Information flow from and to the customer during planning (regular meetings, conferences)
- Tools/equipment
- Test/inspection/laboratory equipment
- CAD, CAM, CAE.

Product Development (Design)

Element 2: Realizing Product Development

In the realization phase of product development, all defined task of the product plan are to be carried out, possible amendments are to be recognized and considered. The project manager/project management have the decisive task of involving all interfacing areas early in all exercises and of informing the company management and if necessary, also the customer, of any problems which arise.

During the realization, reviews are to be carried out at set regular intervals. When targets are not achieved, corrective actions are to be established, implemented and monitored for their effectiveness.

Questions

2.1: Is the design FMEA raised and are improvement measures established?

2.2: Is the design FMEA updated in the project process and are the established measures realized?

2.3: Is a quality plan prepared?

2.4: Are the required releases/qualification records available at the respective times?

2.5: Are the required resources available?

2.1 Is the design FMEA raised and are improvement measures established?

Requirements/Explanations:

The product risks are to be pointed out and continually reduced with appropriate measures, through interdisciplinary cooperation, also with the customer and suppliers. For complex parts or complete function systems, the use of a system FMEA is sensible (see VDA Volume 4, Part 1 and 2). Other comparable analysis techniques are to be agreed with the customer.

The following points, for example, are to be considered:

- Customer requirements/performance specifications
- Function, safety, reliability, maintainability, important characteristics
- Environmental aspects
- Involvement of all affected areas
- Trial and test results
- Product-specific measures from the process FMEA.

2.2 Is the design FMEA updated in the project process and are the established measures realized?

Requirements/Explanations:

Amendments to the product and process must be evaluated by the project management. In agreement with the FMEA Team, a new analysis, if necessary, is to be initiated. An update is also necessary after realization of measures (Design Review).

The following points, for example, are to be considered:

- Customer requirements
- Important parameters/characteristics, legal requirements
- Function, fitting measurements
- Material
- Environmental aspects
- Transport (internal/external)
- Product-specific measure from the process FMEA.

2.3 Is a quality plan prepared?

Requirements/Explanations:

The quality plan must contain components, subassemblies, assemblies, parts and materials, including the production process from prototype and pilot production phase, which belong to the product. The quality plan is a living document and must be raised/updated for new/amended products. A quality plan (according to DIN EN ISO 8402/3.13) is generally to be raised for the following phases:

a) Prototype phase

   A description of the dimensional, as well as material and functional inspections, which are to be carried out during the construction of the prototype (if required by the customer).

b) Pilot production phase/Interface to process development

   A description of the dimensional, as well as material and functional inspections, which are to be carried out after construction of the prototype and prior to serial production.

It must give details, amongst others, about:

- establishing and marking of significant characteristics
- raising of an inspection and test plan
- provision of equipment and fittings
- timely, planned provision of measuring equipment
- inspections at appropriate points during the production
- clarification of acceptance criteria

Comment: In addition, see also VDA Volume 4.3.

2.4 Are the required releases/qualification records at the respective times?

Requirements/Explanations:

The releases/qualification records of all individual parts, subassemblies and purchased parts are to be proven.

The following points, for example, are to be considered:

- Product trials (e.g. fitting inspections, functional tests, durability checks, environmental simulations)
  Status of the prototype parts
  Pilot series model
  Production/inspection, measuring and test equipment in experimental installation.

2.5 Are the required resources available?

Requirements/Explanations:

The required resources are to taken from the quotation calculation and the preplanning. They must be available, or planned and provided at the respectively appointed time. The required means for this must be included in the project.

The following points, for example, are to be considered:

- Customer requirements
- Qualified personnel
- Lost time through absenteeism
- Through put/Processing time
- Buildings, premises
- Experimental installation
- Prototype construction
- Tools/Equipment
- Test/Inspection/Laboratory equipment.

Process Development

Element 3: Process Development Planning

Basic planning for the manufacture of a product to customer requirements, must already have taken place at quotation stage, which must then be put into precise terms and included in a process development plan, after receipt of contract. Technical and personnel resources, already available, must be considered and expansions preplanned.

When setting all tasks, objectives and deadlines, all interfacing areas are to be included through interdisciplinary cooperation. All tasks and responsibilities are to be clearly established.

When planning and implementing processes, amendments can become necessary due to changed customer requirements or special legislative requirements, which also make a reexamination of the planning necessary.

Questions

3.1: Are the product requirements available?

3.2: Is a process development plan available and are the targets maintained?

3.3: Are the resources for the realization of serial production planned?

3.4: Have the process requirements been determined and considered?

3.5: Are the necessary personnel and technical preconditions for the project process planned/available?

3.6: Is the process FMEA raised and are improvement measures established?

3.1 Are the product requirements available?

Requirements/Explanations:

All requirements of the product to be produced, must be known and included in the planning.

The following points, for example, are to be considered:

- Customer requirements
- Legislation, standards, directives
- Logistic concepts
- Technical specifications
- Quality/target agreements
- Important characteristics
- Material
- Waste management plans, environmental aspects.

3.2 Is a process development plan available and are the targets maintained?

Requirements/Explanations:

The process development plan is an integral part of the project plan and stands in correlation with the product development plan. All activities until start of series are to be determined. The targets must be derived from the requirements and maintained at the established project phases.

The following points, for example, are to be considered:

- Customer requirements
- Costs
- Deadlines: Planning/Purchasing release, Prototypes/pilot productions, Start for serial production
- Resources studies
- Provision of production/testing equipment, software, packaging
- Safeguard concept for amendments (startup problems etc.)
- Logistic/delivery concept
- Setting and monitoring the target
- Regular information to the company management.

3.3 Are the resources for the realization of serial production planned?

Requirements/Explanations:

The required resources are already to be determined and considered in the quotation phase. After award of contract, the details are to be precisely stated. When requirements are altered, an update of the resources study is to be carried out, if necessary. The required means are to be planned and made available.

The following points, for example, are to be considered:

- Customer requirements
- Availability of input material
- Qualified personnel
- Lost time through absenteeism/Standstill times
- Through put times/Processing times/No. of production pieces per plant/Equipment
- Buildings, premises
- Plants, tools, production/testing equipment, auxiliary tools, laboratory equipment
- Transport means, containers, store
- CAM, CAQ.

3.4 Have the process requirements been determined and considered?

Requirements/Explanations:

The process requirements are to be determined through interdisciplinary cooperation, for which QFD and DOE are exemplary methods. Previous experiences and future expectations must be included in the consideration.

The following points, for example, are to be considered:

- Customer requirements
- Legislative requirements
- Capability records
- Suitability of plants, tools, inspection and test equipment
- Arrangement of work and inspection stations
- Handling, packaging, storage, marking.

3.5 Are the necessary personnel and technical preconditions for the project process planned/available?

Requirements/Explanations:

The personnel qualification requirements and means to be provided, are to be determined prior to the start of the project and included in the project plan.

The following points, for example, are to be considered:

- Project management, project planning team/responsibilities
- Qualified personnel
- Plants, tools, production/testing equipment, auxilliary tools, laboratory equipment
- Communication means (e.g. electronic data transfer)
- Information flow from and to the customer during the planning (regular meetings, conferences)
- CAM, CAQ.

3.6 Is the process FMEA raised and are improvement measures established?

Requirements/Explanations:

The process risks are to be pointed out and continually reduced with appropriate measures, through interdisciplinary cooperation, also with the customers and suppliers. For complex parts or complete function systems, the use of a system FMEA is sensible (see VDA Volume 4, Part 1 and 2).

The following points, for example, are to be considered:

- All production stages, including those of suppliers
- Customer requirements, function
- Important parameters/characteristics
- Traceability, environmental aspects
- Transport (internal/external)
- Involvement all affected areas
- Process-specific measures from the design FMEA.

Process development

Element 4: Realizing Process Development

In the realization phase of process development, all defined tasks from the planning of the processes (Process development plans) are to be carried out, possible amendments are to be recognized and considered. For project management/monitoring, the project manager has the decisive task of involving all interfacing areas in all task at an early stage and of informing the company management and if necessary, also the customer of any problems which arise.

During the realization, reviews are to be carried out at set intervals. When targets are not achieved, corrective actions are to be determined, implemented and monitored for their effectiveness.

Questions

4.1: Is the process FMEA updated when amendments are made during the project process and are the established measures implemented?

4.2: Is a quality plan prepared?

4.3: Are the required releases/qualification records available at the respective times?

4.4: Is a pre-production carried out under serial conditions for the serial release?

4.5: Are the production and inspection documents available and complete?

4.6: Are the required resources available?

4.1 Is the process FMEA updated when amendments are made during the project and are the established measures implemented?

Requirements/Explanations:

Amendments to product and process must be evaluated by the project managers. In agreement with the FMEA Team a new analysis, if necessary, is to be initiated. An update is also required after measures have been realized.

Comment: In addition see also VDA Volume 4.2

The following points, for example, are to be considered:

- Customer requirements
- All production phases, including those of suppliers
- Important parameters/characteristics, legislative requirements
- Fitting measurements
- Material
- Traceability, environmental aspects
- Transport (internal/external)
- Process-specific measures from the design FMEA.

4.2 Is a quality plan prepared?

Requirements/Explanations:

The quality plan must contain components, subassemblies, assemblies, parts and materials, including the production processes, which belong to the product. The quality plan (according to DIN EN ISO 8402/3.13) is a living document and must be raised/updated for new/amended processes/ products.

A quality plan is generally to be raised for the following phases:

<u>Pilot production phase</u>

A description of the dimensional, as well as material and functional inspections which are to be carried out prior to serial production.

Serial production phase

A comprehensive documentation of the product and process characteristics, the process control measures, the inspection, test and measurement systems which are to be considered during the serial production.

It must give details, amongst others, about:

- establishing and marking of significant characteristics
- raising of an inspection and test plan
- provision of equipment and fittings
- timely, planned provision of measuring equipment
- inspections at appropriate points during the production
- clarification of acceptance criteria.

4.3 Are the required releases/qualification records available at the respective times?

Requirements/Explanations:

The releases/qualification records of all individual parts, subassemblies and purchased parts, production, inspection , measuring and test equipment, are to be proven.

The following points, for example, are to be considered:

- Product trials (e.g. fitting inspection, functional test, durability check, environmental simulations)
- Pilot production parts
- First sample
- Capability records of important product/process characteristics
- Logistic concept (e.g. checking suitability of packaging by a test dispatch)
- Tools, machines, equipment, inspection, measuring and test equipment.

4.4 Is a pre-production carried out under serial conditions for the serial release?

Requirements/Explanations:

A pre-production is required to be able to evaluate and, if necessary, correct all production factors and influences at an early stage. In serial production, bottlenecks and quality impairment, shall become avoidable.

The following points, for example, are to be considered:

- Customer requirements
- Establishing minimum numbers of production pieces
- Process capability analysis
- Measuring equipment capability
- Readiness of the production materials and equipment for series (measuring records)
- First sample inspection
- Handling, packaging, marking and storage
- Personnel qualification
- Work/Inspection instructions
- Arrangement of work/inspection stations.

4.5 Are the production and inspection documents available and complete?

Requirements/Explanations:

Process parameters/inspection characteristics are always to be given with tolerances, the production and inspection documents must be available at the work/inspection station. The implemented corrective actions for nonconformities are to be documented.

Details are, for example:

- Process parameters (e.g. pressures, temperatures, times, speeds)
- Machine/tool/auxiliary means data
- Inspection requirements (important characteristics, inspection, measuring and test equipment, methods, inspection frequencies)
- Intervention limits in process control charts
- Machine and process capability records
- Operating instructions
- Work instructions
- Inspection instructions
- Information on the current nonconformities.

4.6 Are the required resources available?

Requirements/explanations:

The resources required are to be taken from the quotation calculation and the current process development.

The following points, for example, are to be considered:

- Customer requirements
- Availability of input material
- Qualified personnel
- Lost time through absenteeism/Standstill times
- Through put times/Processing times/No. of production pieces per plant/equipment
- Buildings, premises
- Plants, tools, production/inspection equipment, auxiliary tools, laboratory equipment
- Transport means, containers, store.

Part B: Serial Production

The precondition for a capable serial production is the consistent implementation of all necessary measures from the product development process.

Under consideration of the customer requirements, the processes at suppliers in their own production, product delivery and use, are to be continually assessed and improved.

Customer-orientated handling of all processes is the precondition for customer satisfaction in quality, price and service.

Quality performance is determined by man, machine, material and means/ environment, with lean production processes, low stock levels and high employee qualification. The responsibility of the employees must be dominated by independent recognition of nonconformities on the product and in the process, improvement measures are to be implemented or initiated at their own initiative.

The processes and proceedings are, through suitable methods, to be continually evaluated, nonconformities analyzed and appropriate corrective actions to be taken to maintain, improve and fulfil all requirements on the process capability.

For the maintenance and improvement of customer satisfaction, the supplier has the obligation to observe his products after production. Active cooperation with the customer, early identification of disturbances and faults are the basis for a long term and trusting cooperation.

Element 5: Suppliers/Input Material

Shorter delivery times to the customer (e.g. just in time) and reduction of through put/processing times have an effect on purchasing times and require special activities in individual processes.

This demands a faultless system, as errors or delivery defects cannot normally be corrected by reverting to alternative parts or materials.

Quantitative or logistical disruptions lead directly to interruptions in production, when low or no intermediate stock levels are available.

The audited company has the responsibility and the obligation, together with his suppliers, of securing the processes and procedures for the respective products/materials, and ensuring the process capability of all customer-relevant, important characteristics. This makes internal process and product audits necessary. The effectiveness of established quality assurance measures and continual improvement are to be proven.

Questions

5.1: Are only approved quality capable suppliers used?

5.2: Is the agreed quality of the purchased parts guaranteed?

5.3: Is the quality performance evaluated and are corrective actions introduced when there are deviations from the requirements?

5.4: Are target agreements for continual improvement of products and process made and implemented with the suppliers?

5.5: Are the required releases for the delivered serial products available and the required improvements measures implemented?

5.6: Are the procedures agreed with the customer, regarding customer-supplied products, maintained?

5.7: Are the stock levels of input material matched to production needs?

5.8: Are input materials/internal residues delivered and stored according to their purpose?

5.9: Is the personnel qualified for the respective tasks?

5.1 Are only approved quality capable suppliers used?

Requirements/Explanations:

Prior to determining the suppliers, an evaluation of the quality system (certification/auditing) must be available. During serial application, it must be ensured that only suitable suppliers are used. Experiences from quality performance assessments must be considered.

The following points, for example, are to be considered:

- Supplier discussions/regular support
- Evaluation of the quality capability e.g. audit results/certificates
- Assessment of the quality performance (quality/costs/service).

5.2 Is the agreed quality of the purchase parts guaranteed?

Requirements/Explanations:

The following points, for example, are to be considered:

- Sufficient inspection and test possibilities (Laboratory and measuring equipment)
- Internal/external inspections and tests
- Supplied gauges/surveys
- Drawings/order details/specifications
- Quality assurance agreements
- Coordination of inspection and testing procedures, proceedings and frequencies
- Analysis of nonconformity focal points
- Capability evidence.

5.3 Is the quality performance evaluated and are corrective actions introduced when there are deviations from the requirements?

Requirements/explanations

The capabilities and performances of a supplier are to be checked at defined intervals and recorded and evaluated in a part-specific listing (supplier catalog). Qualification programs are to be established when negative results are found. The implementation is to be proven.

The following points, for example, are to be considered:

- Records about quality meetings
- Agreements about and monitoring of improvement programs
- Inspection and measuring records of improved components
- Analysis of nonconformity focal points/problem suppliers.

5.4 Are target agreements for continual improvement of products and process made and implemented with the suppliers?

Requirements/explanations

The following points, for example, are to be considered:

- Workshops (interdisciplinary working groups)
- Establishing measurable target parameters for quality, price, service e.g.:
- Reducing the inspection and testing magnitude whilst raising process safety
- Reducing rejections (internal/external)
- Reducing the stock in circulation
- Increasing customer satisfaction.

5.5 Are the required releases for the supplied serial products available and the required improvement measures implemented?

Requirements/Explanations:

For all supplier products, a release of new/amended products/processes, must be carried out prior to serial application.

The following points, for example, are to be considered:

- Construction model, trial testing releases
- First sample report according to VDA
- Capability evidence for important characteristics
- Consideration of the safety data sheets, EC guidelines
- Reliability assessments
- Re-qualification inspection reports and the resulting improvement measures.

5.6 Are the procedures agreed with the customer, regarding customer-supplied products, maintained?

Requirements/Explanations:

The customer-supplied product requirements are to be taken from the quality agreements and strictly implemented.

Customer-supplied products can be:

- services
- tools, inspection, measuring and test equipment
- packaging
- products.

The following points, for example, are to be considered:

- Control, verification, storage, transport, maintenance of quality and properties
- Information flow, in cases of nonconformity or loss
- Quality documentation (quality status, quality history).

5.7 Are the stock levels of input material matched to production needs?

Requirements/Explanations:

The required stock levels must already be determined and considered during process planning. When requirements change, the analyzed stock levels, if necessary, are to be updated.

The following points, for example, are to be considered:

- Customer requirements
- KANBAN/Just in time
- Storage costs
- Emergency strategy when input material bottlenecks occur
- FIFO (first in/first out).

5.8 Are input materials/internal residues delivered and stored according to their purpose?

Requirements/Explanations:

The following points, for example, are to be considered:

- Packaging
- Storage administration system
- FIFO (first in/first out)
- Tidiness and cleanliness
- Climatic conditions
- Protection against damage/contamination
- Identification
- (Traceability/Inspection status/Sequence of operations/Application status)
- Safety against mix ups
- Secure storage (fitted and used).

5.9 Is the personnel qualified for the respective tasks?

Requirements/Explanations:

Personnel responsible for the following areas, for example, are to be considered:

- Supplier selection, evaluation, qualification
- Product inspection, measuring and testing
- Storage/Transport
- Logistics.

Knowledge must be available, for example, about:

- Product/specifications/special customer requirements
- Standards/legislation
- Packaging
- Processing
- Evaluation methods (e.g. audits, statistics)
- Quality techniques (e.g. 8D-Method, Cause/Effect diagram)
- Foreign languages.

Element 6: Production

All the following questions are to be used at each process stage.

At the individual production stages of a product, the planned/realized technical and personnel procedures and proceedings must be maintained, monitored and, under consideration of the economic aspects, continually improved. Employee qualifications, suitability and improvement of process and inspection equipment, as well as specially adjusted transport for the parts to be produced and storage facilities of the products, are focal points in this element.

The customer requirements of each product and the corresponding processes are the basis of all activities, which can change until amendment or discontinuation of a product. All changes must be recognized early and included in the processes.

The demand of the customer for zero defects must be a leading thread through all process steps, the company management must provide the necessary conditions to achieve this.

The relationship „customer/supplier“ must also be of special significance with the internal processes. It is distinguished by quality circles and team work; personnel at each process stage are to be given a high degree of responsibility.

All production changes of a product are to be advised to the customer, who decides from his side, in how far additional qualifications measures or new approvals will become necessary (see also VDA Volume 2).

Element 6: Production

Sub-element 6.1: Personnel/Qualification

Selecting employees qualified to their activity, maintaining their qualification and also qualifying them for other, further activities, are management tasks. The qualification of employees for the product or process task they perform, must be proven.

The employees must know the customer requirements and quality objectives. The duties assigned to them have to show a commitment towards quality.

For all processes, sufficiently qualified personnel must be identified and assigned through resources planning. Required replacements in the individual processes must be identified. Qualified personnel must also be available for this.

Questions

6.1.1: Are the employees given responsibility and authority for monitoring the product/process quality?

6.1.2: Are the employees given responsibility and authority for production equipment and environment?

6.1.3: Are the employees suitable to perform the required tasks and is their qualification maintained?

6.1.4: Is there a personnel plan with a replacement ruling?

6.1.5: Are instruments to increase employee motivation effectively implemented?

6.1.1 Are the employees given responsibility and authority for monitoring the product/process quality?

Requirements/Explanations:

The following points, for example, are to be considered:

- Cooperation on improvement programs
- Worker self assessments
- Process approval/release
- Set up release/First/last production piece testing)
- Process control (Interpretation of control charts)
- Authority to stop production.

6.1.2 Are the employees given responsibility and authority for production equipment and environment?

Requirements/Explanations:

The following points, for example, are to be considered:

- Tidiness and cleanliness
- Carrying out or ordering repair and maintenance work
- Providing parts/storage
- Carrying out/ordering the installation and calibration of inspection, measuring and test equipment.

6.1.3 Are the employees suitable to perform the required tasks and is their qualification maintained?

Requirements/Explanations:

The following points, for example, are to be considered:

- Introduction/Training/Qualification records about the process
- Knowledge of the product and nonconformities which have occurred
- Instructions in health and safety at work/Environmental aspects
- Instructions for the handling of „components with special verification requirements“
- Qualification records (e.g. Welder certificates, sight tests, driving license for industrial trucks).

6.1.4 Is there a personnel plan with a replacement ruling?

Requirements/Explanations:

When planning personnel, the absentee figures (illness/holidays/training courses) are to be considered. The required qualifications of replacement personnel are also to be ensured.

The following points, for example, are to be considered:

- Shift plan (contract related)
- Qualification records (Qualification matrix)
- Work analyses/Time and motion studies.

6.1.5 Are instruments to increase employee motivation effectively implemented?

Requirements/Explanations:

The willingness to work must be promoted through targeted information and thereby, the quality awareness increased.

The following points, for example, are to be considered:

- Quality information (Specified/Actual values)
- Improvement suggestions
- Voluntary activities (Training courses, quality circles)
- Low illness frequency rate
- Contribution to quality improvement
- Self assessments.

Comment: The question also stands in connection with question 7.5.

Element 6: Production

Sub-element 6.2: Production Material/Equipment

The product quality requirements must be able to be achieved with the applied production equipment; the required process capability must be met and maintained. Inspection, measuring and test equipment must also fulfill these requirements. When re-starting production, special conditions are to be met, work and inspection stations are to be installed appropriate to the product and product and process approvals are to be raised before production start. Quality and process data from previous production must be known, all established improvement measures must be implemented.

Questions

6.2.1: Are the product-specific quality requirements fulfilled with the production equipment/tools?

6.2.2: Can the quality requirements be monitored effectively during serial production with the implemented inspection, measuring and test equipment?

6.2.3 Are the work and inspection stations appropriate to the needs?

6.2.4 Are the relevant details in the production and inspection documents complete and maintained?

6.2.5 Are the necessary auxiliary means available for adjustments?

6.2.6 Is an approval for production starts issued and are adjustment details, as well as deviations recorded?

6.2.7 Are the required corrective actions carried out on schedule and checked for effectiveness?

6.2.1 Are the product-specific quality requirements fulfilled with the production equipment/tools?

Requirements/Explanations:

The following points, for example, are to be considered:

- Machine/Process capability evidence important characteristics/ process parameters
- Compulsory control/regulation of important parameters
- Warnings when deviations from specified values occur (e.g. lamps, sirens, shutdown)
- Feed and delivery equipment
- Maintenance and repair status of tools/plants/machines (including scheduled maintenance).

6.2.2 Can the quality requirements be monitored effective during serial production with the implemented inspection, measuring and test equipment?

Requirements/Explanations

The following points, for example, are to be considered:

- Reliability, function and corrosion resistance tests
- Measuring accuracy/inspection, measuring and test equipment capabilities
- Data acquisition and analysis
- Calibration records.

6.2.3 Are the work and inspection stations appropriate to the needs?

Requirements/Explanations

The environmental conditions (also for repairs/rework) are to be tuned to the work contents and the products, to avoid contamination, damage and mix up/misinterpretation.

The following points, for example, are to be considered

- Ergonomics
- Lighting
- Tidiness and cleanliness
- Environmental protection
- Surroundings/Handling of the components
- Health and safety at work.

6.2.4 Are the relevant details in the production and inspection documents complete and maintained?

Requirements/Explanations

Process parameters and inspection and testing characteristics are always to be given with tolerances. Manufacturing and inspection documents must be available at the work/inspection stations. Nonconformities and implemented corrective actions must be documented.

The following points, for example, are to be considered:

- Process parameters (e.g. pressures, temperatures, times, speeds)
- Machine/tool/auxiliary means data (Tool and machine numbers)
- Inspection requirements (important characteristics, inspection, measuring and test equipment, methods, frequencies)
- Intervention limits in process control charts
- Machine and process capability records
- Operating instructions
- Work instructions
- Inspection instructions
- Information on the current nonconformities.

6.2.5 Are the necessary auxiliary means available for adjustments?

Requirements/Explanations

The following points, for example, are to be considered:

- Tooling plans
- Tool setting aids/comparison aids
- Flexible tool change equipment
- Limits patterns.

6.2.6 Is an approval for production starts issued and are adjustment details, as well as deviations recorded?

Requirements/Explanations

“Release to serial production“ is the contract-related first and re-release for the start of the production. The release is necessary for product and process and must be carried out, in writing, by authorized employees with the help of acceptance criteria. At this point, known problems in the product/ process planning and/or previous serial production must be eliminated.

The release inspection and tests must be made according to clear inspection instructions, to ensure their reproducibility. Here, the use of a checklist is recommended.

If production is continued after the extraction of test pieces, the products must be placed on hold until release of the test pieces. Reworked products are to be included in the release process.

The following points, for example, are to be considered:

- New, changed product
- Standstill of the equipment/process interruption
- Repair, tool change
- Material change (e.g. Batch/heat change)
- Changed production parameters
- First production piece testing with documentation
- Topicality of the parameters
- Tidiness and cleanliness at the work station
- Packaging
- Release /modification status of tools and inspection, measuring and test equipment.

6.2.7 Are the required corrective actions carried out on schedule and checked for effectiveness?

Requirements/Explanations:

Corrective actions relate to the entire process chain, from input material through to use by the customer. The effectiveness of corrective actions carried out, must be checked and proven.

The following points, for example, are to be considered:

- Risk analyses (Process FMEA) Fault analyses
- Improvement programs from audits
- Information to the responsible party
- Interface discussions internal/external
- Internal complaints
- Customer complaints
- Customer surveys.

Element 6: Production

Sub-element 6.3: Transport/Parts Handling/Storage/Packaging

Production processes shall be continually adjusted to one another; only the amount agreed with the customer is produced. Intermediate storage of incomplete products is to be avoided. The manufacturing and test condition of parts must be recognizable through clear identification, parts for rejection and rework require special attention and identification.

Storage and transport means of the respective products, along the entire process chain, must be agreed with the customer. They must not be allowed to cause damage to the product.

Tools, production and inspection equipment must be adequately preserved and stored without risk of damage during longer production interruption periods. New, immediate application, without time consuming preparation must be ensured.

Questions

6.3.1: Are the quantities/production lot sizes matched to the requirements and are they purposefully forwarded to the next work station?

6.3.2: Are products/components appropriately stored and are the transport means/packaging equipment tuned to the special properties of the product/components?

6.3.3 Are rejects, rework and adjustment parts, as well as internal residues strictly separated and identified?

6.3.4 Is the material and parts flow secured against mix ups/ exchanges by mistake and traceability guaranteed?

6.3.5 Are tools, equipment and inspection, measuring and test equipment stored correctly?

6.3.1 Are the quantities/production lot sizes matched to the requirements and are they purposefully forwarded to the next work station?

Requirements/Explanations:

The following points, for example, are to be considered:

- Sufficiently suitable transport means
- Defined storage areas
- Minimal/no intermediate store
- KANBAN
- Just in time
- First in/first out
- Storage administration
- Modification status
- Only transfer of satisfactory parts
- Recording production pieces numbers/evaluation
- Information flow.

Comment: When material/purchased parts are delivered directly to the respective production plants, the requirements according to question 3.7 are also to be considered.

6.3.2 Are products/components appropriately stored and are the transport means/packaging equipment tuned to the special properties of the product /components?

Requirements/Explanations

The following points, for example, are to be considered:

- Stock levels
- Protection against damage
- Parts positioning
- Tidiness, cleanliness, overstocking (storage areas, containers)
- Monitoring of the storage time
- Environmental influences, air conditioning.

Comment: When material/purchased parts are delivered directly to the respective production plants, the requirements according to question 5.7 and 5.8 are also to be considered.

6.3.3 Are rejects, rework and adjustment parts, as well as internal residues strictly separated and identified?

Requirements/Explanations

The following points, for example, are to be considered:

- Holding store, holding areas
- Marked containers for rejects, rework parts and adjustment parts
- Nonconforming products and nonconformity characteristics
- Identification/marking
- Defined transfer/rework stations in the production department.

6.3.4 Is the material and parts flow secured against mix ups / exchanges by mistake and traceability guaranteed?

Requirements/Explanations

Appropriate to the product risk, the traceability along the entire process chain from supplier to customer, must be guaranteed.

The following points, for example, are to be considered:

- Identification/Marking of parts
- Identification/Marking of the operational, inspection and test and application status
- Batch/heat numbering
- Expiry date
- Removal of invalid identification/marking
- Working documents with parts/production data.

6.3.5 Are tools, equipment and inspection, measuring and test equipment stored correctly?

Requirements/Explanations

Tools, machinery, inspection, measuring and test equipment, not in use and not released, must also be correctly stored and administrated.

The following points, for example, are to be considered:

- Storage without risk of damage
- Tidiness and cleanliness
- Defined storage location
- Administered issue
- Environmental influences
- Identification/Marking
- Defined release and revision status.

Element 6: Production

Sub-element 6.4 Fault analysis/Correction/Continual Improvement

Every company has the obligation, through continuous product and process observation, to recognize deviations from customer requirements and expectations and to eliminate these using appropriate measures. The customer demand for zero defects shall be fulfilled through preventive action in all processes, under consideration of statistic methods.

The precondition for every improvement is a detailed fault analysis, to recognize the true cause of the nonconformity and to be able to initiate suitable corrective actions. The effectiveness of implemented corrective actions must be determined in all cases.

The responsible persons and departments, in the process, are to be involved in the continual improvement and elimination of nonconformities. They themselves carry the responsibility for customer satisfaction.

Questions

6.4.1: Are quality and process data recorded complete and ready to be evaluated?

6.4.2: Are the quality and process data statistically analyzed and are improvement program derived from this?

6.4.3 Are the causes of product and process nonconformities analyzed and the corrective actions checked for their effectiveness?

6.4.4 Are processes and products regularly audited?

6.4.5 Are product and process subject to continual improvement?

6.4.6 Are target parameters available for product and process and is their compliance monitored?

6.4.1 Are quality and process data recorded complete and ready to be evaluated?

Requirements/Explanations

Quality and process data must be completely available to prove the compliance with requirements. They must be able to be evaluated. Special events are to be documented (Logbook).

The following points, for example, are to be considered:

- General charts
- Nonconformity lists
- Control charts
- Data acquisition
- Recorders for process parameters (e.g. temperature, time, pressure)
- Plant standstill
- Parameter changes
- Power cuts.

6.4.2 Are the quality and process data statistically analyzed and are improvement program derived from this?

Requirements/Explanations

Findings and problem points are to be related to the responsible departments, which must then work out and implement improvements.

The following points, for example, are to be considered:

- Process capabilities
- Failure modes/failure frequencies
- Nonconformity costs
- Process parameter
- Rejects/rework
- On hold notifications/Sorting actions
- Cycle, through put/processing times
- Reliability/Failure conduct.

The following, for example, can be used:

- SPC
- Pareto Analysis
- Cause/effect diagrams.

6.4.3 Are the causes of product and process nonconformities analyzed and the corrective actions checked for their effectiveness?

Requirements/Explanations

When product/process failures have occurred, appropriate immediate actions (such as placing on hold, sorting, informing) must be carried out, to ensure compliance with the requirements, until the cause of the failure has been removed and the effectiveness of corrective actions has been proven.

The following points, for example, are to be considered:

- Additional dimensional, material, functional, endurance tests
- Cause/effect diagram
- Taguchi, Shainin
- FMEA/Fault analysis
- Process capability analysis
- Quality Circle
- 8D-Method.

6.4.4 Are processes and products regularly audited?

Requirements/explanation

Audit plans for the product and it's manufacturing process must be available.

Audit reasons are, for example:

- New projects/processes/products
- Nonconformity with quality requirements (internal/external)
- Maintaining records of the compliance with quality requirements
- Identifying improvement potentials.

Nonconformity reports (NCR's) are to be distributed to the responsible parties, the improvement measures are to be monitored.

The following points, for example, are to be considered:

- Customer requirements
- Important characteristics
- Function
- Process parameters/capabilities
- Marking/identification, Packaging
- Established processes/procedures.

6.4.5 Are product and process subject to continual improvement?

Requirements/Explanations

The improvement potential must be determined from previous findings about quality, costs and service.

The following points, for example, are to be considered:

- Cost optimization
- Reduction of waste (e.g. rejects and rework)
- Improving of process safety (e.g. process analysis)
- Optimizing set-up times, raising plant availability
- Reducing through-put/processing times
- Reducing stock levels.

6.4.6 Are target parameters available for product and process and is their compliance monitored?

Requirements/Explanations

Target parameters must be agreed and feasible, the topicality is to be guaranteed. Special measures required are to be established and implemented, if necessary.

The following points, for example, are to be considered:

- Presence and absence of personnel
- Number of production pieces produced
- Quality indices (e.g. failure rates, audit results)
- Through-put/processing times
- Nonconformity costs
- Process characteristic values (e.g. process capability).

Element 7: Customer Service, Customer Satisfaction, Service

The customer has the right to faultless products and the fulfillment of all his requirements during further processing and application. This also includes a support (service) after delivery of the product by the supplier, to enable early identification of deviations from the customer requirements and expectations and to maintain or restore customer satisfaction through appropriate improvement measures. The function „customer service“ therefore, has a key position in the measuring of customer satisfaction. It must be manned by qualified personnel, able to initiate improvements at all levels and departments of the supplier.

It is to be ensured, that quality problems are reacted to quickly and the supply of parts in accordance with the quality requirements of the customer is secured.

Questions

7.1: Are customer requirements fulfilled at delivery?

7.2: Is customer service guaranteed?

7.3 Are complaints quickly reacted to and the supply of parts secured?

7.4 Are fault analyses carried out when there are deviations from the quality requirements and are improvement measures implemented?

7.5 Is the personnel qualified for each task?

7.1 Are Customer Requirements Fulfilled at Delivery?

uirements/Explanations

All requirements are considered, especially those which go into the supplier evaluation by the customer.

The following points, for example, are to be considered:

- Quality agreements
- Dispatch audits
- Endurance testing (Investigating failure conduct)
- Storage/Call off processing/parts provision/dispatch
- Functional testing
- Suitability of inspection, measurement and test equipment
- Agreed inspection and testing procedures
- Topicality of the specifications.

7.2 Is Customer Service Guaranteed?

Requirement/Explanations

It is to be guaranteed, that competent contact people for the various organization departments of the customer are available. Customer support is also a measure of active cooperation. The sub-supplier has the duty to observe and, if necessary, improve, his products across all development and application phases.

The following points, for example, are to be considered:

- Records of customer visits, if necessary, deriving measures
- Knowledge of product application
- Knowledge of product problems
- Implementation of new requirements
- Notification of improvement measures
- Notification of product/process changes/redeployments, (also of suppliers)
- First/repeat samplings (Trial/Series)
- Information about nonconformities.

7.3 Are complaints quickly reacted to and the supply of parts secured?

Requirements/Explanations

Concepts to secure the supply of parts, also for unscheduled problems, are already to be worked out during process planning. These are to be guaranteed in the series phase**.**

The following points, for example, are to be considered:

- Emergency plans
- Resources and reaction times for sorting actions
- Plant modification possibilities, special production means and tools
- Use of subcontracted resources.

7.4 Are fault analyses carried out when there are deviations from the quality requirements and are improvement measures implemented?

Requirements/Explanations

The following points, for example, are to be considered:

- Analysis possibilities (Laboratory, inspection/test equipment, personnel)
- PARETO Analyses of failure characteristics (internal/external)
- Involvement of all affected departments (internal/external)
- Use of problem solving methods (e.g. 8D Report)
- Correction of sampling deviations
- Revision of the specifications
- Check of effectiveness.

7.5 Is the personnel qualified for each task?

Requirements/Explanations

Responsible personnel, for example, for the following areas are to be considered:

- Customer service
- Product inspection and testing
- Storage/Transport
- Logistics
- Fault analysis.

Knowledge of the following, for example, must be available:

- Product/specifications/special customer requirements
- Standards/Legislation
- Processing/Application
- Evaluation methods (e.g. audit, statistics)
- Quality techniques (e.g. 8D Method, Cause/effect diagram)
- Foreign languages.

12 Process Audit Questionnaire
Service Development Process/Providing the Service

12.1 Application

The questionnaire presented in this chapter is a basis for the auditor. He can extract those parts and questions which he needs for a specific audit and complement them with other service-specific questions. However, the given structure has to be followed.

The questionnaire is divided into the following S-Elements corresponding to the net profit chain:

Part A Service Development Process

S1 Planning

Part B Providing the Service

S2 Contract services
S3 Service Process
S3.1 Personnel/Qualification
S3.2 Providing the service
S3.3 Communication, Identification, Information, Data Flow
S3.4 Elimination of Nonconformities and Continual Improvement
S4 Customer Services/Customer Satisfaction

12.2 Structure

The questionnaire provides a brief summary about each D-Element which illustrates focal points.

This is followed by the questions about each D-Element with:-

- Requirements/Explanations
- Lists.

The lists provide hints to aspects which are, amongst others, of special importance depending on the type of service.

12.3 Questions/Requirements/Explanations

Are included in the following chapters.

Part A **Service Development Process**

Element **S1** **Planning**

When planning a new or changed process, it is of prime importance that all customer requirements and expectations are identified and analyzed. All these points have to be included in a project plan, which is the basis for the further procedure.

A very disciplined procedure is required to achieve this, whereby responsibilities and schedules must constantly be monitored.

It must be clear, that all involved areas not only know, but understand the project proceedings.

Prior to the completion of a project or project phase, it has to be ensured that all quality requirements can be fulfilled. The relevant approvals/releases are to be provided to the project personnel.

S1.1 Are the customer requirements and expectations for this process/ service consistently identified and analyzed?

S1.2 Is a development plan, agreed with the customer, implemented for the services and service processes?

S1.3 Are approvals/releases steps available at the required time for all service elements?

S1.4 Are sufficient resources planned and is a scheduled implementation ensured?

S1.5 Has a quality evaluation of the service/process taken place and are further developments derived from it?

S1.1 Are the customer requirements and expectations for this process/service consistently identified and analyzed?

Requirements/Explanations

It is necessary, that customer requirements be considered when planning a service/a new process (e.g. through customer surveys, market research). Sub-suppliers tasks are also to be included here. The responsibility, however, remains with the suppliers.

The following points are, for example, to be considered:

- Type and scope of service
- Deadlines, location details
- Warranty scope
- Customer services/satisfaction
- Pricing, quality requirements
- Confidentiality, Discretion
- Environmental aspects
- Performance specifications
- Determination of important characteristics and process parameters
- Translation of documents into the respective national language
- Benchmarking/Competition analyses.

Customer requirements and expectations are e.g. laid down in:

- General company conditions
- Specifications (e.g.: Drawings, standards)
- Company standards
- Purchasing conditions (incl. legislation/regulations)
- Performance specifications
- Order forms.

S1.2 Is a development plan, agreed with the customer, implemented for the services and service processes?

Requirements/Explanations

Current milestone plans, network plans etc. must be provided for the development plan, which reflects all activities from contract award to service provision. A project manager, as well as all involved areas and their tasks must be identified. A central, continual monitoring function must be ensured.

Monitoring must include the compliance with all set objectives, such as:

- Deadlines
- Qualifications (Type, scope and performance of the service)
- Costs.

The following points must be considered for the service planning:

- Assessment of the requirements with regards to their suitability, clarity and completeness
- Documentation of the results
- Purchasing and use of materials required for the service
- Verification (Review of compliance with the requirements and expectations)
- Release in agreement with customer
- Consideration of changes and modifications
- Preparation of operating and installation instructions
- Information flow to and from the customer during service planning (Meetings, conferences, electronic data transfer in regular intervals)
- Work and procedure processes (flow chart)
- Expediting delivery dates (milestones)
- Specifications (including tolerances)/Scope of the individual services
- Instructions
- Software/Hardware, Inspection, measuring and test equipment
- Training scopes (internal/at customer)
- Framework conditions

- Definition of interfaces with other departments
- Determination of customer's duty to cooperate
- Determination of marketing and information policy
- Personnel requirements/occasional personnel exchanges and qualification
- Performance location
- Deviations from the plan/measures and customer notification
- Risk analysis
- Capability analyses
- Communication and information control.

S1.3 Are approvals/releases available at the required time for all service elements?

Requirements/Explanations

The approvals/releases can be related, for example, to:

- Definitions of approvals/releases and criteria
- Milestones (Approvals/release after finalization of each phase)
- Review/Verification/Validation of content and the service (Test, performance comparison, calculation check, price comparison)
- Amendments administration
- Risk assessment (Fulfillment of future scheduled dates)
- Status report.

S1.4 Are sufficient resources planned and is a scheduled realization ensured?

Requirements/Explanations

The following points are to be monitored e.g.:

- Availability of production material, equipment (Information and communication equipment) premises and documents
- Qualified personnel (Training, capability, information)
- Health and safety at work, environment
- Approval/release and securing of required investments.

S1.5 Has a quality evaluation of the service/process been carried out and are further developments derived from it?

Requirements/Explanations

In each realization phase, improvement programs for the services/processes should be introduced or implemented, whereby emphasis is placed on the prevention, not elimination of nonconformities.

Here, the following points are to be considered:

- Function
- Safety
- Reliability
- Traceability
- Availability
- Environmental aspects
- Qualification test to confirm individual requirements
- Problem areas
- Deficiencies
- Corrective and preventive actions.

The following methods are, for example, applied:

- Risk analyses (System, Design and Process FMEA)
- Function tests
- Reliability checks
- Feasibility studies
- Pilot projects.

Part B **Service**

Element **S2** **Contract Services**

Contract services used by suppliers/contractors are part of the end product.

Contract services can refer to products, as well as services. It has to be ensured, that quality assurance measures have been effectively implemented.

S2.1 What are the criteria for supplier selection and are only approved suppliers used for this service/process?

S2.2 Is the agreed quality of the contract service ensured?

S2.3 Are qualification measures introduced and realized based on the results (unsatisfactory quality performance/insufficient quality capability) of the suppliers evaluation?

S2.4 Are objectives/actions to improve processes and contract services agreed and implemented?

S2.5 Are the used contract services and their processes approved/ released?

S2.1 What are the criteria for supplier selection and are only approved suppliers used for this service/process?

Requirements/Explanations

Prior to supplier selection, an evaluation by the customer has to take place. When services are contracted, it has to be ensured that only suitable suppliers are used. Experiences from quality performance evaluations must be considered.

The suitability can be proven, e.g., through:

- Supplier meetings/ regular support
- Evaluation of quality capability, e.g. audit results
- Evaluation of quality performance
- Topicality of results
- Preventive quality assurance measures.

S2.2 Is the agreed quality of the contract service ensured?

Requirements/Explanations

To evaluate the contract service, typical, known quantities which can be evaluated have to be identified, which allow a classification in terms of suitability of this contract service.

- Agreed evaluation parameters
- Sufficient assessment possibilities
- Internal/external inspections
- Specifications (e.g. order requirements)
- QA agreements
- Coordination of inspection and test procedures and processes
- Evaluation of nonconformity focal points.

S2.3 Are qualification measures introduced and realized based on the results (unsatisfactory quality performance/insufficient quality capability) of the suppliers evaluation?

Requirements/Explanations

The capability and performance of a supplier is to be reviewed at defined time intervals and recorded in a list/supplier catalog. When negative results are found, qualification programs are to be determined. Their implementation is to be proven.

Evidence can be provided through e.g.:

- Basic talks with QA representatives/management of problem suppliers
- Records/comments on the status of improvement programs
- Action plans
- Improved service process
- Audit results.

S2.4 Are objectives/actions to improve processes and service contracts, agreed and implemented?

Requirements/Explanations

Improvements must be target-orientated. The following points are, for example, to be considered:

- Continual improvement
- Determination of measurable target parameters
- Cost optimization.

S2.5 Are the used contract services and their processes approved/released?

Requirements/Explanations

Prior to use of new/changed services/processes an approval/release has to be carried out for all services of a supplier.

Possible approval/release criteria are:

- Capability evidence for important characteristics
- Performance of simulation tests
- Trial releases
- Results of preventive quality assurance
- Compliance with the requirements (e.g. legislation, standards, safety data sheets, EC standards).

Element S3 Service Process

All of the following questions are to be evaluated for each process phase.

Sub-element S3.1 Personnel/Qualification

All company personnel are an important factor for the quality and performance capability of a company. To achieve customer satisfaction, satisfied, motivated and qualified employees are necessary.

Besides the quality-relevant subjects, relationships to the actual products/ services/processes have to be established and communicated. Hereby, simple and clear structures and processes which are understood by everybody, are useful.

Proof should be provided, that training was planned and carried out at all levels and in every area. After a set time period, the effectiveness of the applied training or qualification measure must be confirmed.

S3.1.1 Are the responsibilities/authorities of the personnel responsible for service quality determined and implemented?

S3.1.2 Are the responsibilities/authorities for production equipment and material determined and implemented?

S3.1.3 Is the personnel, used in the service process, able to fulfill it's set tasks and is the qualification monitored on a regular basis?

S3.1.4 Is the required need for personnel for the service/process identified/guaranteed and are alternative resources ensured?

S3.1.1 Are the responsibilities/authorities of the personnel responsible for service quality determined and implemented?

Requirements/Explanations

Responsibilities/authorities must be determined for, e.g.:

- Engagement in improvement programs
- Self assessment
- Process approval/release
- Process placed on hold (Release of units placed on hold)
- Information on the significance and tasks concerning essential characteristics.

Personnel-relevant documents for the process are, e.g.:

- Function description
- Responsibility matrix
- Description of tasks
- Job description
- Qualification matrix (Qualification profile)
- Information for/from the superior (objectives/process status)

S3.1.2 Are the responsibilities/authorities for plants and equipment determined and implemented?

Requirements/Explanations

Responsibilities/authorities must, for example, be determined and implemented for:

- Availability, maintenance
- System responsibility
- Operating instructions
- Work instructions
- Inspection and test instructions.

S3.1.3 Is the personnel, used in the service process, able to fulfill set tasks and is the qualification monitored on a regular basis?

Requirements/Explanations

The qualification of personnel includes, for example, the following points:

- Leadership capabilities
- Instructions/training and qualification records to the process and service
- Legislation and guidelines (Accountability, retention period of documents)
- Introduction to health and safety at work/environmental protection
- Process/service process e.g. work station/surrounding conditions and equipment
- Physical suitability
- Demonstration of targets and degree of conformity
- Promotion of quality awareness
- Knowledge about employee satisfaction
- Further training/ qualification measures.

S3.1.4 Is the required need for personnel for the service/process identified/guaranteed and are alternative capacities ensured?

Requirements/Explanations

Hereby, the following aspects are to be considered, e.g.:

- Investigating the demand for personnel
- Calculating expenditures
- Replacement ruling for important personnel.

Element **S3** **Service Process**

Sub-element **S3.2** **Providing the Service**

In this element, all quality relevant activities required for the provision of the service are summarized.

It is important that all planned measures to ensure quality have been implemented and, in the case of failures or nonconformities, supplemented or changed.

At the core of the evaluation, however, is the process necessary to provide the service.

S3.2.1 Is the service approved/released and are nonconformities to the requirements recorded?

S3.2.2 Are corrective actions reviewed with regards to their realization and effectiveness?

S3.2.3 Are the specific quality requirements of the process guaranteed?

S3.2.4 Is the effectiveness of the service process monitored?

S3.2.5 Are the relevant service process requirements displayed and implemented at the work stations?

S3.2.6 Is it ensured that the work stations and their environment correspond to the requirements?

S3.2.1 Is the service approved/released and are nonconformities to the requirements recorded?

Requirements/Explanations

For all services, an approval/release at site has to be carried out prior to the application of new/changed services/processes. The approval/release reviews have to follow clear criteria to ensure reproducibility.

These criteria can be general or process-/service-specific.

The approval/release has to be issued by „authorized“ employees in writing using acceptance criteria.

When services are released, the following points should, for example, be considered:

- Checklist with set criteria
- Completeness with regards to function, design
- Availability of operation and installation instructions
- When work is handed over (performance transfer)
- After new version/revision status
- Complete records at work station
- Topicality of the requirements and expectations
- Cleanness/tidiness at the work station
- Time frame for introduction phase
- Record nonconformities to enable their evaluation.

S3.2.2 Are corrective actions reviewed with regards to their realization and effectiveness?

Requirements/Explanations

This is valid before and after the process.

- Improvement programs from audits
- Information to the responsible party
- Interface discussion internal/external
- Internal complaints, responsible person principle (polluter-pays-principle), cost recording
- Customer survey
- Customer complaints
- Risk analyses (FMEA)
- Action follow up.

S3.2.3 Are the specific quality requirements of the process guaranteed?

Requirements/Explanations

To guarantee specific quality requirements, corresponding means/aids have to be available and a corresponding organization chosen.

Following has to be considered, e.g.:

- Approval/release status
- Current documents
- Reliability
- Targets
- Servicing and maintenance status of means used in the service process
- Inspection, measuring and test equipment
- Capability evidence
- Data bases
- Ergonomics
- Lighting.

S3.2.4 Is the effectiveness of the service process monitored?

Requirements/Explanations

To monitor the effectiveness of the service process, control mechanisms/ systems have to be introduced.

- Characteristic values for efficiency
- Simulation software
- Benchmarking (e.g. from data bases)
- Checklists (e.g. for audits)
- Inspection, measuring and test equipment
- Reliability and function tests
- Customer surveys
- Measurement accuracy/inspection and test equipment capability
- Data acquisition and it's evaluation.

S3.2.5 Are the relevant service process requirements displayed and implemented at the work stations?

Definition

Process parameters are process-influencing parameters that serve process control and regulation.

Requirements/Explanations

The relevant process parameters must be stated in process descriptions or similar documents.

- Service process/process steps
- Process parameters/data
- Inspection and test requirements (important characteristics, inspection, measuring and test equipment, methods, inspection and test frequencies)
- Capability evidence.

In case of nonconformities, the introduced actions are to be documented.

S3.2.6 Is it ensured that the work stations and their environment correspond to the requirements?

Requirements/Explanations

Work stations and their surroundings are to be matched with the operational content of the services.

- Lighting
- Ergonomics
- Tidiness and cleanness
- Environmental protection
- Health and safety at work.

Element	**S3**	**Service Process**
Sub-element	**S3.3**	**Communication, Identification, Information, Data Flow**

This element summarizes the activities which, in addition to the provision of the service, have a significant influence on the quality of the service.

In detail these are,

- storage and transport
- establishing and coordinating demands
- Handling of nonconforming products
- Securing against mix-up and exchanges by mistake
- Safeguarding
- Information flow.

Measures are to be planned which avoid the deterioration of the service quality.

S3.3.1 Are service products appropriately stored and is the transport tuned to the special characteristic of the respective service?

S3.3.2 Is the scope of the service matched to the demand and process chain and how have the interfaces to the adjacent processes been considered?

S3.3.3 Are nonconforming products from service processes identified, strictly separated and marked?

S3.3.4 Are the services and their results sufficiently protected from mix-up and exchanges by mistake?

S3.3.5 Are means and applicable documents of the service process appropriately safeguarded?

S3.3.6 Is the information flow within the service process and to the customer controlled and ensured?

S3.3.1 Are service products appropriately stored and is the transport tuned to the special characteristic of the respective service?

Requirements/Explanations

It has to be ensured, that the service product is transported and stored without risk of damage at all times. Here, a system has to be in place, which considers the following aspects:

- Damage-free storage (e.g. of data bases)
- Security against unauthorized access
- Protection against loss
- sufficiently suitable transport and storage capacities.

The method of data transfer and information exchange has to be agreed between customer and supplier. Here, the responsibilities and the communication means to be used are to be determined. The service provider has to ensure, that the confidentiality of the data/information given to him and the service provided by him is maintained. Products which are used in connection with service processes must always be currently available.

S3.3.2 Is the scope of the service matched to the demand and process chain and how have the interfaces to the adjacent processes been considered?

Requirements/Explanations

The defined requirements have to be considered in the planning tools of the service provider.

Hereby, the following points are, for example, to be considered:

- Business plan/Marketing plan
- Resources planning
- Access authorization
- Interfaces/Organization plan.

Regular implementation monitoring must be carried out and documented.

S3.3.3 How are nonconforming products from service processes identified, strictly separated and marked?

Requirements/Explanations

In the service process, it has to be ensured when a nonconformity has been identified, that the relevant areas are informed and nonconforming product are separated/marked.

Thereby, the following has to be considered:

- Customer information,
- Information to the involved process positions
- Security against unauthorized use
- Ensuring reworks.

S3.3.4 Are the services and their results sufficiently protected from mix-up and exchanges by mistake?

Requirements/Explanations

It has to be ensured, without risk of mix-up, that access to the established products and data is possible at all times. For application of the service a faultless information and data transfer is necessary.

For this, a system has to be effective, and consider the following aspects:

- Clear marking/identification
- Current (modification) status
- Security against unauthorized access
- Traceability
- Operation instructions.

For the application, the supplier might have to establish operations instructions.

S3.3.5 Are means and applicable documents of the service process appropriately safeguarded?

Requirements/Explanations

Means and applicable documents must be protected against deterioration, damage and unauthorized access. Here, suitable locations have to be chosen. Access, without risk of mix-up through clear marking/identification, must be possible.

The storage method must be agreed between the customer and the supplier. This also includes an agreement about the retention period.

It has to be considered, that when new computer generations are also introduced, continued access to older data material must be ensured.

S3.3.6 Is the information flow within the service process and to the customer controlled and ensured?

Requirements/Explanations

It has to be ensured, that transferred information completely and clearly reaches the right addressee. Defined contact stations are to be identified, which are responsible for the following aspects:

- Selecting the suitable communication means,
- Updating of data,
- Data protection,
- Software back-up copy,
- Securing the data against loss,
- Transfer and completeness,
- Archiving,
- Modifications,
- Failure strategy.

Element	**S3**	**Service Process**
Sub-element	**S3.4**	**Elimination of nonconformity and continual improvement**

This element concerns the analysis, evaluation and improvement of the service quality and the processes which are to provide the service. Therefore, a system for quality data acquisition, it‘s analysis and the evaluation of the results must be effective.

Not only improvement but also preventive actions can be derived from the current information. However, one must not forget, that for all introduced actions, their effectiveness has to be confirmed once completed.

S3.4.1 Are work and inspection and test results consistently recorded and quality processes clearly presented?

S3.4.2 Are process problems recorded, analyzed and corrective actions effectively implemented?

S3.4.3 Are the work/inspection and test results systematically evaluated and improvement programs implemented?

S3.4.4 Are actions for continual improvement introduced and implemented?

S3.4.1 Are work and inspection and test results consistently recorded and quality processes clearly presented?

Requirements/Explanations

Use of new management methods, (CIP, TQM)

- Specified/actual comparison of the set targets
- Personnel statistics (Illness frequency rate, absence, holiday)
- Degree of performance/usefulness
- Throughput/processing times, delivery reliability
- Availability
- Identification of systematic failures.

S3.4.2 Are process problems recorded, analyzed and are corrective actions effectively implemented?

Requirements/Explanations

- Problem analysis/corrective actions/responsibility/deadlines
- Process analysis
- Immediate measures.

S3.4.3 Are the work/inspection and test results systematically evaluated and improvement programs implemented?

Requirements/Explanations

- Determination of characteristic values
- Strict application of statistical methods
- Evaluation of quality records
- Identification of failure conduct and cause
- Pareto Analysis for failure focal points
- Setting up of project teams
- Evaluation of the results from improvement measures (audit).

S3.4.4 Are actions for continual improvement introduced and implemented?

Requirements/Explanations

- Appointment of CIP teams
- Promotion of suggestions for improvement
- Systematic reduction of waste (working hours lost through absenteeism, rejects, rework, nonproductive time, set-up time, insufficient plant availability).
- Examination of customer and employee satisfaction
- Lean Management
- Benchmarking.

Element S4 Customer Services/Satisfaction

This element summarizes the quality relevant activities, required after the initial provision of the service. The communication with the customer is a special key requirement. The aim of all activities must be, to increase customer satisfaction.

S4.1 Is quick, comprehensive customer information/support available when nonconformities in the service process occur and complaints are made?

S4.2 Are current complaints for this service process strictly analyzed and implemented improvements proven?

S4.3 Are failure causes analyzed for long term focal points and are improvement programs derived and implemented for this and similar service processes?

S4.4 How is customer satisfaction ensured during and after the service?

S4.1 Is quick, comprehensive customer information/support available when nonconformities in the service process occur and complaints are made?

Requirements/Explanations

The following concerns internal and external customers:

- Knowledge on current nonconformities/complaints
- Performance evaluation by the customer (quality, delivery dates, price, etc.)
- Intensive customer service (purchase, development, quality, etc.)
- Short reaction times to nonconformities/complaints in the service process
- Sufficient individual statements (no preconceived answers).

S4.2 Are current complaints for this service process strictly analyzed and implemented improvements proven?

Requirements/Explanations

- Identification and distribution of complaints
- Cause analysis by the responsible personnel
- Improvement programs with responsible personnel/deadlines.
- Revision of specifications/documents
- Maintaining the given deadlines
- Assessment of the effectiveness of measures
- Deduction of preventive actions.

Note: It is useful to proceed according to the 8-D-Method (VDA Volume 2).

S4.3 Are failure causes analyzed for long term focal points and are improvement programs derived and implemented for this and similar service processes?

Requirements/Explanations

- Point of criticism
- Initiation/Introduction problems
- Customer surveys
- Repetitive errors
- Quality of analyses
- Change of suppliers without a safeguard concept
- Supply
- Data flow/transport
- Environmental influences
- Traceability in recall actions
- Corrective actions
- Process changes (e.g. machining guidelines)
- Continual Improvement Program (CIP).

S4.4 How is customer satisfaction ensured during and after the service?

Requirements/Explanations

- Customer service
- Product liability
- Liability insurance
- Flexible reactions to market research and analyses
- Cost optimization
- Satisfaction of the end customer
- Contact person known (customer/supplier chain).

13 Comparison Matrix

In the following, the comparison tables to VDA 6.1 Quality System Audit are presented.

13.1 Comparison Matrix VDA 6.3 / VDA 6.1
(VDA 6.3 Process Audit/VDA 6.1 Quality System Audit)

The following summary, the interfaces between VDA 6.3 (Product Development Process/Serial Production) and VDA 6.1 Quality System Audit are illustrated in a table.

The table does not consider the differing intensity of the individual requirement catalogs to one another, but relates to the quality system orientated requirements.

VDA 6.3	Paragraph title/Requirement focal points according to VDA 6.3 (Product development process/serial production)	Element/ Individual questions VDA 6.1
A	***Product development process***	**Element 08/09**
	Product development (Design)	**Element 08**
M 1	**Design planning**	**Element 08**
1.1	Target customer requirements	7.4, 11.1
1.2	Compliance with product development plan/targets	8.1/2.4, 2.5, 2.6,
1.3	Planning Resources Product development	2.4, 8.1.
1.4	Identification/Consideration of product requirements	8.2
1.5	Determining feasibility	7.2, 8.4, 8.5, 9.5
1.6	Planning Personnel/Technical preconditions	8.3

M 2	Product Development (Design) Design Realization	Element 08/09
2.1	Preparation of Design FMEA	8.4
2.2	Up dating Design FMEA	8.4
2.3	Preparation of a quality plan	2.6, 2.5
2.4	Approvals/releases/qualification records	8.5
2.5	Resources Development	2.4, 8.1

VDA 6.3	Paragraph title/Requirement focal points according to VDA 6.3 (Product Development Process/Serial Production)	Element/ Individual questions VDA 6.1
	Process development	**Element 09**
M 3	**Planning of Process Development**	**Element 09**
3.1	Target Product requirements	9.3, 11.1
3.2	Compliance with process development plan/targets	9.1, 2.4, 2.5, 2.6
3.3	Planning resources Serial production	2.4, 9.1
3.4	Determination of process requirements	9.2, 14.3 ,14.5
3.5	Personnel/technical preconditions for project processing	2.4, 9.1
3.6	Preparation of process FMEA	9.4

M 4	**Realization of process development**	**Element 09**
4.1	Up dating process FMEA	9.4, 9.7
4.2	Preparation of quality plan	2.6, 2.5
4.3	Approvals/releases/qualification records	9.4, 9.5
4.4	Performance of pre-production for series release	14.2
4.5	Manufacturing and inspection and test documents	9.6, 15.1, 15.2
4.6	Production resources	14.6

B	***Serial production***	
M 5	**Supplier/ Input material**	**Element 11**
5.1	Supplier Quality capability	11.2, 11.4, 15.3
5.2	Quality guarantee for purchased parts	11.5, 11.6
5.3	Quality performance evaluation	11.4
5.4	Target agreements for continual improvement of products and processes	1.3
5.5	Releases for supplied serial products	11.3
5.6	Compliance with the procedures regarding supplied products	12
5.7	Adjusting stocks of input material	19.3
5.8	Storage of input material/internal residues	11.7, 19.5
5.9	Personnel qualifications	4.5

VDA 6.3	Paragraph title/Requirement focal points according to VDA 6.3 (Product Development Process/Serial Production)	Element/ Individual questions VDA 6.1
	Process development	**Element 09**
M 3	**Planning the process development**	**Element 09**
3.1	Target product requirements	9.3, 11.1
3.2	Compliance with product development plan/targets	9.1, 2.4, 2.5, 2.6
3.3	Planning resources Serial production	2.4, 9.1
3.4	Determination of process requirements	9.2, 14.3 ,14.5
3.5	Personnel/technical preconditions for project realization	2.4, 9.1
3.6	Preparation of process FMEA	9.4

M 4	**Realization of process development**	**Element 09**
4.1	Up dating process FMEA	9.4, 9.7
4.2	Preparation of quality plan	2.6, 2.5
4.3	Approvals/releases/qualification records	9.4, 9.5
4.4	Performance of pre-production for series release	14.2
4.5	Manufacturing and inspection and test documents	9.6, 15.1, 15.2
4.6	Production resources	14.6

B	***Serial production***	
M 5	**Supplier/input material**	**Element 11**
5.1	supplier Quality capability	11.2, 11.4, 15.3
5.2	Quality guarantee for purchased parts	11.5, 11.6
5.3	Quality performance evaluation	11.4
5.4	Target agreements for continual improvement of products and processes	1.3
5.5	Releases for supplied serial	11.3
5.6	Compliance with procedures regarding supplied products	12
5.7	Adjusting stocks of input material	19.3
5.8	Storage of input material/internal residues	11.7, 19.5
5.9	Personnel qualifications	4.5

VDA 6.3	Paragraph title/Requirement focal points according to VDA 6.3 (Product Development Process/Serial Production)	Element/ Individual questions VDA 6.1
M 6	**Production**	
6.1	**Personnel/Qualifications**	**Element 04**
6.1.1	Responsibility of employees towards control of product/process quality	2.2, 4.5
6.1.2	Responsibility of employees towards production equipment/environment	4.4, 4.5, 14.6, 14.5 14.4
6.1.3	Suitability/Employees qualification	4.4, 4.5
6.1.4	Personnel plan with replacement ruling	4.4, 4.5
6.1.5	Application of instruments to increase employee motivation	4.6, 14..7

6.2	Production Material / Equipment	Element 14
6.2.1	Suitability of production equipment/tools	14.1, 14.4
6.2.2	Suitability of used inspection, measuring and test equipment	16
6.2.3	Appropriate work and inspection stations	14.6
6.2.4	Completeness of production and inspection and test documents	9.6, 13.3, 15.1
6.2.5	Aids for set-up work	
6.2.6	Approval of process starts with recording of setting data	13.7
6.2.7	Realization of corrective actions and review of effectiveness	13.2, 14.7, 18.3

6.3	Transport/Handling/Storage/Packaging	Element 13
6.3.1	Determining the quantities required/production lot sizes	13.5
6.3.2	Appropriate storage of products/components	13.4, 19.3
6.3.3	Separation/Marking, rejects, rework, set-up parts, internal residuals	19.5
6.3.4	Securing material and parts flow, guaranteeing traceability	6.2, 13.6, 19.5
6.3.5	Storing tools, equipment and inspection and test equipment	13.4

VDA 6.3	Paragraph title/Requirement focal points according to VDA 6.3 (Product Development Process/Serial Production)	Element/ Individual questions VDA 6.1
6.4	**Fault analysis, corrections, continual improvement programs (CIP)**	**Elements 17/18**
6.4.1	Recording quality and process data	13.2, 13.3, 15.4
6.4.2	Statistical analysis of quality and process data	22.4
6.4.3	Cause analysis of deviations from product and process requirements and effectiveness of corrective actions	18.1, 18.3
6.4.4	Auditing processes and products	3.3, 3.4
6.4.5	Continual improvement of products and processes	1.3
6.4.6	Monitoring target parameters	1.2

M 7	Customer services/Customer satisfaction	Element 21
7.1	Fulfillment of customer requirements at delivery	15.5, 15.6
7.2	Guaranteeing customer service	21.4
7.3	Reaction to complaints and securing parts supply	17.2
7.4	Carrying out fault analysis and implementing improvement measures	18.1, 21.3
7.5	Personnel qualification	4.5

14 Process audit forms

It is helpful when performing process audits to use forms, as this enables the results to be summarized, quickly and efficiently and clearly for all parties.

14.1 Audit plan

- Form -

Audit plan VDA 6 Part 3 - Process audit

Audit Process/Organizational/Functional unit:

Date:

Report no.:
Issuer:
Page of

Auditors (Lead Auditor is underlined):

Seq. no.	Organizational/ Functional unit	Date/time	Location	Participants	Reference to questionaire	Necessary documents	Comments
	Closing meeting			Participants:			

14.2 Audit report

- Form A: Overall Evaluation Sheet 1/Sheet 2
- Form B: Results Summary - Product Development Process/Serial Production
- Form C: Results Summary Services
- Form D: Summary of the Evaluated Questions - Product Development Process/Serial Production
- Form E: Summary of the Evaluated Questions - Services
- Form F: Explanations to the Actual Status
- Form G: Action Plan

VDA 6, Part 3 - Process Audit
Overall Evaluation

Report no.:
Page 1

Auditing company/Organizational/Functional unit:

Auditors:

Auditid company/Works/Organizational unit

Adress:

Responsible representative:

Audited process/product/service:

Reason for the audit:

Audit date:

Degree of conformity: %

Grading:

Comment:

Completion of action plan/Responsibility/Scheduled date:

Date, Signature
Audited company

Date, Signature
Auditor(s)

VDA 6, Part 3 - Process audit
Overall Evaluation

Report no.:
Page 2

Process Audit Evaluation Scheme

Overall degree of conformity in percent	Grading of the process	Descriptionm of the grading
90 to 100	full compliance	A*)
80 to less than 90	predominant compliance	AB*)
60 to less than 80	partial compliance	B*)
less than 60	no compliance	C

*) see comment under Paragraph 7.3.1

Audit history (last result):

Comments to the audit result:

VDA 6, Part 3 - Process audit: Summary of the Results

Product Development Process/Serial Production

Customer: Supplier:
Report no.: Date:

A Product Development Process

Evaluation elements	Degree of conformity (%)		60	70	80	90	100
Product Development (Design)	$E_{A,1}$						
Process Development	$E_{A,2}$						

B Serial Production

Evaluation elements/Process steps	Degree of conformity (%)		60	70	80	90	100
Suppliers/Input material	$E_{B,1}$						
Customer services/satisfaction	$E_{B,2}$						
Process step 1	$E_{B,3}$						
Process step 2	$E_{B,4}$						
Process step 3	$E_{B,5}$						
Process step 4	$E_{B,6}$						
Process step 5	$E_{B,7}$						
Process step 6	$E_{B,8}$						
Process step 7	$E_{B,9}$						
Process step 8	$E_{B,10}$						
Process step 9	$E_{B,11}$						
Process step 10	$E_{B,12}$						
Degree of conformity (Mean $E_{B,1}$-$E_{B,n}$)	$E_{B,n}$						

Evaluation of the sub-elements with quality system reference (Mean Process step 1-n)

Sub-elements	Degree of conformity (%)		60	70	80	90	100
Personnel/Qualification	$E_{U,1}$						
Production material/equipment	$E_{U,2}$						
Transport/Parts handling/Storage	$E_{U,3}$						
Fault analyses, corrections, CIP	$E_{U,4}$						

Form B

VDA 6, Part 3 - Process audit: Summary of the Results
Product Development Process/Serial Production

Customer: Supplier:nt:
Report no.: Date:

A Product Development process

Evaluation elements	Degree of conformity (%)		60	70	80	90	100
Product Development (Design)	$E_{V,1}$						
Process Development	$E_{V,2}$						

B Serial Production

Evaluation elements/Process steps	Degree of conformity (%)		60	70	80	90	100
Suppliers/Input material	E_{V}						
Customer services/Satisfaction	E_{K}						
Process step 1	E_{1}						
Process step 2	E_{2}						
Process step 3	E_{3}						
Process step 4	E_{4}						
Process step 5	E_{5}						
Process step 6	E_{6}						
Process step 7	E_{7}						
Process step 8	E_{8}						
Process step 9	E_{9}						
Process step 10	E_{10}						
Degree of conformity (Mean E_{1}-E_{n})	E_{ges}						

Evaluation of the sub-elements with quality system reference (Mean Process step 1-n)

Sub-elements	Degree of conformity (%)		60	70	80	90	100
Personnel/Qualification	$E_{V,1}$						
Production material/equipment	$E_{V,2}$						
Transport/Parts handling/Storage	$E_{V,3}$						
Fault analyses, corrections, CIP	$E_{V,4}$						

Form B

VDA 6, Part 3 - Process audit: Summary of the Evaluated Questions

Product Development Process/Serial Production

Customer: Supplier:
Report no.: Date:

A Product Development Process

Degree of conformity (%)

a) Product Developmen(Design)

1 Planning .1 .2 .3 .4 .5 .6 **2 Realization** .1 .2 .3 .4 .5 $E_{a\,c}$

b) Process Development

1 Planning .1 .2 .3 .4 .5 .6 **2 Realization** .1 .2 .3 .4 .5 .6 $E_{P\,c}$

B Serial Production

5 Suppliers/Input material .1 .2 .3 .4 .5 .6 .7 .8 .9 E_z

6 Production (Evaluation per process step)

	6.1 Personnel/Qualification	6.2 Production material/equipment	6.3 Transport/Parts handling	6.4 Fault analysis/Corrections/CIP	
	.1 .2 .3 .4 .5	.1 .2 .3 .4 .5 .6 .7	.1 .2 .3 .4 .5	.1 .2 .3 .4 .5 .6	
Process step 1:					E_1
Prozess step 2:					E_2
Prozess step 3:					E_3
Process stept 4:					E_4
Prozess step 5:					E_5
Process step 6:					E_6
Process step 7:					E_7
Process step 8:					E_8
Process stept 9:					E_9
Process step10:					E_{10}

Assesment of the sub-elements with quality system reference Element BG (Mean Process step 1-n)

.1 .2 .3 .4 .5	.1 .2 .3 .4 .5 .6 .7	.1 .2 .3 .4 .5	.1 .2 .3 .4 .5 .6
$E_{a\,1}$ (%)	$E_{a\,2}$ (%)	$E_{a\,3}$ (%)	$E_{a\,4}$ (%)

7 Customer services/satisfaction .1 .2 .3 .4 .5 E_K

Degree of conformity $E_{P\,a}$ according to product groups Element B6 (%) Mean E_1 - E_n)

Product groups						
Process step						

$E_{P\,a}$ (%)

Overall degree of conformity E_a (%) according to product groups: E_a (%) = $\frac{E_{a\,a}+E_{P\,a}+E_z+E_{P\,a}+E_K}{\text{No. of evaluated elements}}$ (%)

Comment: Question is not applicable = entry is na

Form D

VDA 6, Part 3 - Form D “Explanations”

A Product Development Process (1)

Degree of conformity (%)

a) Product Developmen(Design) (11)

	.1	.2	.3	.4	.5	.6		.1	.2	.3	.4	.5		
1 Planning	6	8	4	8	10	8	**2 Realization**	4	nb	nb	nb	nb	$E_{D\,E}$	69

b) Process Development

	.1	.2	.3	.4	.5	.6		.1	.2	.3	.4	.5	.6		
1 Planning	6	10	4	10	10	nb	**2 Realization**	nb	6	nb	nb	nb	nb	$E_{P\,E}$	77

B Serial Production (2)

	.1	.2	.3	.4	.5	.6	.7	.8	.9		
5 Suppliers/Input material	8	8	10	10	8	10	8	8	10	E_{5}	87

6 Production (Evaluation per process step)

	6.1 Personnel/Qualification					6.2 Production material/equipment							6.3 Transport/Parts handling					6.4 Fault analysis/Corrections/CIP							
	.1	.2	.3	.4	.5	.1	.2	.3	.4	.5	.6	.7	.1	.2	.3	.4	.5	.1	.2	.3	.4	.5	.6		
Process step 1: **Pressing/Punching**	10	10	8	8	6	8	8	8	8	6	0	6	10	10	10	6	10	10	0	4	8	10	10	E_{1}	76
Prozess step 2: **Welding**	10	10	6	10	4	6	6	4	8	10	8	6	10	10	10	6	10	6	0	4	8	8	6	E_{2}	72
Prozess step 3: **Machining**	10	8	6	10	6	8	6	6	8	10	8	6	10	10	10	6	10	6	0	4	8	6	6	E_{3}	76
Process stept 4: Assembly	8	10	10	10	8	10	10	10	10	10	0	6	10	10	10	6	10	10	8	8	6	8	10	E_{4}	86
Prozess step 5:																								E_{5}	
Process step 6:																								E_{6}	
Process step 7:																								E_{7}	
Process step 8:																								E_{8}	
Process stept 9:																								E_{9}	
Process step10:																								E_{10}	

Assesment of the sub-elements with quality system reference Element BG (Mean Process step 1-n)

.1	.2	.3	.4	.5	.6	.7	.1	.2	.3	.4	.5	.1	.2	.3	.4	.5	.6	
10	10	8	10	8			8	8	6	8	10	4	6	10	10	10	6	10	8	0	4	8	8	8	(23)
E_{B1} (%)				92			E_{B2} (%)				71			E_{B3} (%)			92		E_{B4} (%)				60		

7 Customer services/satisfaction

.1	.2	.3	.4	.5		
8	8	6	10	10	E_{7}	84

Degree of conformity $E_{P\,B}$ according to product groups Element B6 (%) Mean E_{1} - E_{n})

Product groups	1	B	C			
Process step	1	1+2	1, 3+4			
$E_{P\,B}$ (%)	70	74	79			(3)

Overall degree of conformity E_{V} (%) according to product groups: E_{V} (%) = $\frac{E_{B\,B}+E_{P\,B}+E_{7}+E_{P\,B}+E_{8}}{\text{No. of evaluated elements}}$ (%)

Comment: Question is not applicable = entry is na

= 78 % (4)

1. A *Product Development Process*
   Evaluations when developing new products and processes (if a comparable serial production is available, a combination with Block B Serial Production is possible, otherwise one evaluates these separately). The structure of the questionnaire corresponds to the chronological progress of a project. The current status of the project on the date of the audit is evaluated. One evaluation can be carried out when several projects exist.

1.1 A1-2/A3-4 *Product* development/Process development:
   Process development can also be evaluated, if the product development is already completed or not carried out (e.g. at a second supplier).

2. B *Serial production*
   Evaluation after completion of the product/process development (resp. in combination with Block A Product Development Process, if a comparable production situation is given – as supplement to the evaluation). All measures of the product /process development must have been implemented, if only the serial production is to be evaluated.

2.1 B6 *Production*:
   (Focal point blocks e.g. Personnel/Qualification – vertical assessment) The focal points form the interfaces to the quality system and are additionally assessed (1.1, 1.2, 1.3, ..., 4.4, 4.5, 4.6).

2.2 B6 *Production*:
   (Process stages e.g. Pressing/Punching, Welding, Machining; etc. – horizontal evaluation) Determination, Evaluation and analysis of the individual process stages (Operational process). (E_1, E_2, E_3, ... E_n)

2.3 B6 *Production*:
   (Analysis with quality system reference) Through the vertical analysis across several process stages, possible present nonconformities are identified. Average degrees of conformity result with reference to the system (E_{U1}, E_{U2}, E_{U3}, E_{U4})

3. *Degree of conformity E_{PG} according to Product groups Element B6*:
   (Product groups/Process stages) Degrees of conformity of the individual product groups, calculated from each relevant process stage (e.g. B.: Product group A with the process stages Pressing/Punching; Product group B with the process stages Pressing/Punching and Welding; Product group C with the process stages Pressing/Punching, Machining and Assembly)

4. *Overall degree of conformity EP according to production groups*:
   Overall degree of conformity to the production groups (product groups, process stages) calculated from the degrees of conformity of the individual elements:

   e.g. B. $E_{DE}+E_{PE}$, $E_Z+E_{PG}+E_K$ or E_{DE} to E_K.

   The overall result is documented on page 1.

VDA 6, Teil 3 - Process audit: Summary of the Evaluated Questions

Services

Customer: Supplier:
Report no.: Date:

A Service Development Process

Degree of conformity (%)

1 Planning .1 .2 .3 .4 .5 $E_{1.}$

B Service

2 Contract Services .1 .2 .3 .4 .5 $E_{2.}$

3 Service Development Process (Evaluation per process step)

	3.1 Personnel/ Qualification .1 .2 .3 .4	3.2 Providing the service .1 .2 .3 .4 .5 .6	3.3 Communication, Identification, Information, Data flow .1 .2 .3 .4 .5 .6	3.4 Fault analysis/ Corrections/CIP .1 .2 .3 .4	
Prozess stept 1:					$E_{3.}$
Process step 2:					$E_{3.}$
Process step 3:					$E_{3.}$
Process step 4:					$E_{3.}$
Process step 5:					$E_{3.}$
Process step 6:					$E_{3.}$
Process step 7:					$E_{3.}$
Process step 8:					$E_{3.}$
Process step 9:					$E_{3.}$
Process step 10:					$E_{3.}$

Evaluation of the sub-elements with quality system reference Element BG (Mean Process step 1-n)

.1 .2 .3 .4	.1 .2 .3 .4 .5 .6	.1 .2 .3 .4 .5 .6	.1 .2 .3 .4
$E_{3.1}$ (%)	$E_{3.2}$ (%)	$E_{3.3}$ (%)	$E_{3.4}$ (%)

4 Customer services/satisfaction .1 .2 .3 .4 .5 $E_{4.}$

Degree of conformity $E_{x.}$ according to product groups Element B6 (%) Mean $E_{4.}$ - $E_{x.}$)

Product groups						
Process step						
$E_{x.}$ (%)						

Overall degree of conformity $E_{.}$ (%) according to product groups: EP (%) = $\frac{E_{x.}+E_{x.}+E_{x.}+E_{x.}+E_{x.}}{\text{No. of evaluated elements}}$ (%)

Comment: Question is not applicable = entry is na

Form E

VDA 6, Part 3 - Process Audit

Explanation

Report no.:
Page of

Comments to element/question:

Form F

14.3 Action Plan

- Form -

Form G

VDA 6 Part 3 - Process Audit

Action Plan

Audited Process/Organizational/Functional unit:

Report No.:
Issuer:
Page of

Date:

Reference to Process Audit:

Seq. No.	Reference to Questionnaire	Nonconformities	Corrective actions	Responsible	Schedulded date	Degree of completion in %

14.4 Other VDA-Forms

FIRST SAMPLE TEST REPORT - new version

- **Cover Page**, Order No. 2661
- **Test results**, Order No 2662
  Multipart form set, 5 copies (packed of 50 sets)
- **Outline form for process capability verification**, Order No. 2663
  Pad of 50 sheets - Minimum order 1 pad

FIRST SAMPLE TEST REPORT - present edition
First Sample Test Report - Report result, Order No. 5331
Multipart form set, 7 copies (packed of 50 sets)

First Sample Test Report - Test result, Order No. 5332
Pad of 100 sheets

SYSTEM - FMEA
- new version -
Order No. 7422, DIN A3 format, Pad of 50 sheets

FAILURE-POSSIBILITY- AND INFLUENCE-ANALYSIS (EMEA)
- old Version -
Order No. 769, DIN A3 format, Pad of 50 sheets

QUALITY SYSTEM AUDIT (Material products)

Questionnaire (only questions)
DIN A5, Pad of 10 sets á 12 sheets

Evaluation documents
Final evaluation of the quality system
Summary of results
Total grading
Summary of evaluated questions
Individual measures
Corrective Aotions-Outline
DIN A4, Pad of 10 sets of 5 sheets

The two pads form a unit and are only offered as **a set**
Order No. 1749

Order:
DRUCKEREI HENRICH GMBH
Schwanheimer Straße 110, D-60528 Frankfurt
Telephone (069) 96777-158, Telefax (069) 96777-159

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Quality Assurance prior to Serial Application
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Volume 6 Part 1
Quality System Audit, Basics DIN EN 150 9001 and DIN EN ISO 9004

Volume 6 Part 2
System Audit - Services

Volume 6 Part 3
Process Audit

Volume 6 Part 5
Product Audit

Volume 7
Basics for Interchange of Quality Data
- Electronic Transfer of Quality Data -

Volume 8
Guidelines for Quality Assurance of Trailer, Superstructure and Container Manufacturers

Volume 9
Emissions and Consumption

Notes

Notes

Notes