

# Quality Management in the Automotive Industry

---

## Process Audit

## Part 3

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

---

**3<sup>rd</sup> Completely revised edition July 2016**  
**Online-Download-Document ©**

# **Process Audit**

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

3<sup>rd</sup> Completely revised edition, July 2016

**Verband der Automobilindustrie e.V. (VDA)**

ISSN 0943-9412  
Yellow-draft\_Online-Download-Document

Copyright 2016 by

Verband der Automobilindustrie e.V. (VDA)  
Qualitäts Management Center (QMC)  
10117 Berlin, Behrenstr. 35

Overall production:  
Henrich Druck + Medien GmbH  
60528 Frankfurt am Main, Schwanheimer Straße 110

Printed on chlorine-free bleached paper

## **Non-binding VDA Standard recommendation**

The Association of the German Automotive Industry (VDA) recommends its members to apply the following standard for the implementation and maintenance of quality management systems.

## **Exclusion of Liability**

VDA volumes are recommendations available for general use. Anyone applying them is responsible for ensuring that they are used correctly in each case.

This VDA volume takes into account state of the art technology, current at the time of issue. Implementation of VDA recommendations relieves no one of responsibility for their own actions. In this respect everyone acts at their own risk. The VDA and those involved in VDA recommendations shall bear no liability.

If during the use of VDA recommendations, errors or the possibility of misinterpretation are found, it is requested that the VDA be notified immediately so that any possible errors can be corrected.

## **Referenced standards**

The quotations from standards identified with their DIN number and issue date are reproduced with the permission of the DIN Deutsches Institut für Normung e.V.

The version with the latest issue date, available from the publishers Beuth Verlag GmbH, 10772 Berlin, is definitive for the use of the standard.

## **Copyright**

This publication including all its parts is protected by copyright. Any use outside the strict limits of copyright law, is not permissible without the consent of VDA-QMC and is liable to prosecution. This applies in particular to copying, translation, microfilming and the storing or processing in electronic systems.

## **Translations**

This publication will also be issued in other languages. The current status must be requested from VDA QMC.

## Preface

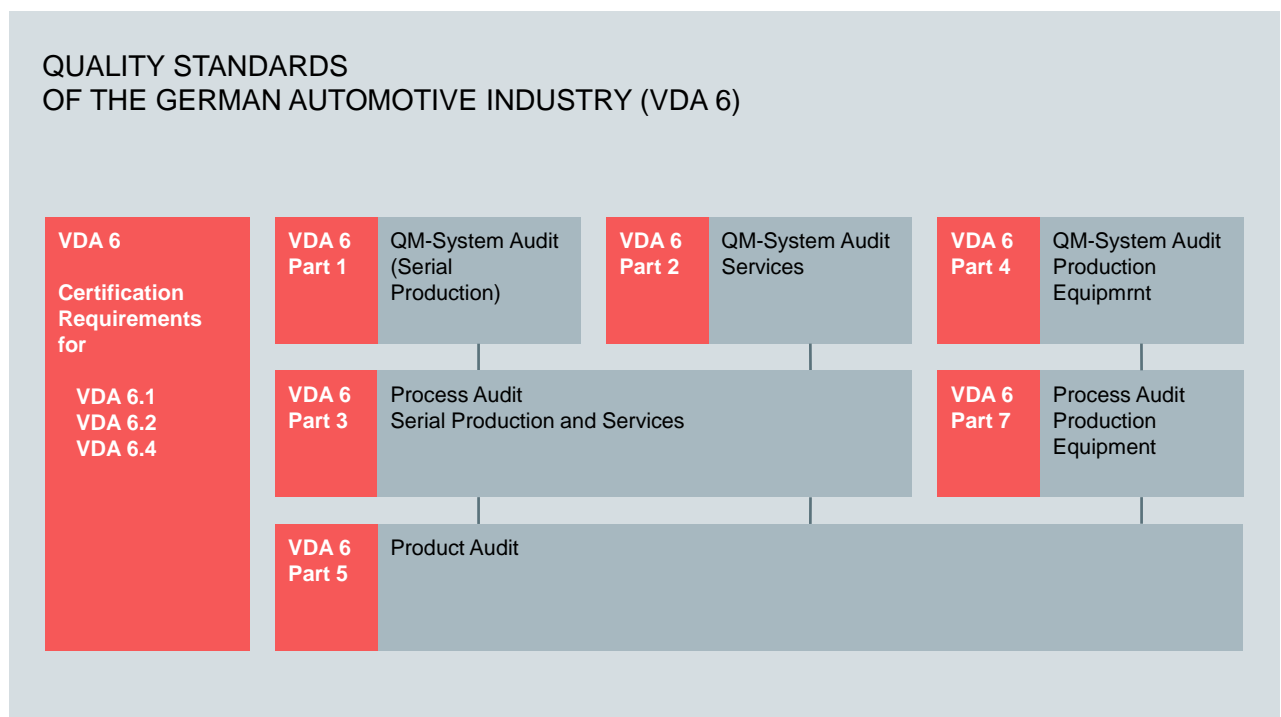
Technical progress, customer expectations and new production technologies lead to increasing demands in the entire chain of customer and supplier processes. This continually poses the quality management of companies with new and challenging tasks. It is necessary to ensure that robust processes are in place and secure throughout the manufacturing and supply chain.

The process audit following VDA 6.3 is an important and well established method for the analysis of processes. The process audit exhibits a high effectiveness through the evaluation of the real performance of the processes on site, by examining the interfaces and the supporting functions in the project and serial phase.

After a first edition was published in 2008 a complete revision was made in 2010. With the 2016 edition we have used our collective experience to update and optimise the volume.

The process standard VDA 6.3 contains the current questionnaire and evaluation criteria and additionally the requirements for the qualification of process auditors and the preparation and implementation of process audits.

The process audit following VDA 6.3 is part of the VDA strategy „Quality Standard for the Automobile Industry“ (VDA6.x Volumes).



There is agreement between automobile manufacturers and suppliers on the execution of audits in accordance with this publication.

We thank the organisations involved and their employees for their contributions to the preparation of this publication. The following firms have cooperated in drawing up the publication:

Adam Opel AG

Audi AG

Benteler Automobiltechnik GmbH

BMW AG

Borg Warner GmbH

Continental AG

Daimler AG

Harman Becker GmbH

Knorr-Bremse Systeme für Nutzfahrzeuge GmbH

Magna International Europe AG

MAN Truck & Bus AG

Otto Fuchs KG

Dr. Ing. h.c. F. Porsche AG

Robert Bosch GmbH

Rollax GmbH

Schaeffler AG

Volkswagen AG

ZF Friedrichshafen AG

Technical and administrative assistance:

TU Berlin, Department of Quality Strategy and Quality Competence

VDA QMC

Berlin, 2016

Verband der Automobilindustrie (VDA e.V.)



## Contents

<b>Preface</b>	<b>4</b>
<b>1 Introduction</b>	<b>9</b>
<b>2 Instructions for use</b>	<b>11</b>
2.1 Definition of Process Audit	11
2.2 Area of application for a process audit	11
2.3 Classification Process audit – Potential analysis	13
2.4 Identification of process risks (risk analysis)	14
<b>3 Requirements for Process Auditors</b>	<b>16</b>
3.1 Auditor Qualification	16
3.1.1 Internal Auditors	16
3.1.2 Supplier auditor	16
3.1.3 Auditing as an independent auditor	17
<b>4 Audit process</b>	<b>19</b>
4.1 Audit programme	19
4.2 Audit contract	21
4.3 Audit preparation	23
4.4 Implementation	28
4.5 Evaluation	31
4.6 Presentation of results	33
4.7 Follow up and closure	36
<b>5 Potential Analysis (P1)</b>	<b>39</b>
5.1 Definition of Potential Analysis	39
5.2 Requirements	39
5.3 Preparation	39
5.4 Operational sequence of a potential analysis	40
5.5 Evaluation of a potential analysis	41
5.6 Follow-up activities after contract award	43
<b>6 Evaluating a process audit for material products</b>	<b>44</b>
6.1 Evaluation of the individual questions	44
6.2 Detailed Evaluation and Downgrading Rules	46
6.3 Overall Level of Performance	47
6.4 Evaluation of Product Groups	50
6.5 Using the questionnaire (Process elements P2 to P7)	51



<b>7</b>	<b>Questionnaire</b>	<b>53</b>
7.1	Overview Questionnaire	53
7.2	Project management (P2)	57
7.3	Planning the product and process development (P3)	61
7.4	Implementation of the product and process development (P4)	65
7.5	Supplier Management (P5)	69
7.6	Process Analysis Production (P6)	73
<b>8</b>	<b>Process Audit Services</b>	<b>93</b>
8.1	Overview Questionnaire for Services	93
8.2	Project management (S2)	96
8.3	Planning of the service development (S3)	100
8.4	Implementation of the service / service development (S4)	102
8.5	Supplier Management (S5)	106
8.6	Providing the Service (S6)	109
8	Evaluating a process audit for services	124
8.1	Evaluation of the individual questions	124
8.8.2	Detailed Evaluation and Downgrading Rules	126
8.8.3	Overall Level of Performance	127
<b>9</b>	<b>Assessment forms</b>	<b>129</b>
9.1	Process Audit for Material Products	129
9.2	Potential analysis (P1) as an extract from the VDA questionnaire	131
<b>10</b>	<b>Best Practice / Lesson Learned</b>	<b>133</b>
10.1	Example of a supplier self-assessment	133
10.2	Knowledge Database	137
<b>11</b>	<b>Glossar</b>	<b>140</b>
11.1	Terms and Definiton	140
11.2	List of Abbreviations	146
<b>12</b>	<b>Downloads</b>	<b>147</b>
<b>13</b>	<b>Overview Matrix</b>	<b>148</b>

# 1 Introduction

The well established Audit Standard VDA 6.3 from 2010 has been completely revised. With the 2016 edition we have used our collective experience to update and optimise the volume.

The interaction of the process audit standard VDA 6.3 with other VDA publications, especially „Maturity Level Assurance for New Parts (MLA)“ und „Robust Production Processes (RPP)“, is strengthened. In this volume the requirements are given for process specific content. Thus the distinction between process and system audits is made clearer.

Furthermore the questionnaire has been revised both in content and structure. The interface between hardware and software in products with embedded software has been included. However, for a detailed evaluation of software development other methods are to be used (Automotive SPICE, CMMI....)

The content of the process audit for services has also been revised.

The calculation of results has been adjusted. All questions are now weighed equally. The generic approach has been deleted. The classification system using A, B and C and the reliable downgrading rules, including the provision for \*-questions have been retained.

Within this volume, the requirements for the qualification of process auditors are given in more detail. Different requirements for internal and external process auditors are given. The qualification of auditors regarding this audit standard is set out. Focus is also given to the actual implementation of the audit.

Assessment questions in the areas of sustainable development, compliance with social standards, environmental protection and conservation of resources are not contained in the questionnaire. For these areas there are special monitoring methods as well as legal and normative directives.

However, if the auditor observes obvious points that are contrary to the requirements of this process audit standard or have a negative impact on the product characteristics, these should be documented and included in the evaluation.

The other volumes of the VDA series and the AIAG manuals are given as a reference in a matrix that relates to the questionnaire.

Current information and the latest status of the VDA publications can be found on the VDA QMC website.

## **2 Instructions for use**

### **2.1 Definition of Process Audit**

A process audit is a method for impartial analysis and evaluation of the performance of a product development cycle and the effectiveness for the defined product.

The goal of the process audit is to check the conformity of the requirements / process step with the specifications. Any deviations that are detected are documented as audit findings and evaluated based on the product risk and / or the process risk. The evaluation must consider what the resulting risks would be if the findings indicate non-compliant products.

### **2.2 Area of application for a process audit**

Process audits can be used internally as well as externally throughout the entire product life cycle. The questionnaire is constructed in such a way that it can be used for small and medium-sized companies as well as for large corporations.

Using the VDA 6.3 process audit, the processes in the product development process (PEP) can be analysed and the maturity level and process risk evaluated before SOP.

After SOP the process audit can be used for example for the regular monitoring of the serial production and event orientated failure analysis and elimination. The use of the individual process elements in the project phase can vary in content and implementation period between internal and / or external applications.

Fig. 2-1 shows possible use of the individual process elements within the context of a specific project.

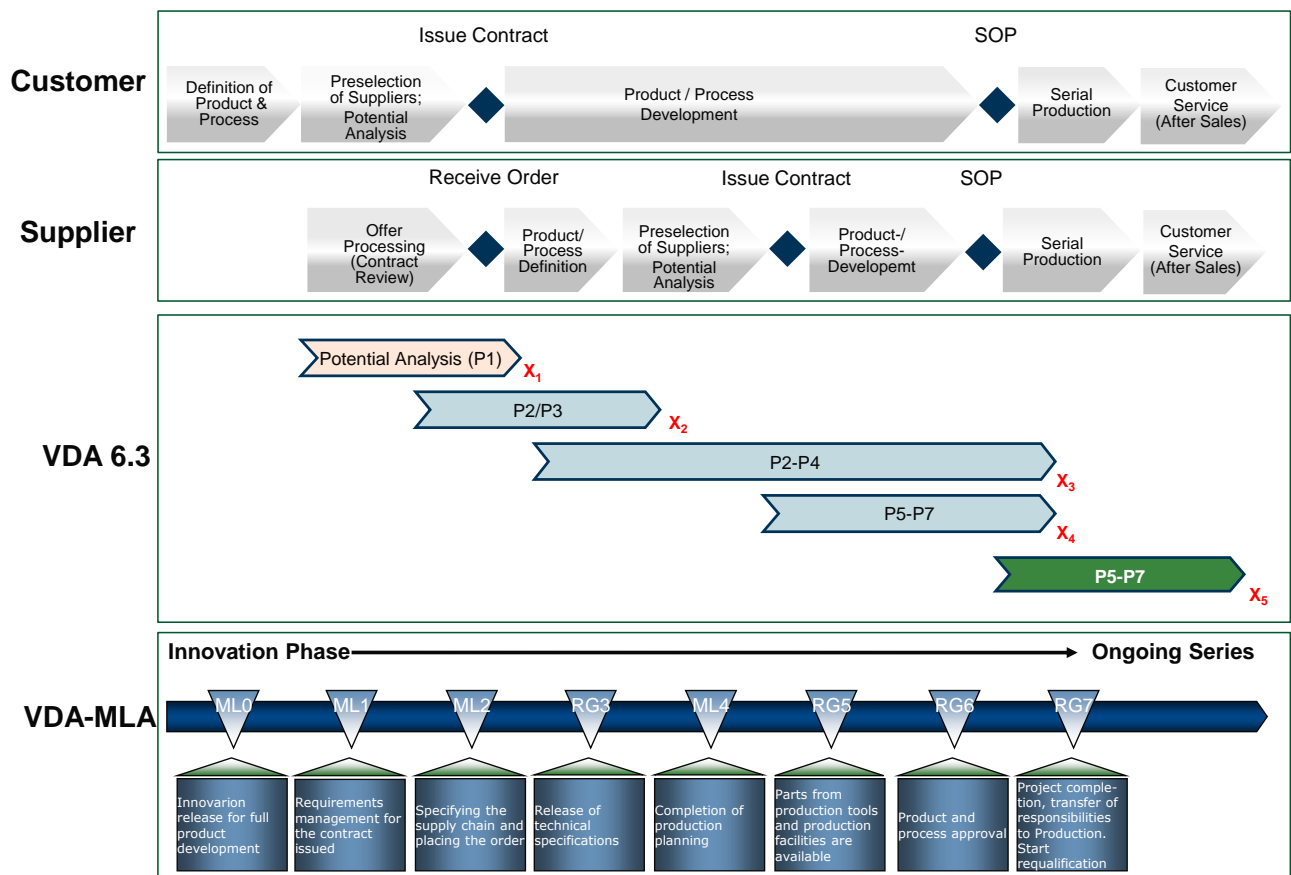


Fig. 2-1: Possible use of the process elements

- P1: Potential analysis
- P2: Project management
- P3: Planning the product- und process development
- P4: Implementation of the product and process development
- P5: Supplier management
- P6: Process analysis / Production
- P7: Customer support, customer satisfaction, service

For the potential analysis (x1) see chapter 5.

The focus of the use of process elements P2 to P4 is on the early phase of the product development process (X<sub>2</sub> + X<sub>3</sub>). Both the process element P2 and the process element P3 are used ideally to analyse the planning activities after contracting (X<sub>2</sub>).

The process element P4 can be scheduled at a later time to analyse and evaluate the implementation of the planning activities in accordance with process element P3 (X<sub>3</sub>).

If applied appropriately, the breakdown of the process elements offers the possibility to act on the potential identified during the audit. This ensures the fulfilment of customer requirements by influencing planning activities and implementation of changes. The application of the process elements P2 to P4 is utilised for early identification of maturity level and process risks from the contracting stage to SOP.

The process elements P5 to P7 (X4) are ideally applied at SOP analogous / according to maturity level RG 6 from VDA-MLA. As part of the serial production process elements P5 to P7 (X5) can be used for the regular monitoring of the serial process or to support an event-based reactive process analysis.

In principle, each user / company has the right to align the use of the process elements to meet their needs during the product development and production

## 2.3 Classification Process audit – Potential analysis

As can be seen from Fig. 2-2, an analysis of potential (P1) can be carried out before a project is launched. The questionnaire, with a reduced scope, can be used to assess potential suppliers who may be suitable as serial production suppliers. Because these are potential suppliers the audit, when necessary must be based on other processes / products which should be comparable with the product to be supplied.

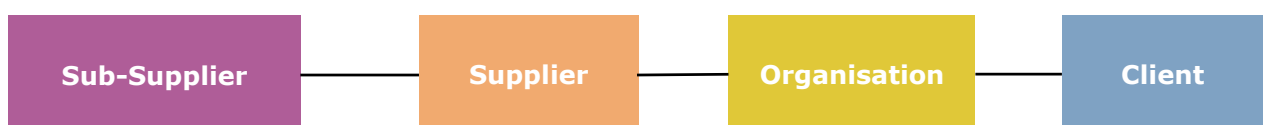
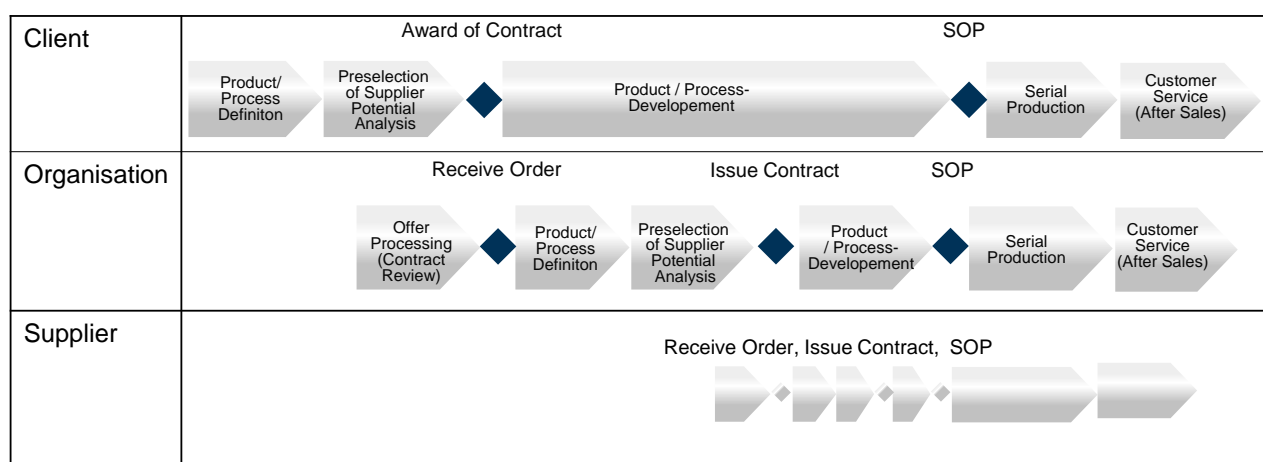


Fig 2-2: Scope of application in the supply chain

## 2.4 Identification of process risks (risk analysis)

In a process audit, the effect of the individual processes on the product is decisive and the assessment must therefore be made from the stand-point of the product risks involved. For this reason, the potential risks within the process must be determined as early as the preparations for the audit (see also Section 4.3), so that they may be assessed adequately in the process audit itself.

An example of the turtle model using process element 6 is shown below, but the model can be used for all process elements.

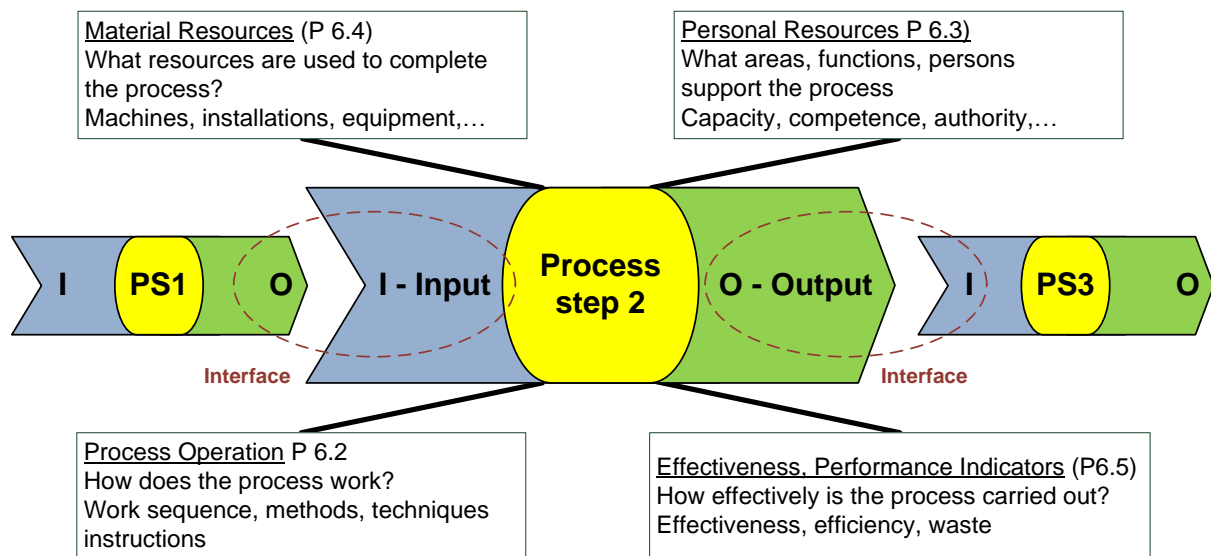


Fig. 2-3: Turtle Model

Firstly a description is given of what "input" is converted into an "output" by the process. This is expanded by considering the following questions:

- How does the process work? (work content, workflow, methods, process, instructions – see questionnaire element 6.2).
- What functions/areas/personnel support the process? (human resources, resources such as capacities, competencies, authorities, qualifications – see questionnaire element 6.3).
- What means are employed to carry out the process? (material resources such as machines, tools, testing equipment, facilities other equipment – see questionnaire element 6.4).
- How effectively is the process carried out? (effectiveness, performance indicators, efficiency, waste avoidance, reduction in process variation – see process element 6.5).

In a second stage the potential risks arising from these questions are determined. These potential risks must then be questioned and evaluated in the audit. This ensures a reasonable degree of risk minimisation.

The auditor and / or the audit team should make use of their know-how to identify potential product and process risks that could affect the product quality. This allows focusing on specific points and / or limiting the scope of the audit. Interfaces have a substantial influence. At interfaces information can be lost or incorrect information can be passed on (change management).



## 3 Requirements for Process Auditors

### 3.1 Auditor Qualification

Auditor qualification is a precondition for achieving the audit objectives. Audit results and comparability are greatly influenced by the qualification of the auditors. In addition to the minimum requirements, each organisation determines their qualifications for auditors. The organisation determines and documents the procedure for auditor evaluation including the approval, maintenance and improvement of auditor qualifications (e.g. observation during audits / approval and witness audits).

#### 3.1.1 Internal Auditors

##### Specialised knowledge:

- Good knowledge of quality tools and methods (e.g. audit process, FMEA, 8D Method, PPF, SPC, FTA)
- Knowledge of the relevant customer specific requirements
- Knowledge of the relevant management system requirements (e.g. ISO/TS, DIN EN ISO 9001, VDA 6.1)
- Specific knowledge regarding the product and process

##### Evidence of specialised training:

- Successful participation in a VDA 6.3 training (pass mark in the knowledge test)

##### Professional Experience:

A minimum of 3 years professional experience (from 2 years professional experience company training periods may be considered additionally), preferably in manufacturing companies within the automobile industry, including at least one year experience in quality management.

#### 3.1.2 Supplier auditor

##### Specialised knowledge:

- Excellent knowledge of quality tools and methods (e.g. audit process, FMEA, 8D Method, PPF, SPC, FTA)
- Auditor qualifications (negotiation, conflict management, audit procedure) Knowledge of the relevant customer specific requirements
- Knowledge of the relevant management system requirements (e.g. ISO/TS 16949, DIN EN ISO 9001, VDA 6.1)

- Knowledge of the relevant management system requirements (e.g. ISO/TS, DIN EN ISO 9001, VDA 6.1)
- Specific knowledge regarding the product and process

#### Evidence of specialised training:

- Auditor qualification as EN ISO 19011 (e.g. VDA6.3 – basic qualification, first / second party auditor for DIN EN ISO 9001, ISO/TS 16949, or VDA 6.1)

#### Professional Experience:

- A minimum of 5 years professional experience (from 3 years professional experience company training periods may be considered additionally), preferably in manufacturing companies within the automobile industry, including at least one year experience in quality management.
- Successful participation (pass mark in the knowledge test) in a VDA 6.3 training carried out by VDA QMC or one of its licensees

### **3.1.3 Auditing as an independent auditor**

External auditors are from independent, third party organisations and carry out audits as a service for the organisation.

#### Specialised knowledge:

- Excellent knowledge of quality tools and methods (e.g. audit process, FMEA, 8D Method, PPF, SPC, FTA, SWOT; DOE)
- Auditor qualifications (negotiation, conflict management, audit procedure)
- Knowledge of the relevant customer specific requirements
- Knowledge of the relevant management system requirements (e.g. ISO/TS 16949, DIN EN ISO 9001, VDA 6.1)
- Specific knowledge of the product and process

#### Evidence of specialised training:

- Qualification as an auditor on the basis of EN ISO 19011 (e.g. VDA-6.3-Basic qualification, 1st/2nd party auditor for DIN EN ISO 9001, ISO/TS 16949, or VDA 6.1)

- Successful participation (pass mark in the knowledge test for the qualification certificate) in a VDA 6.3 training carried out by VDA QMC or one of its licensees

#### Professional Experience:

A minimum of 5 years professional experience (from 3 years professional experience company training periods may be considered additionally), preferably in manufacturing companies within the automobile industry, including at least two years' experience in quality management.

## **3.2 Code of Conduct for Auditors**

- Process auditors must use their professional skills and judgement, while respecting the law and upholding the principles of honesty and integrity.
- Process auditors must continually develop their expertise. They maintain their knowledge and skills with respect to audit procedures, QM systems, products and processes as well as specialised methods, procedures and relevant standards. They must be knowledgeable about the quality requirements for products as well as the specific process risks and the possible impact on the manufactured products.
- Process auditors must at all times behave in a way that does not endanger the image and reputation of their own organization
- Process auditors must not accept assignments that would cause them a conflict of interests.
- Process auditors must not accept assignments that they cannot carry out properly because of lack of knowledge.
- Process auditors are bound to secrecy regarding confidential information that they have acquired through their professional activities. This obligation does not apply if the disclosure of information is required by law.
- Process auditors must not use information obtained during audits dishonestly giving an unfair advantage to themselves or to others.
- Auditors protect the reputation and standing of the profession.

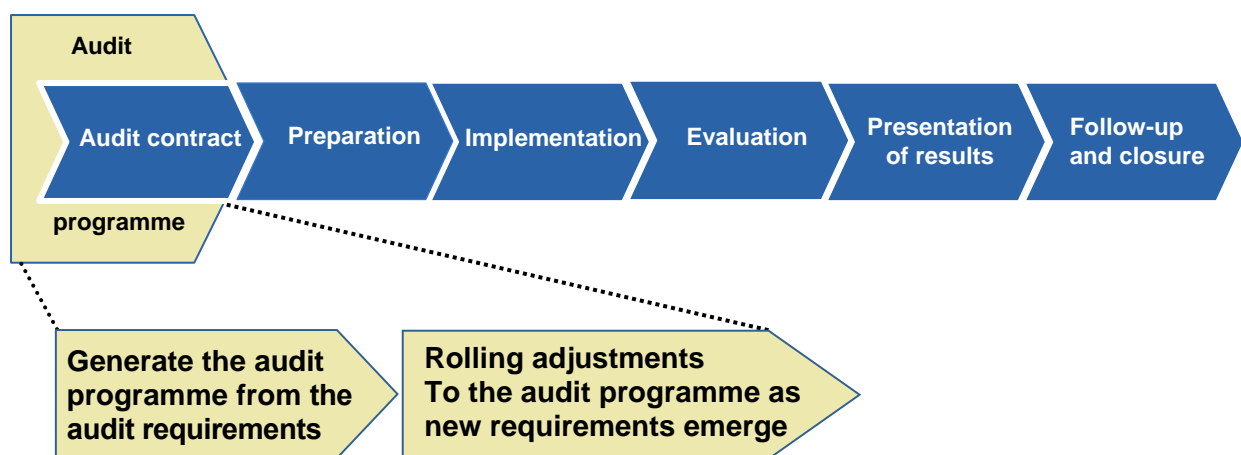
## 4 Audit process

This section describes the procedure for the implementation of internal and external audits



Fig. 4-1: Audit process

### 4.1 Audit programme



Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Audit requirements</li> <li>- Time frame</li> <li>- Auditor pool</li> <li>- Current audit programme</li> <li>- Experience from previous years</li> </ul>	<div>Generate the audit programme from the audit requirements</div>	<ul style="list-style-type: none"> <li>- Audit programme</li> </ul>

#### Objective:

Audits are planned in accordance with their priority and the company's in-house requirements. Qualified auditors are used to achieve the objective.

#### Responsibility:

The person responsible for the audit programme draws up an audit schedule for a defined period.

**Description:**

The number of audits is determined and prioritised by the person responsible for the audit programme. From this, this person works with the audit client (and, where appropriate, the organisation to be audited) to set out the following details regarding the audit:

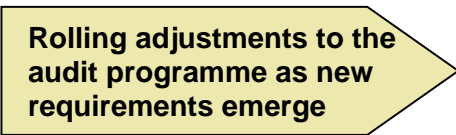
- The main focus of the audit
- The calendar week of the audit
- The number of days required for the audit
- Details of the auditors, in particular the process experts

In addition to technical qualifications and the necessary neutrality, the choice of auditors should also take language skills and inter-cultural aspects into account.

A process expert is necessary to assess process-specific questions beyond the competence of the process auditor. This process expert need not necessarily be a VDA process auditor. In conclusion, the audit programme is approved by the respective management.

**Method / documentation**

Audit programme

Input:	Process stage:	Output:
<ul style="list-style-type: none"><li>- <b>Event-driven audit need</b></li></ul>		<ul style="list-style-type: none"><li>- <b>Current audit programme</b></li><li>- <b>Up-dated resource planning</b></li></ul>

**Objective:**

As a result of continuous adjustment the audit programme is kept current (e.g. addition of event-driven audits)

**Responsibility:**

The person responsible for the audit programme continually adjusts the audit schedule and plans resources accordingly

**Description:**

Current quality problems in production or at the supplier's premises, production downtimes, supply shortfalls, new product launches or changed priorities can create new audit requirements at any time.

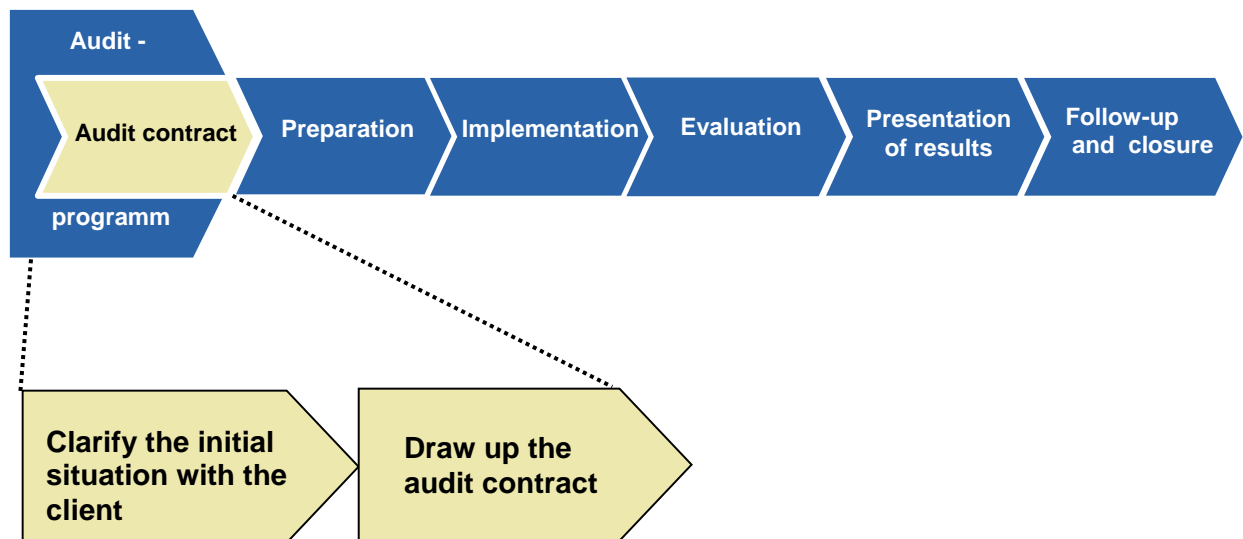
During the whole course of validity of the audit programme, the person responsible for the audit programme must ensure that these additional audits are included in the audit schedule. The existing resources must be adapted to meet the new requirements. To achieve this, the person responsible for the audit programme up-dates the existing programme and resource planning before coordinating with the organisations to be audited and if necessary the audit client.

Management must be involved in up-dating the audit programme.

**Method / documentation**

Up-dated audit programme

## 4.2 Audit contract



Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Reason for the audit</li> <li>- Audit programme</li> </ul>	<div>Clarify the initial situation with the client</div>	<ul style="list-style-type: none"> <li>- Audit contract</li> </ul>

### Objective:

The requirements of the audit client are set out in a precisely detailed audit contract.

Examples of requirements:

- determine / assess / approve the current status
- analyse / estimate risks
- qualify / encourage / improve
- check the effectiveness of actions from a previous audit
- escalation


The audit contract is coordinated between all parties involved in the audit.

### Responsibility:

Person responsible for the audit programme with the support of the client.

### Method / documentation

---

Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Initial situation</li> <li>- Reason for audit</li> </ul>		<ul style="list-style-type: none"> <li>- Audit contract</li> </ul>

#### Objective:

Draw up an audit contract with all the information required for a structured implementation of the audit

#### Responsibility:

The audit client, with support from the person responsible for the audit programme

#### Description:

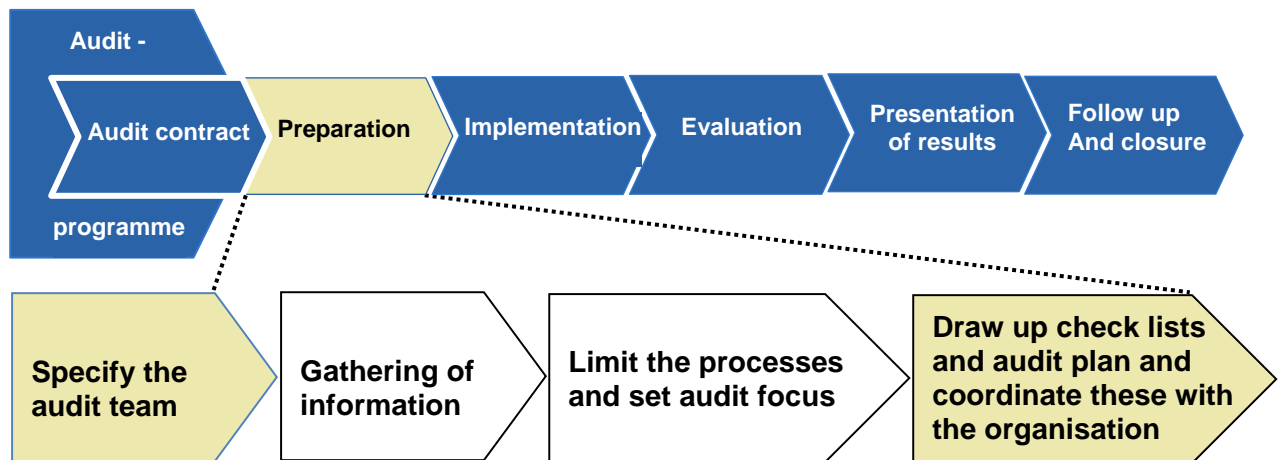
The following factors are for example to be taken into account in an audit contract:

- |                            |  |
|----------------------------|--|
| - Reason for the audit     | e.g. new supplier, compliants, evaluation of status  |
| - Audit objective          | Assessment; process release; status check; etc.  |
| - Audit type               | Internal/external audit, potential analysis, special audit                                 |
| - Audit location           | internal, external   |
| - Audit team (provisional) | Auditor, process experts(s)  |
| - Audit extent             | Processes, products, manufacturing locations, interfaces, outsourced processes             |
| - Client                   | Person responsible for the audit programme, management, person responsible for the product |
| - Audit date               | Desired date, audit period, shifts   |
| - Date of the contract     |  |
| - Comments                 | Background information   |
| - Essential documents      | Testing specifications, contracts, important agreements, cost stipulations etc.            |
| - History                  | Complaints, rejects, delivery performance, project status                                  |

#### Method / documentation:

Audit contract form

## 4.3 Audit preparation



Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Audit contract</li> <li>- Process documents</li> </ul>	<div>Specify the audit team</div>	<ul style="list-style-type: none"> <li>- Audit team</li> </ul>

### Objective:

Selection of a suitable audit team with appropriate qualifications

### Responsibility:

The lead auditor specifies the final audit team and organises the audit with the team.

### Description:

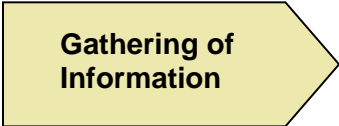
The audit team is appointed on the basis of the audit contract, any other relevant information and by the schedule in the audit programme.

In addition to the personal suitability of the auditors and any technical experts (see Section 3.2: "Code of conduct for auditors") the qualifications for the auditor must be taken into account, especially technical knowledge. A process expert should be provided to assess process-specific questions beyond the competence of the process auditor. This process expert need not necessarily be a VDA process auditor.

### Method / documentation:

Code of conduct, audit contract



Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Audit contract</li> <li>- Audit team</li> <li>- Information</li> </ul>		<ul style="list-style-type: none"> <li>- Documents</li> <li>- Gathered information</li> </ul>

#### Objective:

The audit team obtains all the information required to plan the audit.

#### Responsibility:

Audit team with the support of the client and the organisation to be audited.

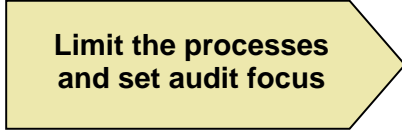
#### Beschreibung:

The information collected for the audit must be able to describe the process as well as the interplay and interfaces between processes. The following documents can be taken into account:

Organisational charts, process flow chart, control plans (internal audit), FMEAs (internal audit), standards, specifications, customer specific requirements, target requirements (e.g. PPM), process descriptions, quality control charts, audit results, action plan from last audit, results of supplier quality assessments (quality performance), complaints, layouts, project plans etc.

#### Method / documentation:

---

Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Audit contract</li> <li>- Documents / Gathered information</li> </ul>		<ul style="list-style-type: none"> <li>- Process limits</li> <li>- Process stages</li> <li>- Focus points for the audit</li> </ul>

#### Objective:

The process is limited and broken down into process steps which can be audited. The focus points for the audit are determined.

#### Responsibility:

Audit team

#### Description:

The first stage in narrowing down the process is to identify the starting and finishing points of process. The second step is to break down the process into separate operations in such a way that they can be assessed as separate entities. It is essential to specify the responsibilities involved to ensure that the findings at each process / process step are properly addressed.

The breakdown of the process can be based on existing documentation (e.g., process flow chart) or it must be carried out by the audit team.

The process risk estimation for the isolated process must be based on the information which is gathered.

The auditor sets main focus points for the audit in the areas where he/she expects the greatest potential risk for product and process. One method of detecting potential risks is the "turtle" procedure.

The following investigations can be carried out, depending on the audit contract and the potential risks which have been identified:

#### Investigation of the process flow:

An audit is carried out along the value creation chain. Various process inputs are specified as relevant and the review is restricted to their influence on the process chain and/or further operations in the process chain.

#### Process interface investigation:

The interface between two processes with different tasks is investigated in regard to responsibilities, communications, the transfer of goods and information, etc.

The two investigations can be combined.

To narrow down the manufacturing processes, the range of the audit scope is broken down into individual process steps and/or product groups (see Fig. 5). A product group may contain one or several process operations.

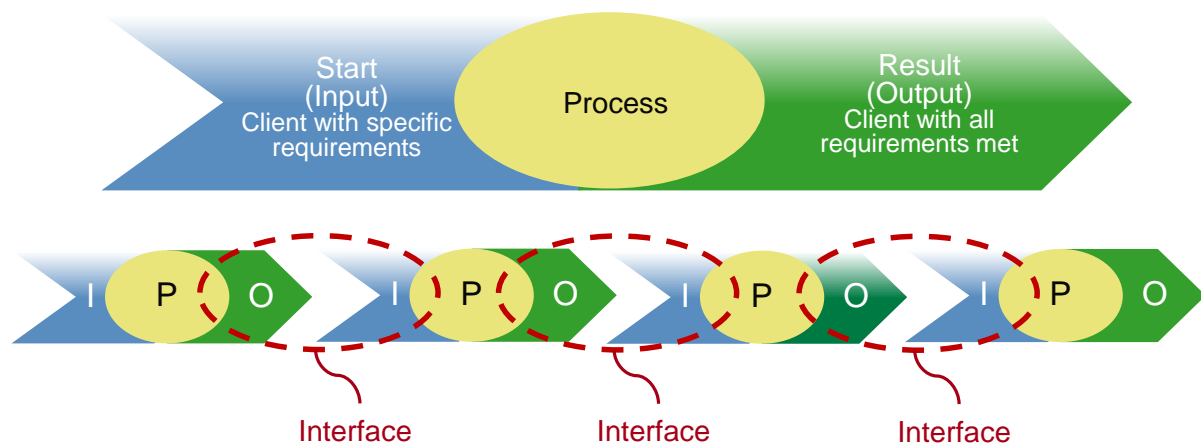


Fig. 4-2: Principle of linked processes

Before and during the audit (and particularly in the case of external audits) it is essential that the auditors have access to all relevant information. The participation of other personnel must be agreed upon. Any restrictions should be clarified in advance.

Input	Process stage	Output
<ul style="list-style-type: none"> <li>- Audit contract</li> <li>- Process limits</li> <li>- Process stages</li> <li>- Audit focus</li> </ul>	<div>Draw up checklists and audit plan and coordinate these with the organisation</div>	<ul style="list-style-type: none"> <li>- Audit plan</li> <li>- Checklists</li> </ul>

**Objective:**

The specific checklists are set based on the coordinated audit contract.

**Responsibility:**

Audit team

**Description:**

From the information obtained and the company's own knowledge database (see section 10.3), the audit team extends and completes the minimum requirements covering assessments set out in the VDA 6.3 audit questionnaire.

If any item cannot logically be assigned to an existing question, further questions can be added. However, this means that the results will no longer necessarily be comparable. In such cases the assessment matrix will need to be adapted.

In agreement with the organisation being audited, the audit team sets out the audit plan, which will contain the following as a minimum:

- the participants
- the names of the auditors
- the audited organisation/functional unit
- the duration of the audit → the time required for documenting each audit step must be taken into account (for example, 10 minutes for documentation for every hour of the audit)

- audit locations
- process steps/product groups

Breaks in production (lunch-breaks, etc.) must be taken into account when drawing up the audit plan, as well as the use of foreign languages, inter-cultural aspects, changes in shifts and transfer times.

In agreement with the auditor and the organisation being audited on site changes are possible.

The planning of the audit time and capacity depends on the process element to be audited, the structure of the organisation, the location, the complexity of the product and process, the risk and the process chain with the associated process step.

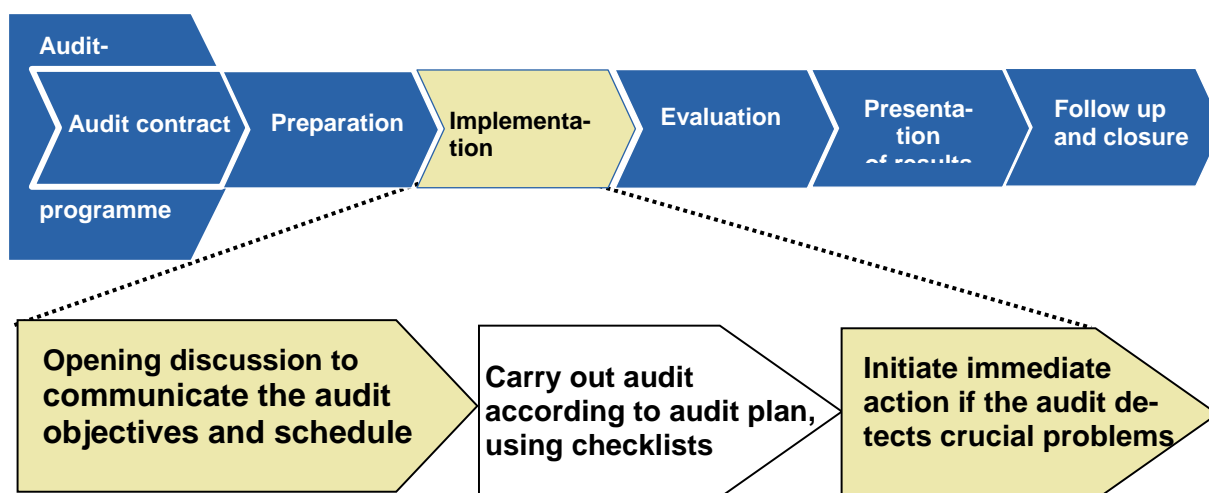
The use of a partial audit can be sensible. In this case, it can be used to distinguish the identification of the audit results (as described in the example in Section 6.3).

A special audit may be used in particular for weak point analysis, complaints, project flow problems, repeated defects etc.

The use of this flexible and efficient method ensures the results reflect the assessed process elements.

<b>Method / documentation:</b>
Audit plan, checklists, questionnaire

## 4.4 Implementation



Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Audited organisation (on site)</li> <li>- Audit plan</li> <li>- Audit team</li> <li>- Specific checklists</li> </ul>	<b>Opening discussion to communicate the audit objectives and schedule</b>	<ul style="list-style-type: none"> <li>- Current audit plan</li> <li>- Contact personnel</li> </ul>

### Objective:

Important points of the audit process are set in the opening discussion.

### Responsibility:

Lead auditor

### Description:

The opening discussion takes place with the management of the organisation to be audited. The objectives of the audit are presented, together with the extent of the audit and the audit criteria. The audit plan is confirmed and the audit leader explains briefly the planned audit activities.

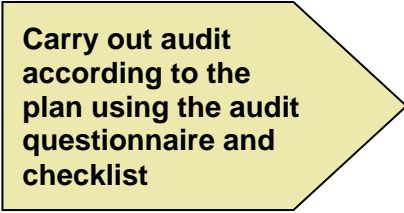
The time schedule is checked, any necessary corrections are made and the time for the closing discussion is determined.

The units/processes to be audited can be presented by those responsible. The auditors introduce themselves and explain their roles in the audit. The contact personnel between the audit team and the organisation to be audited are specified.

The process of reporting and the assessment procedure is presented. Reference is made to the confidentiality of the information and results obtained. The organisation to be audited confirms the availability of the necessary facilities (rooms, printer, etc.) for the audit team. In the event that personal protective equipment is necessary, this is clarified in advance.

**Method / documentation:**

---

Input:	Process stage:	Output:
<ul style="list-style-type: none"><li>- Checklists</li><li>- Time schedule</li><li>- Contact personnel</li><li>- Documents</li><li>- Audit questionnaire</li><li>- Information from the knowledge database</li></ul>		<ul style="list-style-type: none"><li>- Audit evidences</li><li>- Audit records</li></ul>

**Objective:**

The quality standard is documented and verified taking account of the audit plan and the situation on site

**Responsibility:**

Audit team

**Description:**

The auditor analyses whether the audited division implements the general specifications of the organisation, the requirements of standards, the customer requirements and legal obligations.

The analysis is carried out by asking questions and making spot checks based on the chronological sequence of activities within the process, using the questionnaire and any checklists which have been specifically drawn up. The auditor is required to ask open questions (see "Audit pyramid" in Section 6). Based on concrete cases and evidence the auditor must investigate the suitability and effectiveness of the processes

Technical facilities (equipment, tools, test equipment, parts, fixtures etc.) are inspected and evaluated if they are suitable and in good condition. As a general rule, the discussion moves from general questions to concrete, detailed questioning.

The auditor carries out spot checks on the implementation of instructions and requirements relating to the products and processes, by examining appropriate documents and records. Findings relevant for the results are noted. The employees on-site must be brought into the audit by questioning and their responses verified by inspection of the QM documentation. Any audit deviations must be communicated directly on the spot with the relevant personnel.

The audit team should meet periodically, exchange information, assess the progress of the audit and (if necessary) to reallocate the distribution of tasks within the team.

Information regarding the progress and status of the audit can be given periodically to the organisation being audited or those responsible. The audit plan must be verified regularly by the audit team regarding the time schedule and modified if necessary in agreement with the organisation being audited.

### **Audit termination**

An audit can be terminated at the discretion of the audit team, for example on the following grounds:

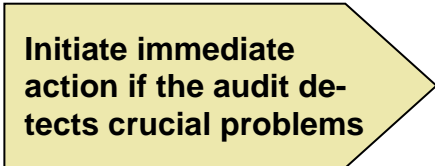
- refusal to provide necessary information during the audit
- clear infringements of the law
- refusal to allow access to areas relevant to the audit, despite previous agreement
- deficient preparations for the audit by the organisation
- presentation of obviously false information

The termination of an audit must be justified by stating the reasons. Audit findings up to the point when the audit is broken off must be documented.

The organisation being audited decides on the implementation of a new audit.

### **Method / documentation:**

Audit questionnaire, database, checklists

<b>Input:</b>	<b>Process stage:</b>	<b>Output:</b>
<ul style="list-style-type: none"><li>- Audit evidences</li><li>- Records</li><li>- Deviation report</li></ul>		<ul style="list-style-type: none"><li>- List of corrective actions which have been introduced</li></ul>

### **Objectives:**

To prevent the further spread of serious failures (customer complaints, vehicle breakdowns, loss of function, safety-critical components, critical characteristics, etc.).

### **Responsibility:**

The lead auditor is responsible for demanding immediate measures in the occurrence of serious failures.

### **Description:**

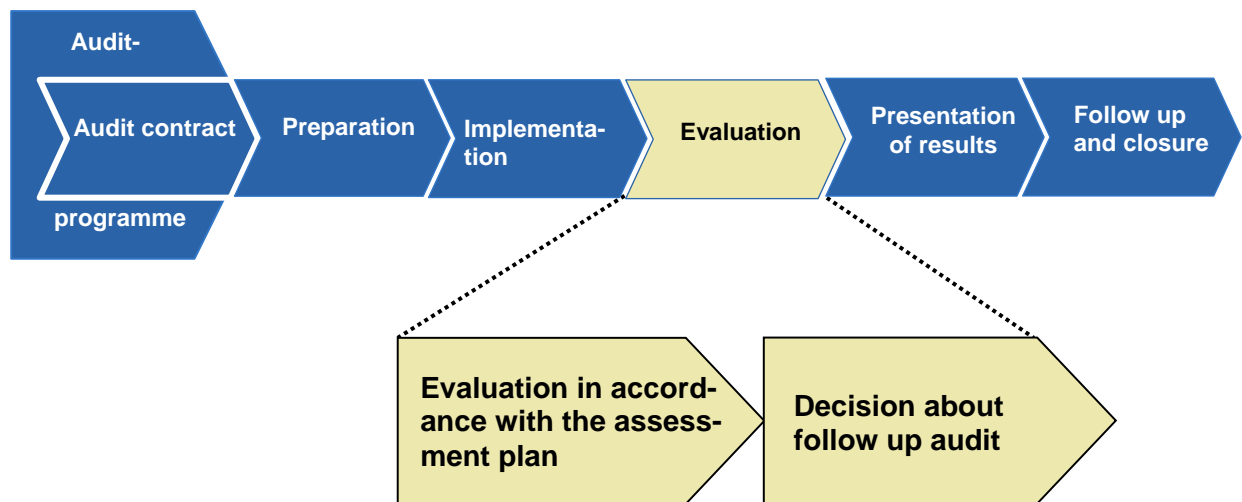
Facts which identify a serious risk must be pointed out to the organisation without delay, so that appropriate, immediate action can be taken.

If serious failures occur that pose a risk for the product / and process quality the organisation being audited must define immediate actions to be used as a safeguard.

### **Method / documentation:**

Audit report

## 4.5 Evaluation



Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Findings</li> <li>- evaluation scheme</li> <li>- individual questions from the checklists</li> </ul>	<div>Evaluation in accord- ance with the evalua- tion scheme</div>	<ul style="list-style-type: none"> <li>- Findings</li> <li>- Quantitative assesment</li> </ul>

### Objective:

The quantitative assessment reflects the quality capability status of the process under consideration. The comparability of the audit results is ensured and changes in regard to previous audits are noted in the sense of a continuous improvement process.

### Responsibility:

Lead auditor, audit team

### Description:

Based on the findings of the audit the audit team evaluates the individual questions as described in the assessment procedure in Section 6.1. The basis for the evaluation is whether or not the relevant requirements are achieved and the risks involved.

If a question is not answered (n.a.) a reason for this must be stated.

The assessments of the individual questions lead to the overall audit assessment.

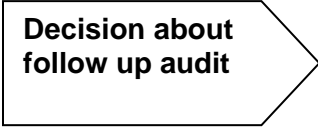
To distinguish the scope of the audit the identification given in Section 6.3 can be utilised. This allows the audit results to be compared.

### Method / documents:

Assessment matrix – Section 9

Evaluation Section 6



Input:	Process stage:	Output:
<ul style="list-style-type: none"> <li>- Audit evaluation</li> <li>- Classification</li> <li>- Deviation report</li> </ul>		<ul style="list-style-type: none"> <li>- Decision about the necessity of a follow-up audit</li> </ul>

**Objective:**

The decision about a follow-up audit is taken on the basis of the findings.

**Responsibility:**

Lead auditor

**Description:**

Under what circumstances a repeat audit is necessary must be specified. Rules for a repeat audit can be:

- not reaching a defined level of achievement
- risks associated with a critical process
- not achieving required results (zero points) for one or more questions marked (\*)
- red traffic light (potential analysis)

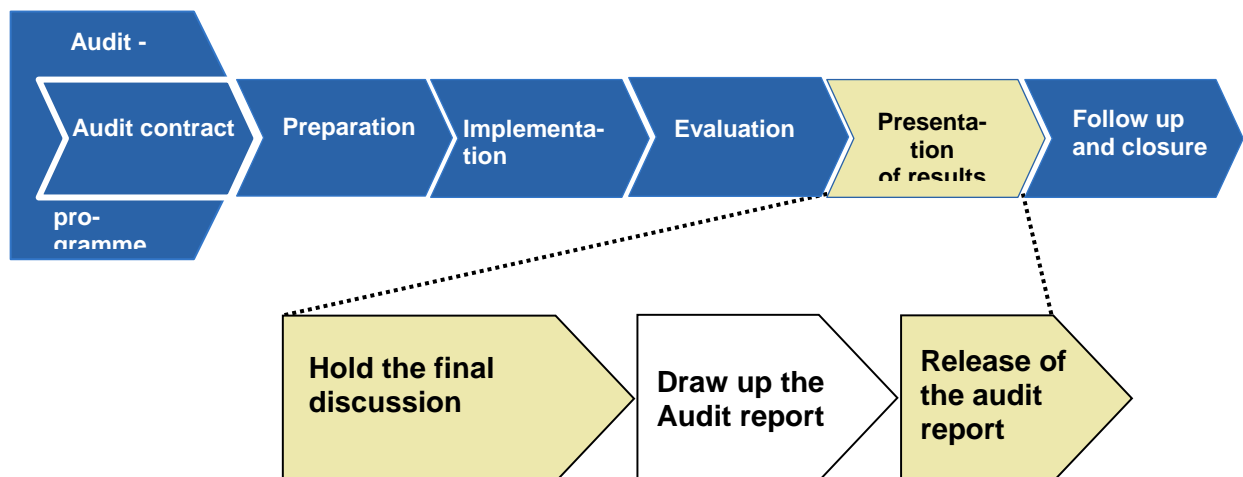
This repeat audit must be carried out within a specified timeframe. Within this timeframe the audited organisation must introduce actions to eliminate the deviations effectively.

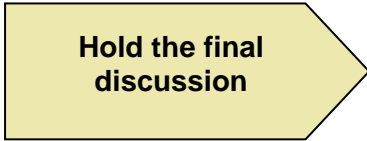
In the case of a repeat audit, this must be carried out to the same extent as the previous audit. A reduction of the audit scope to just a review of the effectiveness of introduced measures is not allowed.

**Method / documentation:**

Audit report

## 4.6 Presentation of results



<b><u>Input:</u></b>	<b><u>Process stage:</u></b>	<b><u>Output:</u></b>
<ul style="list-style-type: none"> <li>- Findings</li> <li>- Audit evidences</li> <li>- Notes on documents which have been examined</li> </ul>		<ul style="list-style-type: none"> <li>- Draw up report with focus on the audit contract</li> <li>- Results / findings regarding quality capability</li> <li>- Decide on follow-up audit if necessary</li> </ul>

### **Objective:**

In the final discussion the organisation being audited and its representatives are presented with a report. This report focuses on:

- Notification of the audit results and the audit findings, when necessary with explanations.
- Specifying the next steps, such as dates for defining the corrective actions (action plan), or arranging a repeat audit if necessary.

### **Responsibility:**

Lead auditor; Audit team

### **Description:**

The following are required in preparation for the final discussion:


- invitations to the participants as set out in the audit plan
- sufficient space for all participants / availability of presentation facilities
- presentation of results and if necessary the (preliminary) audit results (overall estimation of the quality capability)

The contents of the final discussion are:

- presentation of the audit results
  - presentation of the status of immediate actions which have been taken (if necessary) by the organisation being audited
  - specification of further procedure
  - specification of the distribution of the audit report
  - agreement on forwarding the data within the company
- closing comments by the management of the organisation which has been audited.

#### Method /documentation:

---

Input:	Process stage:	Output:
<ul style="list-style-type: none"><li>- <b>Observation notes (positive or negative)</b></li><li>- <b>Notes on documents which have been examined</b></li><li>- <b>Personnel involved in the audit</b></li></ul>	 <p><b>Draw up the audit report</b></p>	<ul style="list-style-type: none"><li>- <b>Audit report</b></li></ul>

#### Objective:

The audit report is an accurate, concise and clear record of the audit.

#### Responsibility:

Lead auditor, Audit team

#### Description:

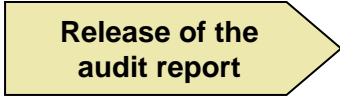
The audit report is drawn up jointly within the auditor team. It consists of:

- a cover sheet
- the audit findings with regard to the documents which have been inspected
- explanations regarding the assessment scheme
- process descriptions, if appropriate

The cover sheet contains the following information:

- the audit procedure
- fundamental internal and external requirements
- details of the organisation and processes which have been audited, including products and customer requirements which have been evaluated
- the audit result
- a summary of the findings
  - must be included: main deviation areas and need for action
  - can be included: positive findings and potential for improvement
- time schedule for the action plan

<b>Method / documentation:</b>
Audit report form

<b>Input:</b>	<b>Process stage:</b>	<b>Output:</b>
- Audit report		- Released audit report

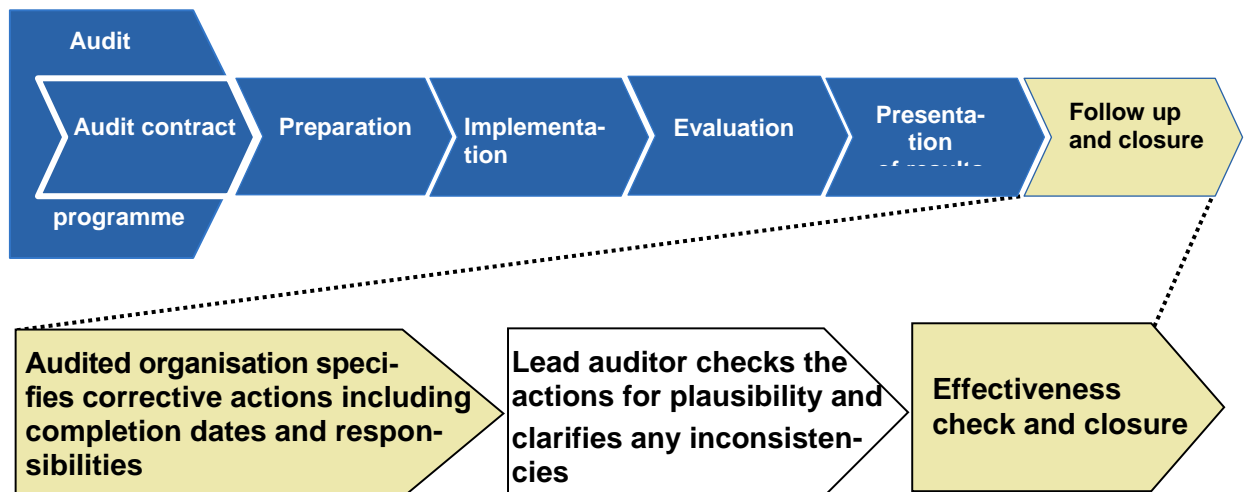
<b>Objective:</b>
The audit report becomes released and valid following its signature by the audit leader and the audited organisation.

<b>Responsibility:</b>
Lead auditor

<b>Beschreibung:</b>
---

<b>Method / documentation:</b>
Audit report form

## 4.7 Follow up and closure



Input:	Process stage:	Output:
- Released audit report	Audited organisation specifies corrective actions including completion dates and responsibilities	Action plan with causes, time schedules and responsibilities

### Objective:

To a reasonable degree, causes, actions, responsibilities and completion dates are allocated to the findings.

### Responsibility:

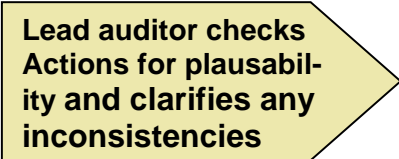
The audited organisation

### Description:

The action plan must be drawn up within a time frame coordinated with the auditor. It contains all the activities involved, stating responsibilities and completion dates and is designed to permanently eliminate the deficiencies in the process.

### Method / documentation:

Form improvement program / action plan

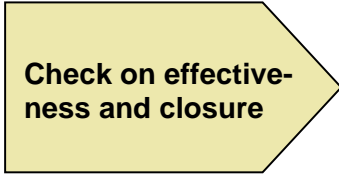
Input:	Process stage:	Output:
- Action plan with causes, time schedule and responsibilities		- Action plan (checked)

Objective:
Plausibility check of action plan

Responsibility:
Audit team

Description:
<p>The auditor checks the action plan for plausibility and decides if the actions are appropriate for eliminating the deficiencies (a check on documents). Here the focus should be on the permanence of the actions taken, so that repeat failures are prevented.</p> <p>Even when the action plan is considered plausible by the auditor, the audited organisation is responsible for the efficiency of the actions taken.</p> <p>If there is any lack of clarity or disagreement, the auditor will call for improvements to the plan. If no response is received the auditor can launch an appropriate escalation procedure.</p> <p>NOTE:</p> <p>In particular in the case of supplier audits (2<sup>nd</sup> and 3<sup>rd</sup> party audits) the usual escalation procedures should be applied if action plans are not provided, or are withheld or are not plausible. However, these escalation procedures should have been agreed upon with the supplier as part of the contract before the audit takes place.</p>

Method / documentation:
Action plan

Input:	Prozessschritt:	Output:
- Checked action plan		<ul style="list-style-type: none"> <li>- Corrective measures</li> <li>- Contract for follow-up audit (if necessary)</li> <li>- Improved process</li> <li>- Defect-free product</li> </ul>

#### Objective:

Closure of the control loop covering the implementation of actions with an effectiveness check.

#### Responsibility:

Audited organisation: Implementation of effective measures  
The person responsible for the process: Check on effectiveness.

#### Description:

The audited organisation is responsible for implementing the corrective actions and the person responsible for the process must monitor the implementation. Checking the effectiveness of the actions agreed upon is carried out primarily by the person responsible for the process.

Confirmation of the effectiveness of the actions which have been taken is documented in a dated note in the action plan by the person responsible for the process. This person also informs the auditor, and when necessary, the monitoring organisation of the effectiveness of the corrective action.

Possible follow-on actions if the effectiveness of the actions is not confirmed are:

- escalation procedure
- definition of further actions
- problem analysis

#### Method / documentation:

Among others, the following methods can be used for verification:

- sampling
- product audit
- process audit
- capability studies on machinery and process
- intermediate status / extent of completion
- examination of the measured indicators before and after implementing the actions (ppm statistics; achievement of the objective; reject patterns)

## **5 Potential Analysis (P1)**

### **5.1 Definition of Potential Analysis**

A potential analysis is used to evaluate new suppliers (contenders). For existing suppliers the potential analysis can be used at new locations, with the introduction of new technologies or for new products.

An estimation is made of the potential to meet the requirements for the requested products and corresponding processes. The analysis takes into account the experience and skills of the supplier in developing and manufacturing the scope of products requested and their capability to fulfil customer specific requirements for the product and process implementation. The assessment is based on existing processes for products (if necessary, competitor products).

The result can be used as preparation for an award decision. It gives a prognosis of the quality capability of the considered supplier/location for the implementation of the product and process in the event the contract is awarded.

A potential analysis can also be applied independently of a project at times of a supplier change or relocation. As part of a current serial production (completed product development phase) the questions from the process element P2 to P4 related to the process development can be used for an assessment.

### **5.2 Requirements**

Because no contractual relationship exists between the customer and the applicant during the enquiry and quotation stages, there should be an agreement made regarding confidentiality and access permission.

### **5.3 Preparation**

Obtaining information in preparation for the potential analysis is of particular importance. In addition to the customer's own research, one valuable means of obtaining information is to ask the prospective supplier to provide a self-assessment (see Section 10.1).



## 5.4 Operational sequence of a potential analysis

The following diagram (Fig. 5.1) shows the operational sequence of a potential analysis. The evaluation questions in the P1 analysis are selected from the process elements P2 to P7. An overview of the questions is given in Section 7.1.

If suppliers are in house, a process analysis can be carried out using a similar product and/or component produced for another manufacturer / customer. The analysis is performed by using the VDA 6.3 potential analysis evaluation questionnaire and if necessary, with the use of further specialised information.

A separate evaluation is required for the potential analysis because the objective here is less to arrive at a classification in percentage terms and more to decide on "suitable" or "not suitable".

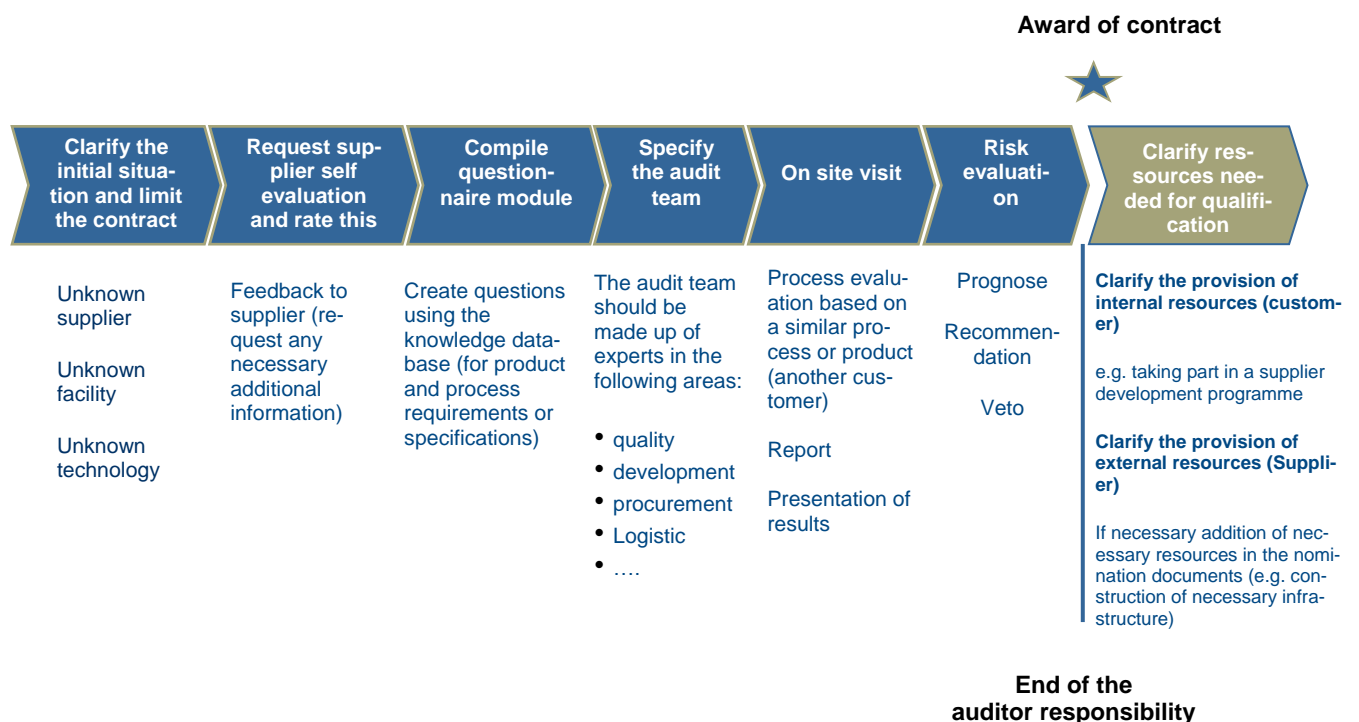





Figure 5-1.: Operational sequence of a potential analysis

## 5.5 Evaluation of a potential analysis

Each question is evaluated in terms of consistent compliance with the requirement under review and the risk involved.

If a question is not answered (shown as n.a.), a reason for this must be stated. A maximum of 3 questions may be marked n.a. It should be noted that the comparability of results and the mutual acceptance of audit results from other parties may no longer apply.




The assessment is marked, using the traffic light system of "red", "yellow" or "green" (see below).

Assessment of individual questions	
The requirement of the question is not met.	
The requirement of the question is partially met.	
The requirement of the question is met.	

If a question is marked "red" or "yellow" the reasons must be stated.

If the requirements of a question are not met and it is assumed that in the event of awarding the contract the requirements will still not be met at SOP, the corresponding question should be marked red.

Adding the marks for each question results in an overall classification (s. below).

Classification	Evaluation based on questionnaire		
		Yellow	Red
Barred supplier		more than 14	one or more
Conditionally approved supplier		max. 14	none
Fully approved supplier		max. 7	none

## Interpretation of results:

**Green** = Fully approved potential supplier.

A contract award (nomination) for the project, component or product group by the customer is possible without restriction.

**Yellow** = Conditionally approved supplier

The supplier is able to meet the customer requirements for the questioned product scope and can be considered when awarding the contract.

Only a conditional approval for a contract award can be given. In some cases the supplier needs support from the client to implement the requirements of the project. Under certain conditions a limited approval for a contract may be given (quantity reduction, smaller series.....)

An award (nomination) is possible, but is linked to defined conditions:

The conditions to minimize the risk may be:

- restriction to a defined quantity (small-scale production)
- restriction to a defined product
- restriction to part-quantities of the overall enquiry
- the (potential) supplier receives a trial order on probation
- the (potential) supplier is included in a supplier development programme
- special support from supplier development teams with careful monitoring of the progress of the project.

Note: Conditions must be specified between the relevant quality and procurement departments.

**Red** = The (potential) supplier is barred

It is not possible to award (nominate the company for) the project, component or product group in question

A positively evaluated potential analysis ("green", "yellow") is not necessarily coupled to an award of contract. A negatively evaluated potential analysis ("red") excludes a contract award.

## 5.6 Follow-up activities after contract award

The results of the potential analysis are used as input when planning the selection of methods or method applications (e.g. Process audit for release of location, VDA-RGA).

A validation of the quality capacity in terms of a release for serial production can only be given through a PPA-process which corresponds to the analysed customer scope.

To achieve this a process audit can be held at the same time as a process release.

## 6 Evaluating a process audit for material products

### 6.1 Evaluation of the individual questions

Each question is assessed in terms of compliance with the requirements and the risk involved. The assessment of each question can result in the award of 0, 4, 6, 8 or 10 points, with the number of points awarded being based on proven compliance with the requirements.

Points	Assessment of compliance with the requirements
10	Full compliance with requirements
8	Requirements mainly <sup>++</sup> fulfilled; minor deviations
6	Requirements partially fulfilled; significant deviations
4	Requirements inadequately fulfilled; major deviations
0	Requirements not fulfilled

<sup>++</sup>) The term "mainly" means that the relevant requirements are met in most instances and no special risks have been identified.

The following table illustrates the appropriate allocation of points for the evaluation of the questions:

Points	Evaluation of the compliance of the individual requirements		
	Risk assessment from the perspective of the process / process step; specific	Risk assessment from the perspective of the product; specific	Systematic view; abstract
10	Technical requirements and specifications for the process are fulfilled.	No product defects, the product meets the technical standards	Requirements are completely met
8	Small deviations in the process which do not affect compliance with the customer specifications or have an effect on following process steps.	Some product defects but no influence on the function, use or further process steps.	Requirements are mainly fulfilled, minor deviations.

6	The process does not always meet the defined requirements. This has an impact on the customer or following process steps.	Product non-conformities do not affect the function; however the failure has a negative impact on the use or on further process steps.	Requirements are partially met; larger deviations
4	The process does not meet the defined requirements and has a significant impact on the customer or following process steps.	Product non-conformities have an impact on the function, the failure leads to usage restrictions, significant impact on the following process steps.	Requirements insufficiently met: serious deviations
0	The process is not capable of ensuring compliance with the defined requirements	Product non-conformities, no function, the use of the product is considerably reduced, further process steps are not possible.	Requirements are not met

The auditor may require immediate actions depending on the risk of the findings.

If a question is not answered (n.a.), a reason for this must be stated. At least 2/3 of the questions for each evaluated process element, sub-element or process step must be answered. To ensure comparability the entire list of questions from the VDA 6.3 process element should be covered in full.

If non-conformities from previous audits are repeated, the lack of implementation of corrective can also be regarded as a deviation: e.g. “cause analysis”, “implementation of measures”, “meeting customer requirements”.

#### Questions involving special product and process risk (\* Question):

In the process elements, questions involving special risks in terms of product and process are identified by an asterisk (\*). The specific risks in the \* questions are already taken into account by the classification rules. The evaluation is carried out analogously to the remaining questions, this means, \* questions are not evaluated more severely than other questions.

## 6.2 Detailed Evaluation and Downgrading Rules

Evaluation of the process elements and the sub-elements from P6 and the individual process steps.

### Process Element

The compliance  $E_{Pn}$  of a process element (P2, P3, ..., P7) is calculated as:

$$E_{Pn} [\%] = \frac{\text{Total points awarded for the relevant questions}}{\text{Total possible number of points for the relevant questions}}$$

### Exception: When more than one result is given for a question

In process elements P3, P4 and P6 several results for one question may be given. In this case the arithmetic mean of all results for the question must be calculated first. In calculations following this step, the average is rounded to two decimal places.

These averages are used in place of “**total points**” when calculating the compliance of a process element. For each question only 10 points may be awarded for the **total possible** number of points – regardless of the number of results per question.

### Sub-elements of P6

In the process element P6 the following sub-elements are evaluated:

- $E_{U1}$  Process Input
- $E_{U2}$  Process management
- $E_{U3}$  Personnel resources
- $E_{U4}$  Material resources
- $E_{U5}$  Efficiency
- $E_{U6}$  Process Output
- $E_{U7}$  Transport, Handling of parts

The calculation of the sub-elements is carried out in the same manner as the process elements using the exception: more than one result is given for a question.

$$E_{Un}[\%] = \frac{\text{Total points awarded for the relevant questions in sub-elements of P6}}{\text{Total possible number of points for the relevant questions in sub-element P6}}$$

### Individual Process Steps

The questions from P6 are used for the evaluation of the individual process steps. All questions from P6 can be answered in each process step. The compliance level  $E_n$  of each process step can be calculated as follows:

$$E_n [\%] = \frac{\text{Total points awarded for the P6 questions for this process step}}{\text{Total possible number of points for the P6 questions for this process step}}$$

### Application of the downgrading rules

These results (process element, sub-element of P6, or process step) are considered in the downgrading rules, but not used as intermediate results to calculate the percentage of the overall results.

## 6.3 Overall Level of Compliance

Process elements for material products	
Project Management (P2)	$E_{P2}$
Planning the product and process development (P3)	$E_{P3}$
Implementation of the product and process development (P4)	$E_{P4}$
Supplier Management (P5)	$E_{P5}$
Process analysis / production (P6)	$E_{P6}$
Customer care, customer satisfaction, service (P7)	$E_{P7}$

The overall compliance  $E_G$  for the process audit is calculated as follows:

$$E_G [\%] = \frac{\text{Total points from all evaluated questions from } E_{P2}, E_{P3}, E_{P4}, E_{P5}, E_{P6} \text{ und } E_{P7}}{\text{Total of all possible points from these questions}}$$



For the process elements P3 and P4 separate evaluations for product development ( $E_{P3}$  Product) or for process development ( $E_{P3}$  Process) can be made. For the calculation of the overall result of all process elements (e.g. P2 to P7) the mean values of the respective questions in section P3 and/or P4 are used. The downgrading rules are applied to the entire process element P3 and / or P4 (joint assessment of product and process development).

If during the audit individual process elements from the questionnaire are used, the result is calculated based only on the evaluated process elements. Which process elements have been used in the evaluation must be made clear in the audit report.

#### Example P5/P6/P7:

If the process elements P5, P6, P7 are evaluated (e.g. auditing of serial production) then the result is calculated as follows:

$$E_{GP(5P6P7)} [\%] = \frac{\text{Total points awarded for all evaluated questions from } E_{P5}, E_{P6} \text{ and } E_{P7}}{\text{Sum of all possible points from these questions}}$$

#### Example P4:

If only process element P4 is evaluated (e.g. audit at the time of handing over the project to serial production) then the result is calculated as follows:

$$E_{G(P4)} [\%] = \frac{\text{Total number of points awarded for all evaluated questions from P4 (} E_{P4} \text{)}}{\text{Sum of all possible points from these questions}}$$

The designation  $E_{GP(5P6P7)}$  and  $E_{G(P4)}$  are used to easily identify of the process elements evaluated.

### Overall level of compliance:

Classification	Level of achievement $E_G$ [%]	Description of the classification
A	$E_G$ or $E_{G(Pn)} \geq 90$	Quality capable
B	$80 \leq E_G$ or $E_{G(Pn)} < 90$	Conditionally quality capable
C	$E_G$ or $E_{G(Pn)} < 80$	Not quality capable

### Level of compliance for partial audits:

To classify the compliance of a partial audit the calculated compliance (e.g.  $E_{G(P5P6P7)}$  and  $E_{G(P4)}$ ) is compared to the benchmarks as given above (at least 80% for a “B” classification of conditionally quality capable or at least 90% for quality capable).

### Rules for downgrading

The following rules for downgrading are to be used and documented in the audit report:

#### Reasons for downgrading from A to B even though the level of achievement is $E_G$ or $E_{G(Pn)} \geq 90\%$

- At least one process element (P2 to P7) or process step ( $E_1$  to  $E_n$ ) is evaluated with a level of achievement  $E_G$  or  $E_{G(Pn)}$  or  $E_n$  from  $< 80\%$ .
- A level of achievement in one of the sub-elements of P6 is  $< 80\%$ .
- At least one \*-question is rated with 4 points.
- At least one question from the Process audit is rated with 0 points.

#### Reasons for the downgrading to C even though the level of achievement is $E_G$ or $E_{G(Pn)} \geq 80\%$

- At least one process element (P2 bis P7) or process step ( $E_1$  bis  $E_n$ ) is evaluated with a level of achievement  $E_G$  or  $E_{G(Pn)}$  or  $E_n$  from  $< 70\%$ .
- A level of achievement  $E_{U1}$  to  $E_{U7}$  in one of the sub-elements of P6 is  $< 70\%$ .
- At least one \*-question is rated with 0 points.

The overall result is rounded to the nearest percentage point. Similarly, when applying the downgrading rules (process element, sub-element or process step), the individually calculated results  $E_{Pn}$ ,  $E_{Un}$  are rounded to the nearest percentage point.

## 6.4 Evaluation of Product Groups

If required, the overall assessment of quality capability can be broken down into product groups and individual process stages. This procedure is used by the automotive manufacturers principally for classifying the quality capability of suppliers. In this way suppliers are evaluated for their quality capability restricted to product groups. This forms part of the preconditions for future contract awards.

Product group	Possible process stages			
Pressed & stamped parts	Stamping; drawing; forming	Galvanic plating	Painting	
Plastic injection mouldings	Plastic moulding		Painting	
Control devices	Fitting components	Soldering	Assembly	Functional check

**Note:** To evaluate process steps, additional process requirements are generated from the knowledge database (see Section 10.3)

In the evaluation matrix (see Section 9: Evaluation Forms and Overviews) the relevant process stages are allocated to the product group being evaluated.

The overall compliance for each product group  $E_{G(PGn)}$  is calculated as follows:

$$E_{G(PGn)} [\%] = \frac{\text{Sum of the **points obtained**^{++} from the P6 questions for the process steps of the product group PGn}}{\text{Sum of the **possible points**^{++} obtained from the P6 questions for the process steps of the product group PGn}}$$

Explanations of "points obtained" and "possible points" see chapter 6.2 :: special case.

When evaluating product groups, the downgrading rules are applied specifically to the product group concerned.

## 6.5 Using the questionnaire (Process elements P2 to P7)

The questionnaire is one of the mail tools for the auditor. Depending on the phase of the product life-cycle (see Section 2.1) the auditor selects the relevant process elements for the audit. Additional specific requirements can be added to the questions depending on the product / process risks identified.

The questions can be used for processes, both for material products and for auxiliary materials.

### Structure of the questionnaire

The questions to the process elements are structured as follows:

- questions asked
- minimum requirements relevant for assessment
- possible examples

The relevant examples should be selected on a product / process specific basis and expanded when necessary, analysed and evaluated.

The evaluation is carried out based on the questions in the “Minimum requirements / Relevant for the evaluation” list and not on the “Examples for implementation” list.

For the auditor the audit consists of two mutually independent activities (s. Figure 6):

1. The auditor asks open questions to evaluate compliance with the requirements. The risks identified in the preparations for the audit are taken into account.
2. The auditor uses closed questions to evaluate the performance based on the audit findings.

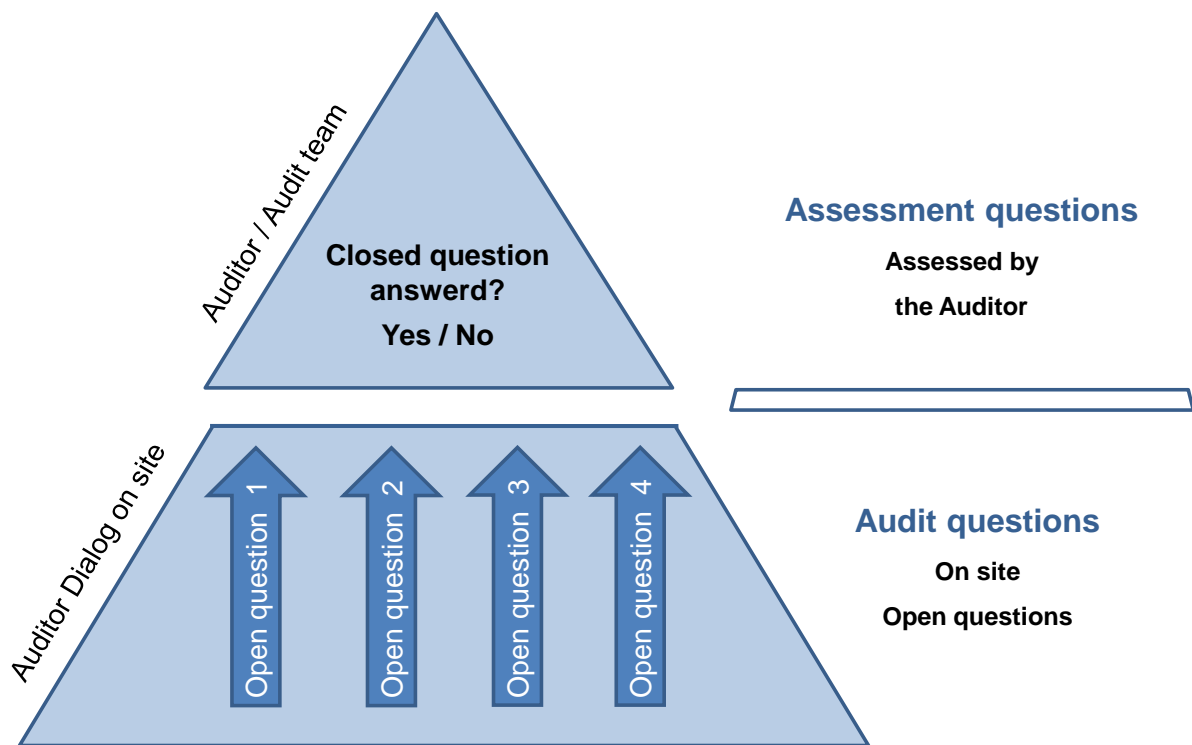


Fig. 6: Audit pyramid

The process elements P3 and P4 can be audited either together or separately when evaluating the product planning / implementation and process planning / process implementation. This depends on the organisation being audited.

If process element P6 “serial production” requires a breakdown into process steps, each step must be specified and evaluated separately.

Additionally to the VDA 6.3 questions listed in this book, it is recommended that a knowledge database be created to store information about the risk associated with individual products and process. The experience stored in the database can be used additionally to the requirements listed for the evaluation.

Based on the risk analysis described in Section 2.4, risks which are identified must be aligned with the questionnaire and integrated into the existing questions. If any item cannot logically be assigned to an existing question, further questions can be added. However, this means that the results will no longer necessarily be comparable. In such cases the assessment matrix will need to be adapted. A note must also be made on the cover sheet of the audit report, pointing out this fact.

## 7 Questionnaire

### 7.1 Overview Questionnaire

		Potential Analysis**	Transport Handling of Parts
<b>P2</b>	<b>Project Management</b>		
<b>2.1</b>	Is a project management established with a project organisation?	X	
<b>2.2</b>	Are all resources required for the project development planned and available and are changes shown?	X	
<b>2.3</b>	Is there a project plan and has this been coordinated with the customer?	X	
<b>2.4</b>	Is the advanced product quality planning implemented within the project and monitored for compliance?	X	
<b>2.5*</b>	Are the procurement activities of the project implemented and monitored for compliance?	X	
<b>2.6*</b>	Is change management within the project ensured by the project organisation?	X	
<b>2.7</b>	Is there an escalation process established and is this effectively implemented?	X	

<b>P3</b>	<b>Planning the product and process development</b>		
<b>3.1</b>	Are the specific product and process requirements available?	X	
<b>3.2*</b>	Can the manufacturing feasibility be evaluated according to the product and process requirements?*	X	
<b>3.3</b>	Are the activities for the product and process development planned in detail?		
<b>3.4</b>	Are the activities for customer support / customer satisfaction / customer service planned?		
<b>3.5</b>	Have the necessary resources been taken into account for the product and process development?		

<b>P4</b>	<b>Implementation of the product and process development</b>		
<b>4.1*</b>	Are the actions which were defined in the product and process development phases implemented?	X	
<b>4.2</b>	Are human resources available and are they qualified to ensure the start of the series?		
<b>4.3</b>	Are the material resources available and suitable to ensure the start of the series?	X	
<b>4.4*</b>	Are the required approvals and releases for the product and process development available?*	X	

4.5	Are the manufacturing and inspection specifications derived from the product and process development and are they implemented?		
4.6	Is a performance test carried out under series conditions for the series release?		
4.7*	Is there a controlled method for the product handover from development to serial production?		

<b>P5</b>	<b>Supplier Management</b>		
5.1	Are only approved and quality-capable suppliers used?	X	
5.2	Are customer requirements taken into account in the supply chain?	X	
5.3	Have target agreements for supplier performance been agreed upon and implemented?		
5.4*	Are the necessary releases available for out sourced products and services?	X	
5.5*	Is the quality of the out-sourced products and services ensured?	X	
5.6	Are incoming goods stored appropriately?	X	
5.7	Are personnel qualified for their respective tasks and are responsibilities defined?		

<b>P6</b>	<b>Process analysis / production</b>		
6.1	<b>What goes into the process? Process input</b>		
6.1.1	Has the project been transferred from development to serial production and is a reliable start guaranteed?	X	
6.1.2	Are the necessary quantities / production batch sizes of incoming materials available at the agreed upon time and at the right location (storage / workstation)?		X
6.1.3	Are incoming materials stored appropriately and are the means of transport / packing facilities suitable for the special characteristics of the incoming materials?		X
6.1.4	Are the necessary identifications / records / releases available and allocated appropriately to the incoming materials?		X
6.1.5*	Are changes to the product or process made during the serial production tracked and documented?		
6.2	<b>Are all production processes controlled? (process management)</b>		
6.2.1	Are the specification of the control plan complete and have they been effectively implemented?	X	
6.2.2*	Is there a restart of production of manufacturing processes?	X	
6.2.3*	Are special characteristics managed in the production?	X	

<b>6.2.4*</b>	Are non-released and / or defective parts managed?	<b>X</b>	<b>X</b>
<b>6.2.5</b>	Is the flow of materials and parts secured against mixing / wrong items?		<b>X</b>

<b>6.3</b>	<b>What functions support the process? (personnel resources)</b>		
<b>6.3.1*</b>	Are the employees able to fulfil their given tasks?	<b>X</b>	
<b>6.3.2</b>	Do the employees know their responsibilities and authority in the monitoring of the quality of product and process quality?		
<b>6.3.3</b>	Are the necessary personnel resources available?	<b>X</b>	

<b>6.4</b>	<b>What means are used to implement the process? (material resources)</b>		
<b>6.4.1*</b>	Can the product-specific requirements from the customer be met with the manufacturing equipment?	<b>X</b>	
<b>6.4.2</b>	Is the maintenance of the manufacturing equipment and tools controlled?	<b>X</b>	
<b>6.4.3*</b>	Can the quality requirements be effectively monitored with the measurement and testing facilities in use?	<b>X</b>	
<b>6.4.4</b>	Are the work and inspection stations appropriate for the needs?	<b>X</b>	
<b>6.4.5</b>	Are tools, equipment and testing equipment stored properly?		

<b>6.5</b>	<b>How effective is the process being carried out? Effectiveness, efficiency, waste avoidance</b>		
<b>6.5.1</b>	Are there targets set for the manufacturing process?		
<b>6.5.2</b>	Is quality and process data collected in a way that allows analysis?		
<b>6.5.3</b>	In the case of deviations from product and process requirements, are the causes analysed and the corrective actions checked for effectiveness?	<b>X</b>	
<b>6.5.4</b>	Are processes and products audited regularly?	<b>X</b>	

<b>6.6</b>	<b>What should the process produce? (process result / output)</b>		
<b>6.6.1</b>	Do the quantities / production batch sizes match needs and are they systematically directed to the next process step?		<b>X</b>
<b>6.6.2</b>	Are products / components stored in an appropriate manner and are transport facilities / packing arrangements suitable for the special characteristics of the products / components?	<b>X</b>	<b>X</b>
<b>6.6.3</b>	Are the necessary records / releases documented?		<b>X</b>
<b>6.6.4*</b>	Are customer requirements met at the delivery of the final product?	<b>X</b>	



<b>P7</b>	<b>Customer care / customer satisfaction / service</b>		
<b>7.1</b>	Are all requirements related to QM-System, product and process fulfilled?	<b>X</b>	
<b>7.2</b>	Is customer service guaranteed?	<b>X</b>	
<b>7.3*</b>	Is the supply of parts guaranteed?	<b>X</b>	
<b>7.4*</b>	If there are deviations from quality requirements, are failure analyses carried out and corrective actions implemented effectively?	<b>X</b>	
<b>7.5</b>	Are personnel qualified for the various tasks and are responsibilities defined?		

Explanatory notes:

Highlighted marking indicates: \*-  
Questions

\*\* Questions from the Questionnaire that must be audited at a minimum within the framework of the potential analysis

## 7.2 Project management (P2)

Process Element P2: Project Management	
Minimum requirements relevant for assessment:	Examples for implementation
<b>P2.1 Is a project management established with a project organisation?</b>	
<p>A process for project management exists.</p> <p>The project organisation is specified and contacts are defined.</p> <p>The responsibilities and authority of the project leader and team members are defined.</p> <p>The team members of the project are qualified to carry out their tasks.</p> <p>The project organisation meets the customer requirements.</p> <p>Suppliers are involved in project management.</p>	<ul style="list-style-type: none"> <li>- Defined rolls, tasks, competence and responsibilities of the project leader / project team expert for technology</li> <li>- Project interface in multi-site projects</li> <li>- Project organisational chart</li> <li>- Composition of the project team</li> <li>- Verification of qualifications</li> <li>- Special customer requirements for project management</li> </ul>

<b>P2.2 Are all resources required for the project development planned and available and are changes shown?</b>	
<p>Resource planning takes account of the customer's requirements, based on the contract covering the project.</p> <p>Resource planning for project members is established and implemented. The staff workload has to be considered.</p> <p>Review and where necessary adjustment of resource planning is carried out when changes occur (dates, scope of development performance...). This applies to changes that are triggered by the customer as well as internal changes or supplier changes.</p> <p>The critical path is given special consideration within the resource planning.</p> <p>The necessary project budget for personnel and equipment (testing and laboratory equipment e.g.) is planned and released.</p> <p>Changes in the project organisation (interface with client) are reported.</p>	<ul style="list-style-type: none"> <li>- Evidence of resource planning (taking other projects into account)</li> <li>- Resource planning for equipment (e.g. development test stand)</li> </ul>

### P2.3 Is there a project plan and has this been coordinated with the customer?

The project plan meets the specific customer requirements.

All internal and customer defined milestones are fully incorporated in the project plan.

A review is carried out at the milestones defined in the project plan to check that all planned activities are carried out and that the level of maturity required is achieved.

If a statutory authorisation procedure for a product is specifically required, the duration of this procedure is included in the project planning.

In-house communication is ensured when changes are made to the project plan. Changes made to the project plan which affect the customer are coordinated with the customer.

The critical path is generated from the project plan and takes account of critical delivery items.

The project plan must include the advanced product quality planning activities. This may be in a separate document that is referred to from the project plan. The plans must take prototype and pre-production into account.

The project plan must include detailed activities for product and process development. Detailed plans may be in a separate document referred to in the project plan. The plans must take prototype and pre-production into account.

The project plan must include the detailed activities concerning procurement. Detailed plans may be in a separate document referred to in the project plan.

- Project plan with milestones
- Specific customer requirements regarding technologies and/or product groups
- Customer's project plan
- Customer's deadlines
- Customer's milestones
- Customer's targets (measurements within the individual milestones)
- Milestone assessments (reviews)
- Quality Plan (e.g. from VDA MLA or APQP)
- Country specific certification requirements (ECE, SAE, DOT, CCC, ...)
- Legal and Regulatory approvals process of critical systems (electroplating, paint, ...)

**P2.4 Is the advanced product quality planning implemented within the project and monitored for compliance?**

The advanced product quality planning meets the specific customer requirements.

Both product and process assurance measures are included as part of the advanced product quality planning.

Verification and validation of the product and process requirements are contained within the planning.

The planning also addresses critical components and scope of supply (internal and external suppliers).

The plan is regularly monitored for compliance and for target achievement.

- Project plan
- Customer milestones
- Customer requirements in regard to quality plans
- Customer specifications

**P2.5\* Are the procurement activities of the project implemented and monitored for compliance?**

The activities have to ensure that only approved and quality-capable suppliers are used in production.

The level of activity depends on the risk classification of procured scope of supplies.

These include the supplier selection and award criteria, award amount and delivery target date. The transfer of customer requirements in the supply chain is ensured.

The activities also include client's required suppliers as stated within the agreement.

The suppliers for facilities, machinery, tools, test and measurement systems and services are integrated.

The appointment of suppliers must be appropriately documented and traceable.

Dates for the assignment, supplier milestones and release have been laid down in the plan and coordinated with the overall schedule.

- Make or buy decisions
- Supplier selection criteria
- Supplier development plan
- List of suppliers for the project
- List of approved suppliers
- Risk appraisal of each supplier
- Interface agreement for directed suppliers
- Component classification
- Suppliers of services such as development, laboratories and maintenance etc.

<b>P2.6* Is change management within the project ensured by the project organisation?</b>	
<p>Change management within the project meets the customer's specific requirements.</p> <p>Changes (initiated by the customer, in-house or by the client) must be evaluated and if necessary the project plan must be adapted. This evaluation must include the risk assessment for the product quality as well as the deadlines.</p> <p>Suppliers (critical supplies) are actively involved in change management.</p> <p>Changes are reported in a timely manner and are agreed upon with the customer.</p> <p>Compliance must be ensured at change stop points. If deviations from this occur they must be documented between the client and the supplier.</p> <p>All changes must be documented.</p> <p>The persons responsible for change management are defined for the client, in-house and to suppliers.</p>	<ul style="list-style-type: none"> <li>- Time schedules</li> <li>- Process description</li> <li>- Change management</li> <li>- Change forms</li> <li>- Change history for the product and the process</li> <li>- Evaluation of change</li> <li>- Approvals of changes</li> </ul>

<b>P2.7 Is there an escalation process established and is this effectively implemented?</b>	
<p>The escalation process in the project meets the specific client requirements.</p> <p>An escalation model (risk management) must be available for deviations in the project affecting the overall schedule. Project risks are identified, assessed and reduced through measures applied to the product group concerned in each case.</p> <p>The criteria for escalation are defined, responsibilities and authorities are regulated and measures are taken when deviations occur.</p> <p>If risks have been identified in technologies, suppliers or supplier countries, these risks should be considered within the escalation management.</p>	<ul style="list-style-type: none"> <li>- Time periods for escalation depending on the risk have been agreed upon.</li> <li>- Contact personnel/ decision makers in the escalation process are defined.</li> <li>- Escalation criteria and paths of communication are defined.</li> <li>- Protocols of milestone reviews including measures</li> </ul>

## 7.3 Planning the product and process development (P3)

Process Element P3: Planning the product and process development	
Minimum requirements relevant for Assessment:	Examples for implementation
<b>P3.1 Are the specific product and process requirements available?</b>	
<p>All requirements regarding the product to be developed are known.</p> <p>For products with integrated software, the requirements at interfaces between hardware and software are defined. Requirement management is implemented for this.</p> <p>The organisation must determine the logistical requirements and the statutory and regulatory requirements relevant for the product that are necessary to meet specific client requirements.</p> <p>The organisation must take into account and use requirements on the product and the process known from previous experience.</p> <p>Special characteristics must be identified on the basis of their own requirements, customer requirements, legal requirements, manufacturing technology and characteristics that arise from the purpose / use of the product.</p> <p>The quality requirements from the client for the product and the process must be available.</p> <p>Inquiry and contract documents are checked for completeness.</p> <p>If customer requirements cannot be fulfilled the customer must be notified or deviations "allowed" / approved from the customer (if the contract has been awarded).</p> <p>Customer requirements regarding the selection of sub-suppliers or incoming materials must be documented.</p> <p>Interface agreements are available when required (designated) suppliers are agreed upon with the client.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Inquiry documents</li> <li>- Contract documents</li> <li>- Requirement specifications (product, process)</li> <li>- Customer requirements</li> <li>- Legal requirements</li> <li>- Purchasing conditions</li> <li>- QM specific requirements</li> <li>- Quality agreements</li> <li>- Requirements for documentation</li> <li>- Logistics requirements (JIT, JIS, on consignment)</li> <li>- Schedules, technical delivery conditions</li> <li>- Access to portals Information platform in Internet</li> <li>- Definition of responsibilities for suppliers (e.g. qualification, sample submissions, approval, testing...).</li> <li>- Testing regulations</li> <li>- Catalogue of characteristics / reference examples for decorative surfaces.</li> <li>- Experience with previous projects</li> <li>- Product / Process characteristics</li> <li>- Order documents with item lists and schedules</li> <li>- Laws / regulations</li> <li>- Environmental aspects, recycling requirements</li> <li>- Proof for capability</li> <li>-</li> </ul> <p><u>Product development</u></p> <ul style="list-style-type: none"> <li>- Specifications, technical drawings</li> <li>- Special characteristics</li> </ul>

	<u>Process development</u> <ul style="list-style-type: none"> <li>- Suitability of facilities, tools and testing equipment</li> <li>- Layout of work and test facilities</li> <li>- Handling, packaging, storage and identification</li> </ul>
--	--

<b>P3.2* Can the manufacturing feasibility be evaluated according to the product and process requirements?</b>	
<p>The procedure for evaluating the manufacturing feasibility must be regulated across divisions.</p> <p>All determined product and process specific requirements (technology, function, quality, logistics, software, ...) must be checked for manufacturing feasibility.</p> <p>Material and personnel resources must be considered in the manufacturing feasibility study.</p> <p>The results of the manufacturing feasibility study must be available before tendering.</p> <p>The manufacturing feasibility of critical purchased parts must be ensured.</p> <p>If customer requirements cannot be fulfilled the customer must be notified or deviations “allowed” / approved from the customer (if the contract has been awarded).</p>	<u>Product / Process Development</u> <ul style="list-style-type: none"> <li>- Customer specifications and standards</li> <li>- Dates, timeframes</li> <li>- Regulations, standards, laws, environmental impact</li> <li>- Requirements regarding product liability</li> <li>- Buildings, premises</li> <li>- CAM, CAQ</li> <li>- Product / process innovation</li> <li>- Inter-divisional manufacturing feasibility analysis (for example, sales, development, purchasing, production planning, production, QM planning, logistics)</li> </ul> <u>Product development</u> <ul style="list-style-type: none"> <li>- Laboratory / testing equipment</li> </ul> <u>Process Development</u> <ul style="list-style-type: none"> <li>- Capacity monitoring</li> <li>- Availability of incoming materials</li> <li>- Manufacturing facilities, manufacturing sites</li> <li>- Equipment, tools, production / testing equipment, laboratory facilities, transport, container, storage</li> </ul>

<b>P3.3 Are the activities for the product and process development planned in detail?</b>	
<p>When planning the product and process development the level of detail is dependent on the component, software and complexity of the process.</p> <p>In the development phase, suitable methods must be used to secure the product and process development so that when the product goes into serial production it fulfils the operational conditions (function, reliability, safety, security). This must be considered in the planning.</p> <p>Risk analysis (Product and process FMEAs or similar methods) are part of the planning.</p> <p>New developments from products and processes should be taken into account at the planning stage At the planning stage, the development of new products and processes should take into account the requirements of the product operational conditions.</p> <p>The plans contain all information for product and process development (including dates and length of time, milestones within the overall project plan, production testing, PPA-date, Software standards).</p> <p>Methods for development release meet customer requirements and a clarified with the customer if deviations occur.</p> <p>Outsourced processes and services are part of the project planning.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Overall schedule or product and process development plan</li> <li>- Customer requirements</li> <li>- Layout inspection and functional verification plans</li> <li>- Client schedule</li> <li>- Lead times</li> <li>- Deadlines for the procurement release, supplier approval and change stop</li> <li>- Methods used to minimize risk (QFD, FMEA, statistical testing plan (e.g. DoE, Shainin, Taguchi)</li> <li>- Detailed plans for prototypes / pre-production</li> <li>- Regular status checks on the progress of the development (reviews)</li> <li>- Project plans for investment items, (facilities and equipment).</li> <li>- Logistics planning for all phases of the of product and process development including packaging</li> </ul> <p><u>Product Development</u></p> <ul style="list-style-type: none"> <li>- Detailed planning for reliability testing, functional testing, trial plan</li> <li>- Deadline for development phase samples</li> </ul> <p><u>Process Development</u></p> <ul style="list-style-type: none"> <li>- Deadlines for the production trial run, tool timing plans (off tool parts)</li> <li>- Detailed planning for test plans, test equipment plans</li> </ul>



<b>P3.4 Are the activities for customer support / customer satisfaction / customer service planned?</b>	
<p>The customer requirements for the supply of parts are taken into account across the product life cycle.</p> <p>Concepts to continually ensure series supply including a safeguard for emergencies are provided in the planning phase.</p> <p>A fallback concept is provided for product and process innovation.</p> <p>The analysis process for 0 km and field reclamation is planned for delivery. The customer requirements are taken into account for failure analysis.</p> <p>When introducing new technologies and products, the employee training, and the creation of the necessary infrastructure are provided also in customer service.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Training plan</li> <li>- Qualification matrix</li> <li>- Investment planning</li> </ul> <p><u>Process Development</u></p> <ul style="list-style-type: none"> <li>- Inspection Planning for standard and stress testing</li> <li>- Triggering criteria are defined</li> <li>- Handbook NTF process</li> <li>- Concept for the supply of spare parts</li> <li>- Emergency plans</li> </ul>

<b>P3.5 Have the necessary resources been taken into account for the product and process development?</b>	
<p>The process for determination of resource is implemented.</p> <p>Determination of resources refers to the availability of qualified personnel, budget, infrastructure such as Building, testing equipment (hardware and software), laboratory equipment, machinery and equipment, ....</p> <p>Capacity for the implementation of prototypes, prototyping, pilot production, production testing and serial production must be planned and considered.</p> <p>The resource planning is regularly adapted to changes in the project; potential bottlenecks are to be considered.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- CAx equipment</li> <li>- Availability of qualified personnel for respective tasks</li> <li>- Capacity planning for all resources</li> </ul> <p><u>Product Development</u></p> <ul style="list-style-type: none"> <li>- Test / Inspection / Laboratory equipment (internal and external)</li> </ul> <p><u>Process Development</u></p> <ul style="list-style-type: none"> <li>- Production sites, tools, production and testing equipment</li> </ul>

## 7.4 Implementation of the product and process development (P4)

Process Element P4: Implementation of the product and process development	
Minimum requirements relevant for assessment:	Examples for implementation
<b>P4.1* Are the actions from the plans implemented for product and process development?</b>	
<p>The conditions defined in the development planning methods for product and process development are applied, so that after implementation in the series the findings fulfill the product conditions of use (function, reliability, safety).</p> <p>In the development phase a FMEA must be used to ensure that the product and the process comply with the requirements of the customer in terms of function, reliability etc.. When carrying out the product FMEA the proposed manufacturing site for the production shall be included.</p> <p>Special characteristics are identified and noted in the relevant documents (FMEAs etc.) and there are measures to ensure them.</p> <p>In the overall plan, a test plan must be included for the components, assemblies, subassemblies, components, software and materials including manufacturing processes from prototype and pilot production.</p> <p>The out-sourced products and services are taken into account. The implementation of product and process development is ensured in the supply chain.</p> <p>The documentation of the findings from the prototype phase and the pre-production phase are available for reference in the serial phase.</p> <p>The requirements for the test equipment are defined and implemented.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Methods to minimize risk (QDF, FMEA)</li> <li>- Statistical design of experiments (for example: DoE, Shainin, Taguchi...)</li> <li>- Poka-Yoke Principles</li> </ul> <p><u>Product Development</u></p> <ul style="list-style-type: none"> <li>- Testing planning</li> <li>- Assembly test and system test</li> <li>- A, B, C Samples</li> <li>- Endurance Tests</li> <li>- Environmental simulation testing (e.g. salt spray test)</li> </ul> <p><u>Process Development</u></p> <ul style="list-style-type: none"> <li>- Control plan / inspection plan</li> </ul>

<b>P4.2 Are human resources available and are they qualified to ensure the start of the series?</b>	
<p>A general personnel plan must be available.</p> <p>Personnel must be qualified for the relevant tasks. This also applies to the staff of external service providers. Appropriate certification must be available.</p> <p>Needs assessments will be carried out regularly during product and process development with regard to possible emerging bottlenecks and additional requirements.</p> <p>Qualified personnel resources are available for the implementation of prototypes and samples. Human resources for pre-production, production start-up and serial production are planned and personnel are qualified in accordance with the project plan.</p> <p>Processes that have been outsourced have also been considered.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Customer requirements</li> <li>- Requirements profile for the relevant position</li> <li>- Determine the need for training</li> <li>- Proof of training</li> <li>- Knowledge of methods and foreign languages</li> </ul>

<b>P4.3 Are the material resources available and suitable to ensure the start of the series?</b>	
<p>A process to determine resources has been established.</p> <p>Resource determination refers to the availability of test equipment, laboratory equipment, machinery, equipment, and the utilization of machinery and equipment. Supporting processes must be considered.</p> <p>Within the resource determination the necessary infrastructure is taken into account.</p> <p>Regular needs assessment must be carried out during product and process development with regard to possible emerging bottlenecks and additional requirements.</p> <p>Material resources for the realization of prototypes and sample are available. Material resources for pre-production, series start and serial production is planned and provided in accordance with the project plan.</p> <p>Outsourced processes must be considered.</p> <p>The resources must be available with a suitable lead time before the start of customer's serial production.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Customer requirements</li> <li>- Technical interface to customer and suppliers</li> </ul> <p><u>Product development</u></p> <ul style="list-style-type: none"> <li>- Test planning</li> </ul> <p><u>Process Development</u></p> <ul style="list-style-type: none"> <li>- Facility planning</li> <li>- Facility layout</li> <li>- Machinery and equipment planning</li> <li>- Quantities and throughput times</li> <li>- Transport routes</li> <li>- Transport, containers, storage</li> <li>- Capacity before series start (initial stock)</li> <li>- Supporting processes for example from logistics and IT should be considered.</li> </ul>

<b>P4.4* Are the required approvals and releases for the product and process development available?</b>	
<p>The releases and verification of suitability is confirmed for all the items, assemblies, software versions and out-sourced products and services in accordance development schedules.</p> <p>The material data is confirmed and released.</p> <p>The actions from the FMEA have been implemented and confirmed in their effectiveness.</p> <p>The (Production process and product approval) PPA must be available at production release. For products with integrated software an additional software test report is available.</p> <p>Reference parts from sampling must be kept for at least the time laid down in the customer requirements.</p> <p>The verification and validation of the product and process are ensured before the customer SOP.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Test reports, protocols</li> <li>- Supporting documents for purchased parts / suppliers</li> <li>- Sampling results</li> </ul> <p><u>Product Development</u></p> <ul style="list-style-type: none"> <li>- Specifications, drawings, requirement specifications</li> <li>- FMEA IMDS, REACH, RoHS</li> <li>- Product testing (for example: installation inspection, function testing, endurance testing, environmental simulation)</li> <li>- Prototypes</li> <li>- Confirmation of conformity with legal requirements</li> <li>- Development releases from customers.</li> </ul> <p><u>Process development</u></p> <ul style="list-style-type: none"> <li>- Logistics concept (e.g. suitability of packaging through sample shipping)</li> <li>- Proof of capability of special characteristics</li> <li>- Capacity studies</li> <li>- Tool approvals</li> </ul>

<b>P4.5 Are the manufacturing and inspection specifications derived from the product and process development and are they implemented?</b>	
<p>The manufacturing and inspection characteristics contain all characteristics from the product and process development (including special characteristics). These must take into account all the components, assemblies, subassemblies, parts, software and materials including manufacturing processes that are part of the product.</p> <p>Results of the risk analysis are considered.</p> <p>The specifications include information for product control, production process control, methods and response plans and corrective actions.</p> <p>Product audits and layout inspection and a functional verification plans are defined.</p> <p>The specifications must be available for all phases: prototype phase (if required by the customer), pre-series and series phase.</p>	<p><u>Product / Process Development</u></p> <p><u>Product development</u></p> <ul style="list-style-type: none"> <li>- Risk analysis (FMEA, FTA etc.)</li> <li>- Process control plan (prototypes pre-series)</li> </ul> <p><u>Process development</u></p> <ul style="list-style-type: none"> <li>- Risk analysis (FMEA, FTA etc.)</li> <li>- Production control plan (pre-series, series)</li> <li>- Product audit plan <ul style="list-style-type: none"> <li>- Inspection plan</li> <li>- Response plan</li> </ul> </li> <li>- Layout inspection and functional verification plan <ul style="list-style-type: none"> <li>- Series release (first and last piece)</li> <li>- Testing within the series</li> </ul> </li> </ul>

<b>P4.6 Is a production trial run carried out under series conditions for the series release?</b>	
<p>A production trial run must be carried out in order to assess all production factors and influences at the appropriate time and make any necessary corrections.</p> <p>The production trial run has provided evidence that the quality capability of the entire production process is given under serial production conditions (tools, equipment, cycle time, personnel, manufacturing and inspection specifications, measuring and testing equipment ...).</p> <p><b>Note:</b> Depending on the time of the audit some parts of the relevant production test could still be at the planning stage!</p> <p>The question is not relevant for the product development!</p>	<p><u>Product / Process Development</u></p> <p><u>Process Development</u></p> <ul style="list-style-type: none"> <li>- Customer requirements</li> <li>- Determination of minimum quantities (intended production rate and flexibility as agreed upon)</li> <li>- Process capability study</li> <li>- Measurement capability</li> <li>- Equipment and infrastructure are ready for start of series (measurement reports)</li> <li>- Personal concept for serial production</li> <li>- Work/inspection instructions</li> <li>- Production tests according to customer schedule</li> <li>- Packaging requirements</li> </ul>

<b>P4.7* Is there a controlled method for the product handover from development to serial production?</b>	
<p>A process exists for transferring work results from the project to the production.</p> <p>For products with integrated software, the results of the development (including the intermediate results and their documentation) are documented.</p> <p>Prerequisite for project delivery is a successful internal PPA process. Prerequisite for a series delivery release is the successful customer approval. Resulting actions from internal and external releases are implemented on time.</p> <p>Proof of capability can be shown for all special characteristics.</p> <p>The human resources are available in accordance with the planning and are qualified.</p> <p>The material resources include buildings, test facilities, laboratory facilities, equipment, facilities, etc. These are available and have been released.</p> <p>Releases for volumes of procurement are available.</p> <p>Measures to safeguard the SOP are specified and introduced when necessary.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Customer requirements</li> <li>- Handover protocols/ checklists with handover criteria</li> <li>- Acceptance reports</li> <li>- Production control plan</li> <li>- inspection plans</li> <li>- Part history</li> <li>- A method has been determined to carry out failure analysis and to introduce corrective measures</li> <li>- Production metrics such as OEE, rejects,...</li> <li>- Experience from the ongoing project</li> <li>- Measurement capability</li> </ul>

## 7.5 Supplier Management (P5)

Process Element P5: Supplier Management	
Minimum requirements / Relevant for Assessment:	Examples for implementation
<b>P5.1 Are only approved and quality-capable suppliers used?</b>	
<p>It must be ensured in serial production that only approved suppliers are used. An evaluation of the qualification capability must be available.</p> <p>An analysis of the quality performance of existing suppliers has to be considered using defined criteria. Risks in the supply chain have been identified, evaluated and reduced using suitable measures (emergency strategy).</p>	<ul style="list-style-type: none"> <li>- Defined and documented criteria are used for supplier selection.</li> <li>- Evidence of a qualification programme for suppliers who did not meet the selection criteria</li> <li>- Evaluation of the quality capability (QM- System, Process) for example self-assessment, audit results, supplier certificates</li> <li>- Results of the potential analysis</li> </ul> <p>Also applies to:</p> <ul style="list-style-type: none"> <li>- research and development suppliers / prototype suppliers</li> <li>- Suppliers of intangible products such as software</li> <li>- Suppliers of equipment, machinery, tools</li> <li>- Service providers (eg. sorting companies)</li> <li>- External testing labs</li> <li>- Suppliers in outsourced processes</li> </ul>

## **P5.2 Are customer requirements taken into account in the supply chain?**

The communication of customer requirements must be regulated and traceable.

Customer requirements also include requirements from drawings, components, software or component specifications from QM agreements and other applicable standards.

Likewise, change management has to be considered during serial production.

Interfaces are identified and secured.

- Transmission of requirements, tolerances, time schedule, process releases, releases, complaints etc. with ensuring change management
- Interface Agreement
- QAA (quality assurance agreements)
- Legal, regulatory requirements

## **P5.3 Have target agreements for supplier performance been agreed upon and implemented?**

Target agreements have been made with all suppliers throughout the supply chain for products and processes. These agreements have been verified and implemented.

Supplier output must be checked and evaluated within a defined period.

If deviations occur actions must be agreed upon and their implementation including deadlines are to be monitored.

- Measurable targets for quality, delivery quantity (batches) punctuality, for example to: reduce the ppm rates within the 0-failure strategy
- QM agreements including escalation mechanisms
- Avoidance of special trips
- Reduction of rejects
- Reduction of the work in progress inventory

## **P5.4\* Are the necessary releases / approvals available for out sourced products and services?**

A release must be available for all out-sourced products and services before serial production of new / changed products / processes.

Unless otherwise specified, the supplier for the supply of modules has the full quality control responsibility for all individual components.

- Specifications / standards / testing instructions
- PPA-Reports when necessary with software test reports
- Proof of capability for special characteristics
- Legal / country specific requirements (e.g. CCC, Inmetro, IMDS, REACH)
- Qualification tests / reports
- Model releases
- Change management in the supply chain
- Approval agreements for the scope of small batches and individual requirements



**P5.5\* Is the quality of the out-sourced products and services ensured?**

To monitor the quality of the out-sourced products and services, regular checks are carried out, documented and evaluated.

Deviations from the supplier quality are processed through a standard complaint process.

Layout inspection and functional verification checks are carried out according to customer requirements.

Test, inspection and measurement equipment must be stored in an orderly manner and associated workstations must be laid out appropriately (e.g. climate control, lighting order, cleanliness, and protection against damage and contamination).

- Coordination of test / inspection procedures, processes and frequencies
- Reference parts
- Sample size (e.g. Skip Lot)
- Evaluation of main failures
- ppm evaluations, 8D reports
- Agreement and tracking of improvement programmes
- Testing possibilities (internal and external laboratories and testing facilities, testing in accordance with ISO/IEC 17025) for raw materials (material certificates) and finished parts
- Gauges / fixtures
- Drawings / ordering and packaging requirements / specifications
- Proof of capability
- Layout inspection and a functional verification checks / reports
- Test certificates



#### **P5.6 Are incoming goods stored appropriately?**

Incoming materials and loading equipment must be stored in accordance with their release status so that they cannot be damaged or mixed.

For materials that could be damaged by temperature, humidity, vibration, etc. and affect the quality of the final product, the transport and storage conditions must be defined and verified.

Terms of transport should be determined for critical incoming materials.

“Suspect” / quarantined products must be stored securely to prevent access to them.

FIFO and batch traceability are to be ensured when the materials and goods are further processed.

Material stock figures in the inventory control agree with the quantities actually in stock.

Storage conditions conform with the product requirements.

- Packing
- Inventory control
- Labelling (traceability / test status / work sequence / use status)
- Quarantine stores; quarantine areas
- FIFO
- Batch-related use
- Shelf life requirements
- Climatic conditions
- Protection against damage / contamination / corrosion
- Order and cleanliness
- Precautions to prevent mixing / mistakes
- Remaining quantities from production

#### **P5.7 Are personnel qualified for their respective tasks and are responsibilities defined?**

A description must be given of what responsibilities, tasks and authority the employees have in their relevant task areas (e.g. for incoming inspection, complaint processing, supplier management, supplier audit).

Qualification requirements must be determined for each employee in relation to their tasks and qualifications carried out accordingly.

Knowledge of previous complaints is available when appropriate for purchased products and services.

- Product / specifications/ customer requirements
- Knowledge about product features and production process for the individual parts of modules
- Standards / legislation
- Packaging requirements
- Assessment methods (audits, statistics)
- Quality procedures (e.g. 8D-method, cause / effect diagram)
- Complaints and corrective action
- Qualification matrix
- Foreign languages
- Qualification of supplier auditors

## 7.6 Process Analysis Production (P6)

Process Element P6: Process Analysis Production	
P6.1 What goes into the process? Process input	
Minimum requirements relevant for assessment	Examples for implementation
P6.1.1 Has the project been transferred from development to serial production and is a reliable start guaranteed?	
<p>The project transfer to serial production has been carried out and if necessary unresolved issues are followed up on and implemented on schedule. The responsibilities for the entire handover process are regulated and acknowledged.</p> <p>A complete production process and product release including the documentation required must take place before the first production shipment.</p> <p>Measures are taken to secure the launch of production. A process for the further development of the process / product FMEA is defined and regulated.</p> <p>Tools, test and measurement equipment are available in the necessary quantities.</p>	<ul style="list-style-type: none"> <li>- Project status reports</li> <li>- Transfer reports</li> <li>- Milestone reports</li> <li>- Defined actions with implementation schedule</li> <li>- Process FMEA and actions</li> <li>- Product FMEA and actions</li> <li>- Production release report</li> <li>- Machine and process capability examination</li> <li>- Production test / production trial run and evidence</li> <li>- Transport planning process</li> <li>- Customer release (product release, process release)</li> <li>- Nonconformity permission when necessary</li> <li>- Released software standard</li> </ul>
P6.1.2 Are the necessary quantities / production batch sizes of incoming materials available at the agreed upon time and at the correct storage / work-station?	
<p>The correct product (incoming material, part, component etc.) must be provided to the agreed quality, in the correct quantity and the correct packing, with the correct documentation, at the agreed time and at the agreed place. Parts/components must be available at defined storage areas/work-stations.</p> <p>At the workplace, parts and materials are provided as needed, taking into account the order quantity / lot size (for example, Kanban, Just in time, FIFO). Upstream processes are taken into account.</p> <p>After order completion, the return of unneeded parts (surplus) including their quantity is regulated.</p>	<ul style="list-style-type: none"> <li>- Sufficient and appropriate transport facilities</li> <li>- Defined storage points</li> <li>- KANBAN</li> <li>- Just in time/ just in sequence</li> <li>- Inventory control</li> <li>- Change status</li> <li>- Exchange of information to the return of unnecessary components / surplus</li> <li>- Inventory</li> <li>- Production levels tailored to the customer's requirements</li> <li>- Special requirements for components and containers (ESD-protection for electronic components, residue,.....)</li> </ul>

**P6.1.3 Are incoming materials stored appropriately and are the means of transport means / packing facilities suitable for the special characteristics of the incoming materials?**

Packaging requirements must be consistently taken into account / implemented (also in the production stages).

During manufacture and internal transport and also when being transported to and from service companies, suitable transport units must be used to protect the products from damage and contamination.

Store areas /work-stations / containers must be appropriate for the tidiness and cleanliness required for the parts/products. Cleaning cycles are defined and monitored.

The supply of parts/materials at the work-station/on the assembly line must allow for safe handling.

Specified storage times and use-by dates for special materials/ parts must be monitored by appropriate methods (maximum and minimum storage times; specified interim storage times).

Critical operating and auxiliary materials for plant and machinery with a direct effect on the product / product quality must be monitored accordingly.

Parts / incoming materials / critical operating and auxiliary materials must be protected against environmental / climatic influences.

- Stock quantities
- Storage conditions
- Released special and standard transport containers
- Packaging requirements
- In-house transport containers
- Protection against damage
- Positioning of parts in the workplace
- Cleanliness, order
- Over-filling (bins and containers)
- Monitoring of storage times

<b>P6.1.4 Are the necessary identifications / records / releases available and allocated appropriately to the incoming materials?</b>	
<p>Released incoming materials must be clearly identified and recognizable. The release status must be identifiable and the release identification on bundles / batches/ load containers / parts must be defined.</p> <p>It must be ensured that only released materials/parts are forwarded to production/the next process stage and used.</p> <p>The traceability of the units produced must be ensured within a reasonable framework (e.g., documentation covering the use of batches).</p> <p>Depending on the product risk, traceability must be guaranteed across the entire process chain, from sub-supplier to the customer.</p> <p>Customer identification and traceability requirements must be taken into account.</p> <p>Legal and regulatory requirements are taken into account.</p> <p>The testing results of characteristics with special requirements for documentation and archiving are recorded accordingly.</p>	<ul style="list-style-type: none"> <li>- Customer specifications,</li> <li>- Customer requirements for labelling and tracing</li> <li>- Legal requirements, product liability laws</li> <li>- Identification of replacement parts</li> <li>- Process for the release of released parts / materials</li> <li>- Identification of released parts /materials (stickers, labels, issue slips)</li> <li>- Records of approvals</li> <li>- Traceability system or concept</li> <li>- Documentation of special releases (number, duration, type of identification, ..)</li> </ul>

**P6.1.5 Are changes to the product or process in the course of serial production tracked and documented?**

Change management must be clearly documented from the change request to implementation and responsibilities must be regulated.

Changes that impact on customer requirements must be coordinated, approved and released by the customer. If necessary a new PPA must be carried out. This includes both product and process changes (including software changes).

Documentation of change status must be fully traceable.

It must be ensured that, at all times, the correct design level of the incoming materials or software is used and the correct design level of the finished product is manufactured and shipped to the customer.

- Change release by the organisation and the customer (feasibility; interface to components, effect on costs and schedules,...)
- Information about changes is passed onto process development, production areas, stores or to sub-suppliers
- The level of implementation of the change is tracked (overview with status)
- Documented change record (part life history)
- Up-dating from documents involved (drawings, instructions)
- Up-dates of the FMEA (Product and Process)
- Verification and validation of changes including documentation
- Controlled introduction of changes and modified products / parts
- Lead times for changes, advance production of security stock before major changes which require a production stop (customer requirements etc.)
- Change levels of test/inspection equipment, gauges, tools and drawings
- Parameter changes
- Software

Process Element P6: Process analysis Production	
P6.2 Are all Production Processes controlled? (process sequence)	
Minimum requirements relevant for assessment	Examples for implementation
P6.2.1 Are the requirements of the control plan complete and have they been effectively implemented?	
<p>The production and test/inspection documents are complete and available and based on the production control plan. Inspection characteristics, facilities, methods, frequencies / cycles and re-qualifications must be defined. Access to these documents must be available at all times.</p> <p>Process parameters influencing product characteristics and/or quality must be fully stated. Tolerances must be given for process parameters and inspection characteristics. The control limits in process control charts must be defined, identifiable and traceable.</p> <p>Deviations and actions taken regarding process requirements and inspection characteristics must be documented. Required measures (action plan) for process disturbances are known and initiated and documented by the responsible employees.</p> <p>For products with specific requirements on the manufacturing process the appropriate data about machinery /tools /resources must be noted in the production control plan. When necessary these must also be recorded in the manufacturing and inspection documents.</p> <p>Conditions governing reworking are ensured and secured within the process (parts identification; re-checking/inspection, ...).</p>	<ul style="list-style-type: none"> <li>- Machine and process capability certification</li> <li>- Process parameters and tolerances (pressure, temperatures, times, speeds, )</li> <li>- Inspection specifications (special characteristics, attributive characteristics, inspection specifications, methods and frequency)</li> <li>- Data regarding machines/tools/ auxiliary aids (tool and machine numbers)</li> <li>- Guidelines regarding measurement fixtures/ reference points</li> <li>- Work instructions including reworking</li> <li>- Inspection instructions</li> <li>- Specific requirements on the manufacturing technology, e.g. sampling relevant assignment of machines and plants</li> </ul>

#### **P6.2.2\* Is there a repeat release of manufacturing processes?**

The restart of production is the new release order for the start of production.

Criteria for triggering a restart of production must be defined e.g. after an interruption of production.

The restart of production is necessary for product and process and must be carried out and documented by authorised employees using acceptance criteria. Deviations and measures taken are to be documented.

The restart of production inspection must be carried out using clear inspection instructions (quantity and method).

If production is continued after collection of samples, parts should be considered suspect pending approval until the samples are approved.

At the time of release the necessary reference and tolerance samples must be available.

- Release of a batch
- Release of reworked parts
- First piece release / first part release
- Tooling diagrams/ reference parts / installation parts (e.g. error check, red rabbit)
- Possible triggering criteria for a restart of production:
  - Production interruption (e.g. night time in two shift operations, tool changes, material / batch / product change
  - Repair, tool change
  - Setting data

#### **P6.2.3\* Are special characteristics managed in the production?**

Special product characteristics and process parameters that affect the special characteristics are marked in the production control plan and systematically monitored.

Records are maintained of non-compliances and corrective actions. Deviations affecting the characteristics of the product must be approved by the customer.

Quality records are specified for significant characteristics (duration and type of archiving) and are coordinated with the customer.

- Product FMEA / Process FMEA
- Production control plan
- Quality records
- Statistical evaluations
- SPC evaluations
- Quality control charts
- Proof of capability (Cpk, Cmk, machine capability checks, ...)
- Proof of inspection process
- Inspection results
- Drawings
- Special characteristics

#### **P6.2.4\* Are non-approved and / or defective parts managed?**

Non-approved parts, defective parts and/or parts with defective characteristics (scrap and parts for reworking) must be separated and collected or when necessary safely removed from the production process.

These parts are to be either directly marked or marked on their container.

Reworking criteria including testing are defined, known and implemented.

Storage areas for blocked stock and restricted areas must be clearly labelled. Inadvertent use of restricted parts must be excluded.

Setting masters, setup and reference parts must be labelled and protected against accidental use.

- Labelling of scrap, rework and setting parts
- Labelling of containers for scrap, rework and setting parts
- Defined scrap/rework stations in production
- Storage areas for blocked stock and restricted areas
- Records of rework and scrap

#### **P6.2.5 Is the flow of materials and parts secured against mixing / wrong items?**

A mix of materials or the use of wrong materials, software or components cannot occur.

Appropriate measures and checks must be taken to ensure the early detection and ejection of incorrectly installed items.

Associated topics and actions must be included and examined in the Process FMEA and, if appropriate, in the Product FMEA.

The process and/or inspection status must be clearly visible.

The reuse of residues, separated parts, reworked parts, reusable parts from audits, inspected items etc. must be clearly defined (including regulations for traceability).

Regulations for reintroducing parts or outsourced processed (e.g. sorting service) must be available.

- Material and parts flow
- Product / Process FMEA
- Poka Yoke actions
- Questioning and tests in production facilities
- Parts identification
- Identification of work, inspection and usage status
- Batch identification, traceability of the installation of batches or the production of batches
- Removal of invalid labelling
- Working papers with master data for parts / production
- Design status
- Material flow analysis
- Regulations for reworking



Process Element P 6: Process analysis Production	
P6.3 What functions support the process? (personnel resources)	
Minimum requirements relevant for assessment	Examples for implementation
P6.3.1* Are the employees able to fulfil their given tasks?	
<p>A description of tasks with an appropriate job profile must be available for employees. A qualification programme (if necessary) is derived from this profile.</p> <p>Who is qualified for each task and activity must be documented.</p> <p>Trainings, instruction, briefings, / proof of qualifications that have been performed must be documented.</p> <p>Employees must be instructed in the handling and treatment of products with special characteristics.</p> <p>Suitable evidence of qualification for each activity must be present (e.g. forklift driving license, welding certificate, soldering certificate, vision test, hearing test).</p> <p>Employees responsible for measuring and testing must be trained in the correct use of measurement and testing equipment.</p> <p>Trainings / instructions are given at changes to the product / process and these are documented.</p> <p>The requirements also apply to internal and external temporary employees.</p>	<ul style="list-style-type: none"> <li>- Training / qualification evidence</li> <li>- Qualification matrix</li> <li>- Initial training plan with evidence</li> <li>- Knowledge about the product and failures that have occurred</li> <li>- Handling of measurement and testing equipment</li> <li>- Training in work safety / environmental aspects</li> <li>- Training in special characteristics</li> <li>- Suitable evidence of qualification (e.g. welding certificate, vision test results, driving license for industrial trucks)</li> <li>- Training about the product</li> </ul>

<b>P6.3.2 Do the employees know their responsibilities and authority in the monitoring of the product and process quality?</b>	
<p>Responsibilities, duties and authority of the employees in their task areas are described and implemented (e.g. process release, first piece inspection, employee self-inspections, stopping the process).</p> <p>The employees know the consequences of faulty workmanship (which tasks / function the product has and what happens when they are no longer guaranteed due to faulty installation etc.).</p> <p>Employees receive regular information on the current standard of quality reached, both internally and with the customer (complaints).</p> <p>The requirements also apply to internal and external temporary employees.</p>	<ul style="list-style-type: none"> <li>- Work / inspection instructions</li> <li>- Qualifications matrix</li> <li>- Job descriptions</li> <li>- Employee self-inspections</li> <li>- Process release (setup release, first piece inspection, last piece inspection)</li> <li>- Process control (interpretation of control charts)</li> <li>- Authority to stop and start the process</li> <li>- Order and cleanliness</li> <li>- Repair and maintenance is carried out or when necessary, arranged for</li> <li>- Parts supply / storage</li> <li>- Provision and adjustment of test / measurement is carried out or when necessary, arranged for</li> <li>- Training about the product</li> <li>- Quality information (target / actual values)</li> <li>- Product safety / product liability trainings</li> </ul>

<b>P6.3.3 Are the necessary personnel resources available?</b>	
<p>The required number of qualified employees is available for all shifts. Employee qualifications need to be considered when scheduling staff (e.g. qualification matrix).</p> <p>A scheme exists for supporting areas that are not continually in use (e.g. laboratory, measurement room).</p> <p>Fluctuations in on call staff and through absences (e.g. illness, holidays, training) are taken into account in the schedule.</p> <p>The requirements also apply to internal and external temporary employees.</p>	<ul style="list-style-type: none"> <li>- Shift plan</li> <li>- Evidence of qualifications (qualification matrix)</li> <li>- Documented absence management rules</li> <li>- Workforce scheduling</li> </ul>

Process Element P6: Process analysis Production	
P 6.4 What means are used to implement the process? Material Resources	
Minimum requirements relevant for assessment	Examples for implementation
<b>P6.4.1* Can the product-specific requirements from the customer be met with the manufacturing equipment?</b>	
<p>It must be shown that the processes are implemented in accordance with the customer requirements using the existing production facilities. Further it must be shown that the resulting products meet the customer specifications.</p> <p>The production facilities, machinery and equipment must be able to comply with the specified tolerances for the respective characteristic.</p> <p>Process capability must be determined for selected product and process characteristics and continually proven.</p> <p>The process capability must meet the customer requirements. For long term process capability the minimum requirement of <math>C_{pk} \geq 1,33</math> must be met. In the case of significant characteristics where no capability level can be proven, 100% inspection is required.</p> <p>Layout and condition of the equipment, tools, fixtures and handling facilities meet the requirements under real production conditions.</p>	<ul style="list-style-type: none"> <li>- Evidence of machine / process capability for special characteristics / process-determining parameters (e.g pressure, time, temperature)</li> <li>- Warning at deviations from limit specifications / parameters (e.g. an alarm, lamp, or automatic shut-down)</li> <li>- Feed and removal systems</li> <li>- Capability of replacement tools / reproducibility of fixtures, specifications</li> <li>- Cleanliness requirements</li> </ul>

#### **P6.4.2 Is the maintenance of the manufacturing equipment and tools controlled?**

Maintenance activities (maintenance, inspection and repair) are determined and implemented for all installations, equipment and machines.

Maintenance activities that have been carried out (scheduled and unplanned) are documented and analysed for improvement measures.

A process for the analysis and optimization of downtime, machine utilization and tool life is implemented effectively.

The key processes and critical machines are identified and appropriate maintenance activities (preventative or proactive) are carried out in terms of a risk-based maintenance programme. The availability of replacement parts must be ensured.

Resources needed to carry out necessary maintenance measures are available.

Tools undergo a tool management which includes the following:

- Status indication (OK / NOK/in repair)
- Tool identity card including all changes made to the tool
- Tool life (e.g. operating hours, strokes or shot numbers)
- Protection from damage
- Tool ownership

- Availability / use of the appropriate technical documents
- Maintenance plan / maintenance tasks
- Weak-point analysis
- Preventative tool exchange programme for units subject to increased wear and tear
- Storage and retrieval machines / equipment for transport and storage etc.
- Availability of spare parts at production facilities producing key products
- Compliance with the prescribed maintenance intervals
- Documentation of maintenance activities
- Regular plausibility check of the scheduled maintenance intervals
- Hiring of external service companies to carry out maintenance

<b>P6.4.3* Can the quality requirements be effectively monitored with the measurement and testing facilities in use?</b>	
<p>The test, inspection and measurement facilities used are suitable for the planned purpose and handling in production. They are included in the production control plan.</p> <p>Capability studies are carried out on the measurement devices and measurement systems employed. The accuracy of this equipment is appropriate for the purpose and for the characteristics to be checked. There is an identification system for measurement and inspection equipment. Administration of this equipment is based on the identification.</p> <p>A process for the periodic monitoring of measurement and inspection equipment is installed and implemented (responsibility for collection and return is defined). This process also takes into account the calibration of process-integrated measurement technology with an influence on the product characteristics.</p> <p>Measurement and inspection equipment accessories having an influence on measurement accuracy and the measurement result are monitored in the same way.</p>	<ul style="list-style-type: none"> <li>- Production control plan</li> <li>- Measurement accuracy / capability of inspection equipment</li> <li>- Proof of the capability of inspection processes</li> <li>- Data collection and its evaluability</li> <li>- Evidence of the calibration of inspection equipment</li> <li>- Comparison of inspection equipment / measurement processes with the customer (e.g. interlaboratory comparisons)</li> <li>- Inspection stickers or certificates</li> <li>- Reference component / set-up parts (e.g. Red Rabbit, error test pieces)</li> </ul>

<b>P6.4.4 Are the work and inspection stations appropriate for the needs?</b>	
<p>Conditions for the work-places and their surroundings are appropriate for the products and the work carried out, in order to prevent / eliminate contamination, damage, mixing-up of parts and misinterpretations.</p> <p>This also applies to permanent and temporary established rework, sorting and inspection stations.</p> <p>In addition, the work-place layout is adapted ergonomically to the work to be carried out.</p> <p>.</p>	<ul style="list-style-type: none"> <li>- Lighting</li> <li>- Cleanliness and tidiness</li> <li>- Climate control</li> <li>- Noise pollution</li> <li>- Clean rooms</li> <li>- Work place lay-out</li> <li>- Surroundings / handling parts at the work-place</li> <li>- Work safety</li> </ul>

<b>P6.4.5 Are tools, equipment and testing equipment stored properly?</b>	
<p>Tools, equipment and testing equipment (including gauges) must be stored and managed properly. This also applies for tools, equipment and test equipment not in use or not yet released.</p> <p>All tools, equipment and testing equipment are identified with their current status and all changes are documented (change history).</p> <p>Storage is provided where the equipment is protected against damage and environmental effects. Cleanliness and tidiness are ensured.</p> <p>The issue and use of this equipment is controlled and documented.</p>	<ul style="list-style-type: none"> <li>- Stored free from damage</li> <li>- Cleanliness and tidiness</li> <li>- Defined storage location</li> <li>- Environmental influences</li> <li>- Status identification</li> <li>- Identification showing customer's property, products/tools/devices provided on loan</li> <li>- Defined release status and change level</li> <li>- Storage and retrieval machines / equipment for transport and storage etc.</li> <li>- Reference component / set-up parts (e.g. Red Rabbit, error test pieces)</li> </ul>

<b>Process element P6: Process analysis Production</b>	
<b>P6.5 How effective is the process being carried out? Effectiveness, efficiency, elimination of waste</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<b>P6.5.1 Are there targets set for the manufacturing process?</b>	
<p>Process-specific targets are defined, monitored and communicated (quantities produced; quality metrics such as failure rates, audit results, through-times and process effectiveness figures (Cpk) ).</p> <p>Target requirements are coordinated and achievable; they are guaranteed to be up to date.</p> <p>Customer requirements are taken into account when setting targets.</p> <p>A regular comparison is made between specified and actual results.</p>	<ul style="list-style-type: none"> <li>- Availability of installations and machines</li> <li>- Number of parts produced per unit of time</li> <li>- Rework, scrap</li> <li>- Production runs with no reworking, first passes, first time through quality, first pass yield</li> <li>- Quality metrics (e.g., failure rates, audit results)</li> <li>- Process metrics (process capability)</li> <li>- Reduction of waste (e.g., scrap and rework, energy and process materials)</li> </ul>

### **P6.5.2 Is quality and process data collected in a way that allows analysis?**

To demonstrate compliance with the requirements and objectives which are needed for the evidence of product conformity, it is necessary to define and document quality and process parameters (target values) and record the actual data (actual value).

It must be ensured that data can be evaluated.

Special incidents are documented (shift / equipment book).

The recorded data can be related to a product and process, the data is available, legible, accessible and archived as specified. Requirements for traceability are respected.

The collected data is analysed and appropriate action for improvement is initiated. A risk-based approach is used here. The potential for improvement must be continuously determined from recent findings on quality, costs, services.

Events that result in a change to the process or to the product must be documented in the appropriate FMEA and the respective measures taken are recorded.

- Defect frequency cards
- Control charts
- Special characteristics
- Process parameters (temperature, time, pressure....)
- Factory data collection
- Fault signals (e.g. plant standstill, power failure, programme error message)
- Parameter changes
- Error type / error frequencies
- Error costs (nonconformity)
- Rejects / reworking
- Blocking message / sorting actions
- Cycle times; through-put times
- SPC
- Pareto analyses
- Cause & effect diagrams
- Risk analysis (FMEA, FTA,...)
- Traceability system

### **P6.5.3 In the case of deviations from product and process requirements, are the causes analysed and the corrective actions checked for effectiveness?**

If deviations from product and process requirements occur, immediate containment actions must be taken to comply with the requirements, until the causes of failure are eliminated and evidence has been provided of the effectiveness of the corrective actions. These actions are known by the employees.

Suitable methods for root cause analysis are in use.

Corrective measures are derived, their implementation is monitored and the effectiveness verified.

Production control plan and FMEA are updated as needed.

Nonconformities that affect the properties of the delivered product are communicated to the customer.

- 8 D method
- Cause & effects diagram
- Taguchi, Shainin
- 5 W method
- FMEA / error analysis
- Process capability analysis
- Quality control circles
- Analytical assessment methods
- Information flow to the customer
- Product FMEA and process FMEA
- Waivers / special releases
- Additional dimensional material, functional and endurance checks and tests

<b>P6.5.4 Are processes and products audited regularly?</b>	
<p>The audit programmes for process and product audits are available and implemented. Customer requirements are taken into account.</p> <p>The process and product audits carried out are suitable to identify specific risks and weak points and implement corrective measures.</p> <p>A root cause analysis is carried out when deviations occur. Corrective measures are derived, their implementation is monitored and the effectiveness is verified.</p> <p>Product audits are periodically carried out and documented. Scope of the audit is the end product and where necessary intermediate products. In the product audit specified characteristics are examined and tested according to previously defined specifications.</p> <p>Nonconformities that affect the properties of the delivered product are communicated to the customer.</p>	<p><u>Product and process audit:</u></p> <ul style="list-style-type: none"> <li>- Specifications</li> <li>- Special characteristics</li> <li>- Audit programme for product and process audits including scheduled and event-based audits</li> <li>- Frequency of audits</li> <li>- Audit requirements</li> <li>- Audit results, audit reports</li> <li>- Auditor qualification</li> </ul> <p><u>Process audit</u></p> <ul style="list-style-type: none"> <li>- Process parameter / capability</li> </ul> <p><u>Product audit</u></p> <ul style="list-style-type: none"> <li>- Labelling, packaging</li> <li>- Capacity of the test equipment</li> <li>- Software version</li> </ul>

<b>Process Element P6: Process Analysis Production</b>	
<b>P6.6 What should the process produce? Process result (output)</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<b>P6.6.1 Do the quantities / production batch sizes match needs and are they systematically directed to the next process step?</b>	
<p>Parts/components must be forwarded to defined storage/holding points using suitable means of transport. In this, attention must be paid to the order quantity/batch size so that only the required quantity of parts/materials is moved to the stipulated workstation.</p> <p>The current state of the component (OK parts, reworked parts, scrap) must be evident from the labelling (component, container). Varying change statuses of the component must be taken into account.</p> <p>It is ensured that a further processing / forwarding of NOK parts is not possible.</p>	<ul style="list-style-type: none"> <li>- Adequate, appropriate means of transport</li> <li>- Defined storage points</li> <li>- KANBAN</li> <li>- Just in time / just in sequence</li> <li>- Stores management</li> <li>- Change status</li> <li>- Production quantities tailored to the customer's needs</li> <li>- Special requirements for components and containers (ESD-protection for electronic components, residual dirt)</li> </ul>



<b>P6.6.2 Are products / components stored in an appropriate manner and are transport facilities / packing arrangements suitable for the special characteristics of the products / components?</b>	
<p>The product / components must be protected from damage by suitable storage and packing.</p> <p>Internal and customer-specific packing instructions are available and implemented.</p> <p>Storage points/containers must meet essential requirements for cleanliness &amp; tidiness. Specified storage times must be monitored (specified maximum, minimum and interim storage times).</p> <p>Parts must be protected against environmental and climatic influences during storage and processing.</p> <p>These requirements are valid for the handling within the production process as well as the delivery.</p>	<ul style="list-style-type: none"> <li>- Protection from damage</li> <li>- Positioning of parts</li> <li>- Cleanliness, tidiness, over-filling (storage points &amp; containers)</li> <li>- Monitoring of storage periods / quantities stored</li> <li>- Environmental and climatic influences</li> <li>- Internal and customer-specific packing instructions</li> <li>- Customer specific packaging instructions (inc. packing supplied by the customer)</li> <li>- Information on available stock levels</li> <li>- Substitute packaging</li> <li>- Requirements for cleaning packaging</li> <li>- Sufficient amount of package materials</li> </ul>

<b>P6.6.3 Are the necessary records / releases documented?</b>	
<p>The labelling of the release status on containers / batches / carriers / components must be specified.</p> <p>Released products / components must be clearly marked and the release status must be visible.</p> <p>Special releases and releases with deviation approvals must be traceable by appropriate identification and documentation. The documentation must cover the period and/or quantity of parts involved. These details are documented including the identification on the component / carrier.</p> <p>Customer requirements for the labelling of reworked parts must be implemented and documented (amount / quantity / labelling / part history / use). The traceability of units produced must be ensured.</p> <p>For archiving requirements and duration, the customer requirements are taken into account.</p>	<ul style="list-style-type: none"> <li>- Customer specifications</li> <li>- Significant characteristics</li> <li>- Customer's identification requirements</li> <li>- Customer's requirements for archiving time limits</li> <li>- Archiving requirements/regulations (EDP, paper, fire protection, legibility, ...)</li> <li>- Last piece inspection</li> <li>- Part history</li> <li>- Identification of special releases</li> </ul>

**P6.6.4\* Are the customer requirements met at the delivery of the final product?**

The customer specific requirements of the final product (delivery reliability, quality goals, quality performance etc.) are known and monitored. If deviations occur, corrective actions are defined and implemented.

Final products are shipped in accordance with the customer requirements (shipping audit etc.).

The handling of supplied products is regulated and implemented.

Customers should be informed of delivery stops which affect them and further procedure should be coordinated with them.

- Quality agreements with the customer
- Customer specific requirements
- Customer requirements for the identification of special characteristics
- The planning of the shipping audit
- Storage / recall processing / parts supply / shipping
- Target agreements

Process Element P 7: Customer support, customer satisfaction, service	
Minimum requirements relevant for assessment:	Examples for implementation
<b>P7.1 Are all requirements related to QM System, Product and Process fulfilled?</b>	
<p>The internal and customer specific requirements on the quality system are fulfilled.</p> <p>Layout inspection and a functional verification checks are carried out according to the customer requirements.</p> <p>The customer requirements for the supply of spare parts during and after the production phase must be implemented.</p> <p>Customer requirements for the return of parts and their recycling must be implemented.</p>	<ul style="list-style-type: none"> <li>- Quality agreements with the customer</li> <li>- Layout inspection and a functional verification concept e.g. carried out product audits, function tests, endurance tests</li> <li>- Inclusion of sub-supplier for the supply of spare parts</li> <li>- Supply guarantee after serial production</li> <li>- Certification of the QM system</li> </ul>
<b>P7.2 Is customer service guaranteed?</b>	
<p>It must be ensured that competent contact personnel are available for the various areas in the customer's organisation. Communication is ensured in accordance with the customer specifications.</p> <p>The monitoring of the product in the field is ensured.</p> <p>Access to customer portals in accordance with the customer specific agreement is ensured.</p>	<ul style="list-style-type: none"> <li>- Knowledge of the product application</li> <li>- Knowledge of problems with the product and complaints regarding the product or transport</li> <li>- Implementation of new requirements</li> <li>- Notification of improvement actions</li> <li>- World-wide customer service</li> <li>- Information from the customer by non-compliance with the requirements</li> </ul>

<b>P7.3* Is the supply of parts guaranteed?</b>	
<p>Concepts to ensure supplies are available and up to date. These concepts should also cover emergency situations.</p> <p>For this, not only the in-house processes but also the processes or suppliers must be considered.</p> <p>Procedures must be in place which guarantees that the organisation informs the customer immediately when supply shortages are detected.</p> <p>The information must include the expected duration and extent of the shortages and the actions which have been taken.</p>	<ul style="list-style-type: none"> <li>- Contingency plans (e.g., for alternative production, suppliers, transport)</li> <li>- Capacity and reaction time for sorting actions</li> <li>- Use of external capacity</li> <li>- Communication regarding supply shortages</li> <li>- Regulations covering authority to make decisions / escalation paths when introducing special actions</li> <li>- Blocking of parts</li> </ul>

<b>P7.4* If there are deviations from quality requirements, are failure analyses carried out and corrective actions implemented effectively?</b>	
<p>A complaint process that meets the customer requirements (e.g. 8D) is used for O km and field complaints.</p> <p>Procedures for failure analysis are defined. The necessary human and material resources are available to ensure punctual processing. The customer has to be informed when deviations to the time limits coordinated occur.</p> <p>By field complaints a failure analysis is to be carried out according to customer requirements (e.g. VDA Volume Field Failure Analysis).</p>	<ul style="list-style-type: none"> <li>- Process for processing complaints</li> <li>- 8D process</li> <li>- Internal / external analysis facilities (laboratories, comprehensive testing facilities, personnel)</li> <li>- Use of problem solving methods</li> <li>- Performance tests</li> <li>- Flow of information to the customer by deviations</li> <li>- Knowledge store, lessons learned</li> <li>- Quality control loop</li> <li>- FMEA</li> <li>- Access to the necessary release documents (PPA etc.)</li> <li>- Testing concept for defective parts in the field (standard test/ stress test/ NTF test)</li> <li>- NTF guidelines</li> <li>- Performance indicators for processing of complaints</li> </ul>

<b>P7.5 Are personnel qualified for the various tasks and are responsibilities defined?</b>	
<p>It must be determined which responsibilities, duties and authorisations each employee has in their respective area of responsibility.</p> <p>Training needs must be determined individually and implemented for each person, depending on their tasks.</p> <p>The employees know the product and the consequences of faulty workmanship for the supply of parts and the quality of the final product.</p>	<ul style="list-style-type: none"> <li>- Organisational chart</li> <li>- Evidence of knowledge of the product / specifications / customer requirements</li> <li>- Standards / laws (product liability)</li> <li>- Processing / use</li> <li>- Failure analysis</li> <li>- Evaluation methods (e.g. audits, statistics)</li> <li>- Quality techniques (e.g. Pareto, 8D Method, cause and effect diagram, Ishikawa)</li> <li>- Foreign language skills</li> </ul>

## 8 Process Audit Services

### 8.1 Overview Questionnaire for Services

		Page
<b>D2</b>	<b>Project Management</b>	<b>96</b>
<b>2.1</b>	Is a project management established with a project organisation?	<b>96</b>
<b>2.2*</b>	Are all resources required for the project development planned and available and are changes shown?	<b>96</b>
<b>2.3</b>	Is there a project plan and has this been coordinated with the customer?	<b>97</b>
<b>2.4*</b>	Are all activities of the project implemented and monitored regularly for compliance?	<b>97</b>
<b>2.5</b>	Are the procurement activities of the project implemented and monitored for compliance?	<b>98</b>
<b>2.6*</b>	Is change management within the project ensured by the project organisation?	<b>98</b>
<b>2.7*</b>	Is there an escalation process established and is this effectively implemented?	<b>99</b>

<b>D3</b>	<b>Planning service development</b>	<b>100</b>
<b>3.1*</b>	Is a process established for determining the service requirements?	<b>100</b>
<b>3.2*</b>	Can the feasibility of the service be evaluated according to the requirements?	<b>100</b>
<b>3.3</b>	Are the activities in preparation for the service / service process planned in detail and coordinated with the customer?	<b>101</b>
<b>3.4</b>	Are the resources necessary to carry out the service available?	<b>101</b>

<b>D4</b>	<b>Implementation of the service / service development</b>	<b>102</b>
<b>4.1*</b>	Are the actions which were defined in the development plan for the service implemented?	<b>102</b>
<b>4.2*</b>	Are human resources available and are they qualified to ensure the start of the series?	<b>102</b>
<b>4.3</b>	Are the material resources available and suitable to ensure the start of the series?	<b>103</b>
<b>4.4*</b>	Are the required approvals and releases for the service / service development available?*	<b>103</b>
<b>4.5</b>	Are the service specifications derived from the product and process development and are they implemented?	<b>104</b>
<b>4.6</b>	Is a performance test for the developed service defined and performed to ensure that the service will withstand the stress of working conditions?	<b>104</b>
<b>4.7*</b>	Is there a controlled method for the product handover from development to serial production?	<b>105</b>

<b>D5</b>	<b>Supplier Management</b>	<b>106</b>
<b>5.1</b>	Are only approved and quality-capable suppliers and subcontractors used?	<b>106</b>
<b>5.2</b>	Are customer requirements taken into account in the supply chain?	<b>106</b>
<b>5.3*</b>	Have target agreements for supplier performance been agreed upon and implemented?	<b>106</b>
<b>5.4*</b>	Are the necessary releases available for out sourced products and services?	<b>107</b>
<b>5.5*</b>	Is the quality of the out-sourced products and services ensured?	<b>107</b>
<b>5.6</b>	Are personnel qualified for their respective tasks and are responsibilities defined?	<b>108</b>

<b>D6</b>	<b>Providing the service</b>	<b>109</b>
<b>6.1</b>	<b>What goes into the process? Process input</b>	<b>109</b>
<b>6.1.1</b>	Has the project been transferred from development to the provision of service and is a reliable start guaranteed?	<b>109</b>
<b>6.1.2</b>	Are the necessary materials for providing the service available at the agreed upon time and at the right location?	<b>109</b>
<b>6.1.3</b>	Are incoming materials necessary to provide the service stored appropriately and are the means of transport / packing facilities suitable for the special characteristics of the incoming materials?	<b>110</b>
<b>6.1.4*</b>	Are changes to the service made during the provision of the service tracked and documented?	<b>111</b>

<b>6.2</b>	<b>Are all processes necessary to provide the service determined?</b>	<b>112</b>
<b>6.2.1*</b>	Is the specification of the service level agreement complete and has it been effectively implemented?	<b>112</b>
<b>6.2.2*</b>	Are specific requirements (special characteristics) regulated during the provision of service?	<b>113</b>
<b>6.2.3*</b>	Are defective services identified and are appropriate measures taken (immediate measures and corrective actions)?	<b>113</b>

<b>6.3</b>	<b>What functions support the provision of the service? (personnel resources)</b>	<b>113</b>
<b>6.3.1*</b>	Are the employees able to fulfil their given tasks and ensure that the service is provided?	<b>113</b>
<b>6.3.2</b>	Do the employees know their responsibilities and authority in the monitoring of the quality of the service process and the service?	<b>114</b>
<b>6.3.3*</b>	Are the necessary personnel resources available?	<b>115</b>

<b>6.4</b>	<b>What means are used to provide the service? (material re-sources)</b>	<b>115</b>
<b>6.4.1</b>	Can the specific requirements from the customer be met with the equipment used for the provision of the service?	<b>115</b>
<b>6.4.2</b>	Is the maintenance of the equipment required for the provision of the service controlled?	<b>116</b>
<b>6.4.3*</b>	Can the quality requirements of the service be effectively monitored with the measurement and testing facilities in use?	<b>117</b>
<b>6.4.4</b>	Are the work stations for the provision of the service appropriate for the needs?	<b>117</b>
<b>6.4.5</b>	Are tools, equipment and testing equipment stored properly?	<b>118</b>

<b>6.5</b>	<b>How effective is the process for the provision of the service being carried out?</b> <b>Effectiveness, efficiency, waste avoidance</b>	<b>118</b>
<b>6.5.1*</b>	Are there targets set for the provision of the service?	<b>118</b>
<b>6.5.2</b>	Is quality and process data about the service collected in a way that allows analysis?	<b>119</b>
<b>6.5.3*</b>	In the case of deviations from the service requirements and provision of the service, are the causes analysed and the corrective actions checked for effectiveness?	<b>119</b>
<b>6.5.4</b>	Are service requirements and provision of the service audited regularly?	<b>120</b>

<b>6.6</b>	<b>What should the process produce?</b> <b>Process result (output)</b>	<b>120</b>
<b>6.6.1</b>	Are the necessary records concerning the service provided completed?	<b>120</b>
<b>6.6.2*</b>	Are customer requirements met at the delivery of the service?	<b>121</b>

<b>D7</b>	<b>Customer care / customer satisfaction / service</b>	<b>121</b>
<b>7.1</b>	Are all requirements related to QM-System and the service provided fulfilled?	<b>121</b>
<b>7.2*</b>	Is customer service guaranteed?	<b>121</b>
<b>7.3*</b>	Is the provision of the service guaranteed?	<b>122</b>
<b>7.4*</b>	If there are deviations from quality requirements, are failure analyses carried out and corrective actions implemented effectively?	<b>122</b>
<b>7.5</b>	Are personnel qualified for the various tasks and are responsibilities defined?	<b>123</b>



## 8.2 Project management (D2)

Process Element D2: Project Management	
Minimum requirements relevant for assessment:	Examples for implementation
<b>D2.1 Is a project management established with a project organisation?</b>	
<p>A process for project management exists.</p> <p>The project organisation is specified and contacts are defined.</p> <p>The responsibilities and authority of the project leader and team members are defined.</p> <p>The team members of the project are qualified to carry out their tasks.</p> <p>The project organisation meets the customer requirements.</p> <p>Suppliers are involved in project management.</p>	<ul style="list-style-type: none"> <li>- Defined rolls, tasks, competence and responsibilities of the project leader / project team expert for technology</li> <li>- Project interface in multi-site projects</li> <li>- Project organisational chart</li> <li>- Composition of the project team</li> <li>- Verification of qualifications</li> <li>- Special customer requirements for project management</li> </ul>

<b>D2.2* Are all resources required for the project development planned and available and are changes shown?</b>	
<p>Resource planning takes account of the customer's requirements, based on the contract covering the project.</p> <p>Resource planning for project members is established and implemented. The staff workload has to be considered.</p> <p>Review and where necessary adjustment of resource planning is carried out when changes occur (dates, scope of services provided...). This applies to changes that are triggered by the customer as well as internal changes or supplier changes.</p> <p>The critical path is given special consideration within the resource planning.</p> <p>The necessary project budget for personnel and equipment is planned and released.</p> <p>Changes in the project organisation (interface with client) are reported.</p>	<ul style="list-style-type: none"> <li>- Evidence of resource planning (taking other projects into account)</li> <li>- Resource planning for equipment (e.g. development tests)</li> </ul>

### **D2.3 Is there a project plan and has this been coordinated with the customer?**

The project plan meets the specific customer requirements.

All internal and customer defined milestones are fully incorporated in the project plan and are adjusted or updated as necessary.

In-house communication is ensured when changes are made to the project plan. Changes made to the project plan which affect the customer are coordinated with the customer.

The critical path is generated from the project plan and takes account of critical delivery items.

The project plan must include detailed activities to ensure the quality of the service provided. Detailed plans may be in a separate document referred to in the project plan.

The project plan must include the detailed activities concerning procurement. Detailed plans may be in a separate document referred to in the project plan.

- Project plan with milestones
- Specific customer requirements regarding provision of services
- Customer's project plan
- Customer's deadlines
- Customer's milestones
- Customer's targets (measurements within the individual milestones)
- Quality Plan

### **D2.4\* Are the project activities implemented and are they monitored for compliance?**

Do the project activities meet the specific customer requirements?

Is a review of the milestones identified within the project plan carried out? Are all planned activities implemented and is the required maturity level reached?

Verification and validation of the service requirements are contained within the plan.

The planning also addresses critical service provision (internal and external suppliers).

The plan is regularly monitored for compliance and for target achievement.

- Project plan
- Customer milestones
- Milestone evaluation (review)
- Customer requirements in regard to quality plans
- Customer specifications
- Specifications

## **D2.5 Are the procurement activities of the project implemented and monitored for compliance?**

The activities have to ensure that only approved and quality-capable suppliers are used in production.

The level of activity depends on the risk classification of procured scope of supplies.

These include the supplier selection and award criteria, award amount and delivery target date.  
The transfer of customer requirements in the supply chain is ensured.

The activities also include client's directed suppliers as stated within the agreement.

The suppliers for facilities, machinery, tools, test and measurement systems and services are integrated.

The appointment of suppliers must be appropriately documented and traceable.

Dates for the assignment, supplier milestones and release have been laid down in the plan and coordinated with the overall schedule.

- Make or buy decisions
- Supplier selection criteria
- Supplier development plan
- List of suppliers for the project
- List of approved suppliers
- Risk appraisal of each supplier

## **D2.6\* Is change management within the project ensured by the project organisation?**

Change management within the project meets the customer's specific requirements.

Changes (initiated by the customer, in-house or by the client) must be evaluated and if necessary the project plan must be adapted. This evaluation must include the risk assessment for the service provided as well as the deadlines.

Suppliers (critical supplies) are actively involved in change management.

Changes are reported in a timely manner and are agreed upon with the customer.

Compliance must be ensured at change stop points. If deviations from this occur they must be documented between the client and the supplier.

All changes must be documented.

The persons responsible for change management are defined for the client, in-house and to suppliers.

- Time schedules
- Process description
- Change management
- Change forms
- Change history for the product and the process
- Evaluation of change
- Approvals of changes

<b>D2.7* Is there an escalation process established and is this effectively implemented?</b>	
<p>The escalation process in the project meets the specific client requirements.</p> <p>An escalation model (risk management) must be available for deviations in the project affecting the overall schedule.</p> <p>The criteria for escalation are defined, responsibilities and authorities are regulated and measures are taken when deviations occur.</p> <p>If risks have been identified in technologies, suppliers or supplier countries, these risks should be considered within the escalation management.</p>	<ul style="list-style-type: none"> <li>- Time periods for escalation depending on the risk have been agreed upon.</li> <li>- Contact personnel/ decision makers in the escalation process are defined.</li> <li>- Escalation criteria and paths of communication are defined.</li> <li>- Protocols of milestone reviews including measures</li> </ul>

## 8.3 Planning of the service development (S3)

Process Element D3: Planning of service development	
Minimum requirements relevant for Assessment:	Examples for implementation
<b>D3.1* Are the specific requirements for the provision of service available?</b>	
<p>The process for identifying all requirements, including responsibilities, is regulated.</p> <p>All customer requirements, statutory and regulatory requirements and other requirements of interested parties have been identified and documented.</p> <p>There is an agreement with the customer regarding the release procedure for the acceptance of the developed service.</p> <p>If customer requirements cannot be fulfilled coordination takes place with the customer. The results determined are documented.</p> <p>The conditions needed to fulfil the customer requirements have been determined and allowed for.</p> <p>Identified needs are clear, understandable and verifiable.</p> <p>The effect that changes in the requirements have on the service provided is checked (risk management).</p> <p>The procedure for dealing with nonconforming services is coordinated with the customer.</p>	<ul style="list-style-type: none"> <li>- Inquiry documents</li> <li>- Contract documents</li> <li>- Requirement specifications</li> <li>- Service level agreement</li> <li>- Customer requirements</li> <li>- Legal requirements</li> <li>- Purchasing conditions</li> <li>- QM specific requirements</li> <li>- Quality agreements</li> <li>- Requirements for documentation</li> <li>- Logistics requirements (JIT, JIS, on consignment)</li> <li>- Schedules, technical delivery conditions</li> <li>- Access to portals Information platform in Internet</li> <li>- Definition of responsibilities for suppliers / services (e.g. qualification, approval, testing...) as part of the interface.</li> <li>- Experience with previous projects</li> <li>- Environmental aspects, recycling requirements</li> </ul>
<b>D3.2* Can the feasibility of the service be evaluated according to the requirements?</b>	
<p>The procedure for evaluating the feasibility is regulated.</p> <p>The feasibility assessment is based on the requirements that have been determined and documented. These take into account the technical, scheduling and capacity requirements as well as the administrative specifications (e.g. conditions of purchase).</p> <p>All areas involved are included in the feasibility assessment.</p> <p>The results of the study are documented.</p> <p>The feasibility must be confirmed before an offer is submitted.</p>	<ul style="list-style-type: none"> <li>- List of requirements</li> <li>- Dates, timeframes</li> <li>- Buildings, premises</li> <li>- Service level agreement</li> <li>- CAM, CAQ</li> <li>- Process innovation</li> <li>- Means of transport, container, storage</li> </ul>

<b>D3.3 Are the activities in preparation for the service / service process planned in detail and coordinated with the customer?</b>	
<p>All activities from the contract award to the provision of service are planned, documented (project plan, milestone plan) and agreed upon with the customer.</p> <p>The progress of the activities is monitored regularly and ensured. Action is taken when necessary.</p> <p>The identified requirements are checked regularly for compliance and fulfilment.</p> <p>The development of the service process includes a risk analysis and the resulting measures.</p> <p>The steps necessary for release meet the customer requirements or internal specifications. Deadlines have been set for all release criteria. The results of the respective release are documented.</p>	<p><b>Product / Process Development</b></p> <ul style="list-style-type: none"> <li>- Overall schedule and process development plan</li> <li>- Customer requirements</li> <li>- Client schedule</li> <li>- Lead times</li> <li>- Regular status checks on the progress of the development (reviews)</li> <li>- Project plans for investment items, (facilities and equipment).</li> </ul>

<b>D3.4 Are the resources necessary to carry out the service available?</b>	
<p>The process for determination of resource is implemented.</p> <p>Determination of resources refers to the availability of qualified personnel, budget, infrastructure and facilities.</p> <p>The resource planning must ensure that all requirements specified in the contract with the customer can be met.</p> <p>An analysis of the requirements is carried out regularly during the development phase to ensure that potential bottlenecks are prevented.</p> <p>Processes that have been outsourced have been considered.</p>	<ul style="list-style-type: none"> <li>- Training plan</li> <li>- Qualification matrix</li> <li>- Investment planning</li> <li>- Emergency plans</li> </ul>

## 8.4 Implementation of the service / service development (D4)

Process Element D4: Implementation of the service / service development	
Minimum requirements relevant for assessment:	Examples for implementation
<b>D4.1* Are the actions which were defined in the development plan for the service implemented?</b>	
<p>In the development phase a FMEA must be used to ensure that the service will comply with the customer requirements. When carrying out the FMEA for the provision of service, the proposed location is included.</p> <p>Special characteristics are identified, noted in the FMEAs and secured through implemented measures.</p> <p>The out-sourced products and services are taken into account. The implementation of the service /service development is ensured in the supply chain.</p> <p>The documentation of the findings from the development of the service are available for reference in the serial phase.</p> <p>The requirements for the test equipment are defined and implemented.</p>	<ul style="list-style-type: none"> <li>- Methods to minimize risk (QDF, FMEA)</li> <li>- Statistical design of experiments (for example: DoE, Shainin, Taguchi...)</li> <li>- Poka-Yoke Principles</li> <li>- Control plan / inspection plan</li> </ul>
<b>D4.2* Are human resources available and are they qualified to ensure the start of the series?</b>	
<p>A general personnel plan must be available.</p> <p>Personnel must be qualified for the relevant tasks. This also applies to the staff of external service providers. Appropriate certification must be available.</p> <p>Needs assessments will be carried out regularly during service development with regard to possible emerging bottlenecks and additional requirements.</p> <p>Personnel resources are planned and personnel are qualified in accordance with the project plan.</p> <p>Processes that have been outsourced have also been considered.</p>	<ul style="list-style-type: none"> <li>- Customer requirements</li> <li>- Requirements profile for the relevant position</li> <li>- Determine the need for training</li> <li>- Proof of training</li> <li>- Knowledge of methods and foreign languages</li> <li>- Appropriate behaviour for the quality of service</li> </ul>

<b>D4.3 Are the material resources available and suitable to ensure the start of the series?</b>	
<p>A process to determine resources has been established.</p> <p>Resource determination refers to the availability of the production facility, warehouses, storage areas, test equipment, laboratory equipment, machinery, equipment, and their utilization. Supporting processes must be considered.</p> <p>Within the resource determination the necessary infrastructure is taken into account.</p> <p>Regular needs assessment must be carried out during the service development with regard to possible emerging bottlenecks and additional requirements.</p> <p>Material resources are planned and provided in accordance with the project plan.</p> <p>Outsourced processes must be considered.</p> <p>The resources must be available with a suitable lead time before the start of customer's serial production.</p>	<ul style="list-style-type: none"> <li>- Customer requirements</li> <li>- Technical interface to customer and suppliers</li> </ul> <p><u>Product development</u></p> <ul style="list-style-type: none"> <li>- Test planning</li> </ul> <p><u>Process Development</u></p> <ul style="list-style-type: none"> <li>- Facility planning</li> <li>- Facility layout</li> <li>- Transport routes</li> <li>- Transport, containers, storage</li> <li>- Supporting processes for example from logistics und IT should be considered.</li> </ul>

<b>D4.4* Are the required approvals and releases for the service / service development available?</b>	
<p>The releases and verification of suitability is confirmed for all services and procurement volumes in accordance with development schedules.</p> <p>The actions from the FMEA have implemented and their effectiveness has been confirmed</p> <p>A release procedure is coordinated with the customer.</p> <p>The release of the service must be available at the time agreed upon with the customer.</p> <p>The verification and validation of the product and process are ensured before the customer SOP.</p>	<ul style="list-style-type: none"> <li>- Test reports, protocols</li> <li>- Supporting documents for purchased parts / suppliers</li> <li>- Sampling results</li> <li>- Specifications, requirement specifications</li> <li>- FMEA IMDS, REACH, RoHS</li> <li>- Confirmation of conformity with legal requirements</li> <li>- Development releases from customers.</li> <li>- Logistics concept (e.g. suitability of packaging through sample shipping)</li> <li>- Proof of capability of special characteristics</li> <li>- Capacity studies</li> </ul>



<b>D4.5 Are the service specifications derived from the product and process development and are they implemented?</b>	
<p>The service and inspection specifications contain all inspection characteristics from the service development (including special characteristics).</p> <p>Results of the risk analysis are considered.</p> <p>The specifications include information for control of the service, methods and response plans and corrective actions.</p> <p>Process / service audits are defined.</p> <p>The specifications must be available for all phases.</p>	<p><u>Product development</u></p> <ul style="list-style-type: none"> <li>- Risk analysis (FMEA, FTA,...)</li> <li>- Service control plan</li> <li>- Process / Service audit plan</li> <li>- Inspection plan</li> <li>- Response plan</li> </ul>

<b>D4.6 Is a performance test for the developed service defined and performed to ensure that the service will withstand the stress of working conditions?</b>	
<p>A production trial run of the service must be carried out in order to assess all production factors and influences at the appropriate time and make any necessary corrections.</p> <p>The production trial run has provided evidence that the quality capability of the entire process for the provision of the service is given under serial production conditions.</p>	<ul style="list-style-type: none"> <li>- Packaging requirements</li> <li>- Customer requirements</li> <li>- Determination of minimum quantities (intended production rate and flexibility as agreed upon)</li> <li>- Process capability study</li> <li>- Measurement capability</li> <li>- Equipment and infrastructure are ready for start of series (measurement reports)</li> <li>- Personal concept for serial production</li> <li>- Work/inspection instructions</li> <li>- Service tests according to customer schedule</li> </ul>

<b>D4.7* Is there a controlled method for the product handover from development to serial production?</b>	
<p>A process exists for transferring work results from the project to the production.</p> <p>Prerequisite for project delivery is a successful internal approval and a successful customer approval.</p> <p>Releases for procurement volumes are available.</p> <p>Resulting actions from the releases are implemented on time.</p> <p>Ensure that the service delivery takes place under controlled conditions.</p> <p>The human resources are available in accordance with the planning and are qualified.</p> <p>The material resources include buildings, test facilities, laboratory facilities, equipment, facilities, etc. These are available and have been released.</p> <p>Measures to safeguard the initial provision of service are specified and introduced when necessary.</p>	<p><u>Product / Process Development</u></p> <ul style="list-style-type: none"> <li>- Customer requirements</li> <li>- Handover protocols/ check-lists with handover criteria</li> <li>- Acceptance reports</li> <li>- Production control plan</li> <li>- inspection plans</li> <li>- Part history</li> <li>- A method has been determined to carry out failure analysis and to introduce corrective measures</li> <li>- Production metrics such as OEE, rejects,...</li> <li>- Experience from the ongoing project</li> <li>- Measurement capability</li> </ul>

## 8.5 Supplier Management (D5)

Process Element D5: Supplier Management	
Minimum requirements relevant for Assessment:	Examples for implementation
<b>D5.1* Are only approved and quality-capable suppliers and subcontractors used?</b>	
<p>It must be ensured that only approved suppliers / subcontractors are used.</p> <p>An evaluation of the qualification capability of the supplier / subcontractor using specified criteria must be available.</p> <p>An analysis of the quality performance of existing suppliers / subcontractors has to be considered.</p> <p>Risks in the supply chain have been identified and assessed and appropriate measures for their reduction have been implemented (emergency strategy).</p>	<ul style="list-style-type: none"> <li>- Defined and documented criteria are used for supplier selection.</li> <li>- Evidence of a qualification programme for suppliers who did not meet the selection criteria</li> <li>- Evaluation of the quality capability (QM- System, Process) for example self-assessment, audit results, supplier certificates</li> </ul>
<b>D5.2 Are customer requirements taken into account in the supply chain?</b>	
<p>The communication of customer requirements for suppliers / subcontractors (see S 3.1) must be regulated and traceable.</p> <p>Likewise, change management has to be considered.</p> <p>Interfaces are identified and secured. This concerns the tasks, competencies and responsibilities.</p>	<ul style="list-style-type: none"> <li>- Transmission of requirements, time schedule, releases, complaints etc. with ensuring change management</li> <li>- Interface Agreement</li> <li>- QAA (quality assurance agreements)</li> <li>- Service level agreement</li> <li>- Legal, regulatory requirements</li> </ul>
<b>D5.3* Have target agreements for supplier performance been agreed upon and implemented?</b>	
<p>Target agreements have been made with all suppliers / subcontractors throughout the supply chain for products and processes. These agreements have been verified and implemented.</p> <p>Supplier / subcontractor output must be checked and evaluated within a defined period.</p> <p>If deviations occur actions must be agreed upon and their implementation including deadlines are to be monitored.</p>	<ul style="list-style-type: none"> <li>- Measurable targets for quality, delivery quantity, punctuality</li> <li>- QM agreements including escalation mechanisms</li> <li>- Service level agreement</li> </ul>

To ensure meeting their target agreements, suppliers must consider events such as a disruption in the supply of energy, labour shortages etc. within their risk analysis and develop emergency plans to cover these theoretical events.	
---	--

<b>D5.4* Are the necessary releases / approvals available for out sourced products and services?</b>	
<p>Before serial production starts a release must be given before new or changed services are used.</p> <p>The service supplier has the full quality control responsibility when services / service areas are carried out by a supplier or subcontractor.</p>	<ul style="list-style-type: none"> <li>- Specifications / standards / testing instructions</li> <li>- PPA-Reports</li> <li>- Proof of capability for special characteristics</li> <li>- Qualification tests / reports</li> <li>- Change management in the supply chain</li> </ul>

<b>D5.5* Is the quality of the out-sourced products and services ensured?</b>	
<p>To monitor the quality of the out-sourced products and services, regular checks are carried out, documented and evaluated.</p> <p>Deviations from the supplier quality are processed through a standard complaint process. The complaints process includes a risk assessment with respect to the differences in the scope of procured services.</p> <p>Supplier / subcontractor audits are to be planned and carried out based on the risk given by a difference in the quality of procured services.</p> <p>Test, inspection and measurement equipment for the procured service are available in the required number, they are stored in an orderly manner and associated work-stations are laid out appropriately (e.g. damage, contamination, climate control, lighting, order, cleanliness).</p>	<ul style="list-style-type: none"> <li>- Coordination of test procedures, test processes and frequencies</li> <li>- Evaluation of main failures</li> <li>- ppm evaluations, 8D reports</li> <li>- Agreement and tracking of improvement programmes</li> <li>- Testing possibilities (internal and external laboratories and testing facilities,</li> <li>- Gauges / fixtures</li> <li>- Drawings / ordering and packaging requirements / specifications</li> <li>- Proof of capability</li> <li>- Test certificates</li> <li>- Process or service audits</li> </ul>

<b>D5.7 Are personnel qualified for their respective tasks and are responsibilities defined?</b>	
<p>A description must be given of what responsibilities, tasks and authority the employees have in their relevant task areas (e.g. for incoming inspection, complaint processing, supplier management, supplier audit).</p> <p>Qualification requirements must be determined for each employee in relation to their tasks and qualifications carried out accordingly.</p> <p>Knowledge of previous complaints is available when appropriate for purchased products and services.</p>	<ul style="list-style-type: none"> <li>- Product / specifications/ customer requirements</li> <li>- Knowledge about service features</li> <li>- Standards / legislation</li> <li>- Assessment methods (audits, statistics)</li> <li>- Quality procedures (e.g. 8D-method, cause / effect diagram)</li> <li>- Complaints and corrective action</li> <li>- Job / function descriptions</li> <li>- Qualification matrix</li> <li>- Foreign languages</li> <li>- Qualification of supplier auditors</li> </ul>

## 8.6 Providing the Service (D6)

<b>Process Element D6: Providing the service</b>	
<b>D6.1 What goes into the process? Process input</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<b>D6.1.1 Has the project been transferred from development to the provision of service and is a reliable start guaranteed?</b>	
<p>The project transfer the provision of service has been carried out and if necessary unresolved issues are followed up on and implemented on schedule. The responsibilities for the entire handover process are regulated and acknowledged.</p> <p>Before the first provision of service a complete release for the service is available which includes all documents relevant and necessary for the service provided.</p> <p>Measures are taken to secure the launch of the service.</p> <p>A process for the further development of the FMEA is defined and regulated.</p> <p>Where necessary, tools, test and measurement equipment are available in the necessary quantities.</p>	<ul style="list-style-type: none"> <li>- Transfer reports</li> <li>- Defined actions with implementation schedule</li> <li>- Process FMEA and actions</li> <li>- Service FMEA and actions</li> <li>- Service release report</li> <li>- Verification / validation of the service and evidences</li> <li>- Transport planning process</li> <li>- Customer release (service release)</li> <li>- Service level agreement</li> <li>- Released software standard</li> </ul>
<b>D6.1.2 Are the necessary materials for providing the service available at the agreed upon time and at the right location?</b>	
<p>The correct material must be provided to the agreed quality, in the correct quantity and with the correct documentation, at the agreed time and at the agreed location where the service will be provided.</p> <p>Defined storage areas for materials necessary for the provision of service must be provided and information regarding the release status of these materials is available.</p> <p>At the location where the service is provided, parts and materials are provided as needed, taking into account the order quantity / lot size (for example, Kanban, Just in time, FIFO). Upstream processes in the provision of the service are taken into account.</p> <p>Statutory and regulatory requirements are taken into account.</p>	<ul style="list-style-type: none"> <li>- Sufficient and appropriate storage facilities</li> <li>- Defined storage points</li> <li>- KANBAN</li> <li>- Just in time</li> <li>- Inventory control</li> <li>- Change status</li> <li>- Exchange of information to the return of unnecessary components / surplus</li> <li>- Inventory</li> <li>- Production levels tailored to the customer's requirements</li> <li>- Special requirements for components and containers</li> </ul>

<b>D6.1.3 Are incoming materials necessary to provide the service stored appropriately and are the means of transport / packing facilities suitable for the special characteristics of the incoming materials?</b>	
<p>Packaging requirements must be consistently taken into account / implemented.</p> <p>Suitable transport units must be used to protect materials from damage and contamination during transport as well as transportation to the location of the service being provided.</p> <p>Store areas /work-stations / containers must be appropriate for the tidiness and cleanliness required for the provision of service.</p> <p>The supply of parts/materials at the work-station/on the assembly line must allow for safe handling.</p> <p>Specified storage times and use-by dates for special materials/ parts must be monitored by appropriate methods (maximum and minimum storage times; specified interim storage times).</p> <p>Critical operating and auxiliary materials for plant and machinery with a direct effect on the service / service quality must be monitored accordingly.</p> <p>Critical materials (operating and auxiliary materials e.g.) must be protected against environmental / climatic influences and regulatory requirements are taken into account.</p>	<ul style="list-style-type: none"> <li>- Stock quantities</li> <li>- Storage conditions</li> <li>- Released special and standard transport containers</li> <li>- Packaging requirements</li> <li>- In-house transport containers</li> <li>- Protection against damage</li> <li>- Positioning of parts in the workplace</li> <li>- Cleanliness, order</li> <li>- Over-filling (bins and containers)</li> <li>- Monitoring of storage times</li> </ul>

<b>D6.1.4* Are changes to the service made during the provision of the service tracked and documented?</b>	
<p>Change management (from the change request to implementation) must be clearly documented and responsibilities must be regulated.</p> <p>Changes that impact on customer requirements and expectations must be coordinated, approved and released by the customer. If necessary a new service agreement must be made. This includes both the actual service as well as the process for the provision of service.</p> <p>Documentation of change status must be fully traceable.</p>	<ul style="list-style-type: none"> <li>- Change release by the service provider and the customer (feasibility; interfaces, effect on costs and schedules,...)</li> <li>- Information about changes is passed onto service development, the location where the service is carried out and all sub-suppliers involved with providing the service</li> <li>- The level of implementation of the change is tracked (overview with status)</li> <li>- Documented change record including updated service agreement</li> <li>- Updates of the FMEA (Service and process for provision of service)</li> <li>- Verification and validation of changes including documentation</li> <li>- Controlled introduction of changes or changes to services</li> <li>- Lead times for service changes (customer specifications etc.)</li> <li>- Change levels of test/inspection equipment, gauges, tools and drawings</li> <li>- Changes to software</li> </ul>



Process Element D6: Providing the service	
D6.2 Are all processes necessary to provide the service determined?	
Minimum requirements relevant for assessment	Examples for implementation
D6.2.1* Is the specification of the service level agreement complete and has it been effectively implemented?	
<p>The documentation for the provision of the service is complete and available and is based on the service level agreement.</p> <p>Characteristics of the service, materials and methods used to provide the service must be defined.</p> <p>Access to these documents must be available at all times.</p> <p>Indicators or parameters that influence the quality of the service must be fully documented.</p> <p>When possible, tolerances in relation to indicators or parameters for controlling the provision of services are specified.</p> <p>Deviations to the service agreement and corrective measures must be documented.</p> <p>Required measures (action plan) for disturbances in the provision of service are specified.</p> <p>The service level agreement must include necessary information about services with specific requirements (special characteristics) and the required performance of the service provider.</p>	<ul style="list-style-type: none"> <li>- Parameters, indicators and if necessary tolerances</li> <li>- Special characteristics of the service</li> <li>- Data regarding machines/tools/materials necessary to provide the service</li> <li>- Instructions on providing the service</li> <li>- Parameters for measuring the quality of the service</li> <li>- Specific requirements regarding the practises of service providers</li> </ul>

<b>D6.2.2* Are specific requirements (special characteristics) regulated during the provision of service?</b>	
<p>Special characteristics that significantly affect the provision of the service are noted and systematically monitored.</p> <p>In the case of deviation in regard to special characteristics immediate action is taken and this is documented.</p> <p>If it is not possible to meet the requirements of the special characteristics the customer must be notified and changes agreed upon.</p> <p>When special characteristics are related to the performance of the service being provided direct feedback discussions between the service provider, the service provider management and when necessary, the client, are to be carried out to ensure necessary measures are initiated.</p>	<ul style="list-style-type: none"> <li>- Service FMEA</li> <li>- Process FMEA</li> <li>- Service level agreement</li> <li>- Special characteristics of the service</li> <li>- Special characteristics of the performance of the service provider</li> </ul>

<b>D6.2.3* Are defective services identified and are appropriate measures taken (immediate measures and corrective actions)?</b>	
<p>Defective services must be identified and documented. Whenever possible the customer should be heard and this information captured and documented.</p> <p>Action plans (immediate action and corrective action) covering defective services are documented and initiated.</p>	<ul style="list-style-type: none"> <li>- Records of defective service performance are available.</li> </ul>

<b>Process Element D6: Providing the service</b>	
<b>D6.3 What functions support the provision of the service? (personnel resources)</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<b>D6.3.1* Are the employees able to fulfil their given tasks and ensure that the service is provided?</b>	
<p>A description of tasks with an appropriate job profile must be available for employees. A qualification programme is derived from this profile.</p> <p>Who is qualified for each task and activity must be documented.</p> <p>Trainings, instruction, briefings, / proof of qualifications that have been performed must be documented.</p>	<ul style="list-style-type: none"> <li>- Training / qualification evidence</li> <li>- Qualification matrix</li> <li>- Initial training plan with evidence</li> <li>- Knowledge about the service and failures that have occurred</li> <li>- Handling of measurement and testing equipment</li> </ul>

<p>Employees must be instructed in the handling and treatment of products with special characteristics.</p> <p>Suitable evidence of qualification for each activity must be present (e.g. forklift driving license, welding certificate, soldering certificate, vision test, hearing test).</p> <p>Employees responsible for measuring and testing must be trained in the correct use of measurement and testing equipment.</p> <p>Trainings / instructions are given at changes to the service /service process and these are documented.</p> <p>The requirements also apply to internal and external temporary employees.</p>	<ul style="list-style-type: none"> <li>- Training in work safety / environmental aspects</li> <li>- Training in special characteristics</li> <li>- Suitable evidence of qualification (e.g. welding certificate, vision test results, driving license for industrial trucks)</li> <li>- Training about the service being provided</li> <li>- Employee behaviour training for the provision of a service</li> </ul>
---	--

<b>D6.3.2 Do the employees know their responsibilities and authority in the monitoring of the quality of the service process and the service?</b>	
<p>Responsibilities, duties and authority of the employees in their task areas are described and implemented (e.g. release of services, stopping the provision of services, immediate action, corrective action etc.)</p> <p>The employees know the consequences of faulty services (what reason and the aim of the service and what happens when the service is incorrectly carried out or is not guaranteed).</p> <p>Employees receive regular information on the current standard of quality reached, both internally and with the customer (complaints).</p> <p>The requirements also apply to internal and external temporary employees.</p>	<ul style="list-style-type: none"> <li>- Service level agreement</li> <li>- Qualifications matrix</li> <li>- Job descriptions</li> <li>- Employee self-inspections and self-reflection</li> <li>- Release for the service</li> <li>- Control of the service being provided</li> <li>- Stopping the service</li> <li>- Order and cleanliness</li> <li>- Repair and maintenance is carried out or when necessary or arranged for if necessary</li> <li>- Provision and adjustment of test / measurement is carried out or when necessary / or arranged for</li> <li>- Training about the service</li> <li>- Quality information (target / actual values)</li> <li>- Trainings relevant for applicable legal requirements / regulatory requirements</li> </ul>

### **D6.3.3\* Are the necessary personnel resources available?**

The required number of qualified employees is available during the agreed upon time of service provision. Employee qualifications need to be considered when scheduling staff (e.g. qualification matrix).

Fluctuations in the assignment of the provision of services and through staff absences (e.g. illness, holidays, training) are taken into account in the schedule.

The requirements also apply to internal and external temporary employees.

- Shift plan
- Evidence of qualifications (qualification matrix)
- Documented absence management rules
- Workforce scheduling

## **Process Element D6: Providing the service**

### **D6.4 What means are used to provide the service? (material resources)**

#### **Minimum requirements relevant for assessment**

#### **Examples for implementation**

#### **D6.4.1 Can the specific requirements from the customer be met with the equipment used for the provision of the service?**

It must be shown that the service processes are implemented in accordance with the customer requirements using the existing production facilities. Further it must be shown that the resulting services meet the customer specifications.

The production facilities / equipment (and when applicable measurement or testing equipment) must be able to comply with the specified requirements for the specific features of the service.

Design and condition of the equipment /devices (e.g. tools, fixtures and handling facilities etc.) meet the specific requirements under real conditions for the provision of the service.

- Proof of machine / process capability for special
- Cleanliness requirements

#### **D6.4.2 Is the maintenance of the equipment required for the provision of the service controlled?**

Maintenance activities (maintenance, inspection and repair) are determined and implemented for all installations, equipment and machines.

Maintenance activities that have been carried out (scheduled and unplanned) are documented and analysed for improvement measures.

A process for the analysis and optimization of downtime, machine utilization and tool life is implemented effectively.

The key processes and critical machines are identified and appropriate maintenance activities (preventative or proactive) are carried out in terms of a risk-based maintenance programme. The availability of replacement parts must be ensured.

Resources needed to carry out necessary maintenance measures are available.

Tools undergo a tool management which includes the following:

- Status indication (OK / NOK/in repair)
- Tool identity card including all changes made to the tool
- Tool life (e.g. operating hours, strokes or shot numbers)
- Protection from damage
- Tool ownership

- Availability / use of the appropriate technical documents
- Maintenance plan / maintenance tasks
- Weak-point analysis
- Preventative tool exchange programme for units subject to increased wear and tear
- Storage and retrieval machines / equipment for transport and storage etc.
- Availability of spare parts at production facilities producing key products
- Compliance with the prescribed maintenance intervals
- Documentation of maintenance activities
- Regular plausibility check of the scheduled maintenance intervals
- Hiring of external service companies to carry out maintenance

<b>D6.4.3* Can the quality requirements of the service be effectively monitored with the measurement and testing facilities in use?</b>	
<p>The test, inspection and measurement facilities used are suitable for the planned purpose and handling of service provision. They are included in the service level agreement.</p> <p>Capability studies (when required by the customer) are carried out on the measurement devices and measurement systems employed.</p> <p>The accuracy of the measurement devices is appropriate for the purpose and for the characteristics to be checked.</p> <p>There is an identification system for measurement and inspection equipment. Administration of this equipment is based on the identification.</p> <p>A process for the periodic monitoring of measurement and inspection equipment is installed and implemented (responsibility for collection and return is defined). This process also takes into account the calibration of process-integrated measurement technology with an influence on the product characteristics.</p> <p>Measurement and inspection equipment accessories having an influence on measurement accuracy and the measurement result are monitored in the same way.</p> <p>Testing of behaviour related requirements for services is carried out in an appropriate manner (sales test, service test etc.).</p>	<ul style="list-style-type: none"> <li>- Service level agreement</li> <li>- Measurement accuracy / capability of inspection equipment</li> <li>- Proof of the capability of inspection processes/ MSA</li> <li>- Data collection and its evaluability</li> <li>- Evidence of the calibration of inspection equipment</li> <li>- Comparison of inspection equipment / measurement processes with the customer (e.g. interlaboratory comparisons)</li> <li>- Testing procedures for behaviour-based services (sales test, service test)</li> </ul>

<b>D6.4.4 Are the work stations for the provision of the service appropriate for the needs?</b>	
<p>Conditions for work-places and their surroundings are appropriate for the work carried out and the service performed, in order to prevent / eliminate contamination, damage etc.</p> <p>In addition, the work-place layout is adapted ergonomically to the work to be carried out.</p>	<ul style="list-style-type: none"> <li>- Lighting</li> <li>- Cleanliness and tidiness</li> <li>- Climate control</li> <li>- Noise pollution</li> <li>- Clean rooms</li> <li>- Organisation at the location of the provision of services</li> <li>- Work safety</li> </ul>

<b>D6.4.5 Are tools, equipment and testing equipment stored properly?</b>	
<p>Tools, equipment and testing equipment (including gauges) must be stored and managed properly. This also applies for tools, equipment and test equipment not in use or not yet released.</p> <p>All tools, equipment and testing equipment are identified with their current status and all changes are documented (change history).</p> <p>Storage is provided where the equipment is protected against damage and environmental effects. Cleanliness and tidiness are ensured.</p> <p>The issue and use of this equipment is controlled and documented.</p>	<ul style="list-style-type: none"> <li>- Stored free from damage</li> <li>- Cleanliness and tidiness</li> <li>- Defined storage location</li> <li>- Environmental influences</li> <li>- Status identification</li> <li>- Identification showing customer's property, products/tools/devices provided on loan</li> <li>- Defined release status and change level</li> <li>- Storage and retrieval machines / equipment for transport and storage etc.</li> </ul>

<b>Process element D6: Providing the service</b>	
<b>D6.5 How effective is the process for the provision of the service being carried out? Effectiveness, efficiency, elimination of waste</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<b>D6.5.1* Are there targets set for the provision of the service?</b>	
<p>Process-specific targets are defined for the provision of the service. The targets are defined, controlled and results are communicated.</p> <p>Target requirements are coordinated and achievable; they are guaranteed to be up to date.</p> <p>Customer requirements are taken into account when setting targets.</p> <p>A regular comparison is made between specified and actual results.</p>	<ul style="list-style-type: none"> <li>- Availability of installations and machines</li> </ul> <p>Process indicators</p> <ul style="list-style-type: none"> <li>- Services rendered</li> <li>- Services per unit of time</li> <li>- Quality of service</li> <li>- Number of defective services</li> <li>- Audit results</li> <li>- Throughput times</li> <li>- Costs of defective services etc.</li> <li>- Reduction of waste by the provision of the service (routes, unnecessary trips etc.)</li> </ul>

#### **D6.5.2 Is quality and process data about the service collected in a way that allows analysis?**

<p>To demonstrate compliance with the requirements and targets the necessary quality and process parameters (target values) of the service must be defined and documented as well as the actual data (actual value).</p> <p>The evaluability must be ensured.</p> <p>Special incidents are documented (breakdown of facilities / equipment, customer complaints during the provision of the service).</p> <p>The recorded data can be related to a service and a service process, the data is available, legible, accessible and archived as specified.</p> <p>If requirements for traceability exist, they are taken into account.</p> <p>The collected data is analysed and appropriate action for improvement is initiated. A risk-based approach is used here.</p> <p>The potential for improvement must be continuously determined from recent findings on quality, costs, and services.</p> <p>Events that result in a change to the service process or to the service must be documented in the appropriate FMEA and the respective measures taken are recorded.</p>	<ul style="list-style-type: none"> <li>- Defect frequency cards</li> <li>- Special characteristics</li> <li>- Service parameters (cycle times etc.)</li> <li>- Data collection</li> <li>- Fault signals (e.g. failure or non-performance of services)</li> <li>- Parameter changes</li> <li>- Error type / error frequencies</li> <li>- Error costs (nonconformity)</li> <li>- Rejects / reworking</li> <li>- Stopping of services</li> <li>- Cycle times; through-put times</li> <li>- Pareto analyses</li> <li>- Cause &amp; effect diagrams</li> <li>- Risk analysis (FMEA etc. )</li> <li>- Traceability system</li> </ul>
---	--

#### **D6.5.3\* In the case of deviations from the service requirements and provision of the service, are the causes analysed and the corrective actions checked for effectiveness?**

<p>If deviations to the service / service process requirements occur, immediate containment actions must be taken to comply with the requirements, until the causes of failure are eliminated and evidence has been provided of the effectiveness of the corrective actions. These actions are known by the employees.</p> <p>Suitable methods for root cause analysis are in use.</p> <p>Corrective measures are derived, their implementation is monitored and the effectiveness verified.</p> <p>The service level agreement and the risk analysis are updated as needed.</p> <p>Nonconformities that affect the properties of the service provided are communicated to the customer.</p>	<ul style="list-style-type: none"> <li>- 8 D method</li> <li>- Cause &amp; effects diagram</li> <li>- Taguchi, Shainin</li> <li>- 5 W method</li> <li>- FMEA / error analysis</li> <li>- Process capability analysis</li> <li>- Quality control loops and quality control circles</li> <li>- Analytical assessment methods</li> <li>- Information flow to the customer</li> <li>- Service FMEA and process FMEA</li> </ul>
--	--



<b>D6.5.4 Are service requirements and provision of the service audited regularly?</b>	
<p>The audit programmes for service processes and service audits are available and implemented. Customer requirements are taken into account.</p> <p>Testing of behaviour related requirements for services is carried out (sales test, service test etc.) and verified.</p> <p>The service process and service audits carried out are suitable to identify specific risks and weak points and implement corrective measures.</p> <p>When deviations occur a root cause analysis is carried out. Corrective measures are derived, their implementation is monitored and the effectiveness is verified.</p> <p>Service audits are periodically carried out (if possible after the provision of service) and documented. In the service audit specified characteristics are examined and tested according to previously defined specifications.</p> <p>Nonconformities that affect the properties of the service are communicated to the customer.</p>	<p><u>Service and serves process audit:</u></p> <ul style="list-style-type: none"> <li>- Specifications</li> <li>- Special characteristics</li> <li>- Audit programme for services and service process audits including scheduled and event-based audits</li> <li>- Frequency of audits</li> <li>- Audit requirements</li> <li>- Audit results, audit reports</li> <li>- Auditor qualification</li> </ul> <p><u>Service process audit</u></p> <ul style="list-style-type: none"> <li>- Process parameter for services</li> </ul> <p><u>Service audit</u></p> <ul style="list-style-type: none"> <li>- Labelling, packaging</li> <li>- Capacity of the test equipment</li> <li>- Software version</li> <li>- Sales and service testing</li> </ul>

<b>Process Element D6: Providing the service</b>	
<b>D6.6 What should the process produce? Process result (output)</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<b>D6.6.1 Are the necessary records concerning the service provided completed?</b>	
<p>The scope of the records that are used to document the provision of the service are specified.</p> <p>The acceptance of the service by the customer or subsequent services must be determined.</p> <p>If the terms of the service level agreement cannot be full met the required reduction of services must be coordinated with the customer. Appropriate documented information has to be available. The documentation includes the relevant time period and / or the number of affected services.</p> <p>For archiving requirements and duration, the customer requirements are taken into account.</p>	<ul style="list-style-type: none"> <li>- Customer specifications</li> <li>- Significant characteristics</li> <li>- Customer requirements for Archiving (EDP, paper, fire protection, legibility, ...)</li> <li>- Last piece inspection</li> <li>- Part history</li> <li>- Identification of reduced services</li> </ul>

<b>D6.6.4* Are customer requirements met at the delivery of the service?</b>	
<p>The customer specific requirements in relation to the service provided are known and monitored. If deviations occur, corrective actions are defined and implemented.</p> <p>Services are delivered according to customer requirements to the customer (service to the customer etc.).</p> <p>If services are stopped the customer must be informed immediately and further procedure is to be coordinated.</p>	<ul style="list-style-type: none"> <li>- Service level agreement</li> <li>- Customer specific requirements</li> <li>- Customer requirements for special characteristics of the service</li> <li>- Delivery reliability</li> <li>- Quality targets of the service</li> <li>- Quality of the provision of service</li> <li>- Planning of the shipping audit</li> <li>- Storage / recall processing / parts supply / shipping</li> <li>- Target agreements</li> </ul>

<b>Process Element D7: Customer support, customer satisfaction, service</b>	
<b>Minimum requirements relevant for assessment:</b>	<b>Examples for implementation</b>
<b>D7.1 Are all requirements related to QM System, Product and Process fulfilled?</b>	
<p>The internal and customer specific requirements on the quality system are fulfilled.</p> <p>The customer requirements must be implemented in the development phase, during and after the production phase (spare parts phase).</p>	<ul style="list-style-type: none"> <li>- Quality agreements with the customer</li> <li>- Inclusion of sub-supplier for the supply of spare parts</li> <li>- Certification of the QM system</li> </ul>

<b>D7.2* Is customer service guaranteed?</b>	
<p>It must be ensured that competent contact personnel are available for the various areas in the customer's organisation. Communication is ensured in accordance with the customer specifications.</p> <p>Access to customer portals in accordance with the customer specific agreement is ensured.</p>	<ul style="list-style-type: none"> <li>- Knowledge of problems with the service and complaints regarding the product or transport</li> <li>- Implementation of new requirements</li> <li>- Notification of improvement actions</li> <li>- World-wide customer service</li> <li>- Information from the customer by non-compliance with the requirements</li> </ul>

<b>D7.3* Is the provision of the service guaranteed?</b>	
<p>Concepts including securing service are available and up to date. These concepts also cover emergency situations.</p> <p>Not only in-house processes but also the processes or suppliers/subcontractors must be considered.</p> <p>Procedures must be in place which guarantee that the organisation informs the customer immediately when shortages in the provision of services are detected.</p> <p>The information must include the expected duration and extent of the shortages in the provision of services, the reasons and the actions which have been taken.</p>	<ul style="list-style-type: none"> <li>- Contingency plans (e.g., for alternative services, subcontractors, packaging, transport)</li> <li>- Use of external capacity</li> <li>- Communication regarding supply shortages</li> <li>- Regulations covering authority to make decisions / escalation paths when introducing special actions</li> </ul>

<b>D7.4* If there are deviations from quality requirements, are failure analyses carried out and corrective actions implemented effectively?</b>	
<p>An analytic process for defective services must be defined.</p> <p>The necessary human and material resources are available to ensure punctual processing.</p> <p>The customer has to be informed if deviations to the agreed upon time limits occur.</p>	<ul style="list-style-type: none"> <li>- Process for processing complaints</li> <li>- 8D process</li> <li>- Internal / external analysis facilities (laboratories, comprehensive testing facilities, personnel)</li> <li>- Use of problem solving methods</li> <li>- Effectiveness tests</li> <li>- Flow of information to the customer by deviations</li> <li>- Knowledge store, lessons learned</li> <li>- Quality control loop</li> <li>- FMEA</li> <li>- Access to the necessary release documents (PPA etc.)</li> <li>- Performance indicators for processing of complaints</li> </ul>

**D7.5 Are personnel qualified for the various tasks and are responsibilities defined?**

It must be determined which responsibilities, duties and authorisations each employee has in their respective area of responsibility.

Training needs must be determined individually and implemented for each person, depending on their tasks.

The employees have knowledge of the service and understand the consequences of a defective supply of service to the customer.

- Organisational chart
- Evidence of knowledge of the product / specifications / customer requirements
- Standards / laws (product liability)
- Processing / use
- Failure analysis
- Evaluation methods (e.g. audits, statistics)
- Quality techniques (e.g. Pareto, 8D Method, cause and effect diagram, Ishikawa)
- Foreign language skills

## 8 Evaluating a process audit for services

The application of the questionnaire for a process audit for services is carried out in accordance with section 6.1 of the questionnaire for material products

### 8.1 Evaluation of the individual questions

Each question is assessed in terms of compliance with the requirements and the risk involved. The assessment of each question can result in the award of 0, 4, 6, 8 or 10 points, with the number of points awarded being based on proven compliance with the requirements.

Points	Assessment of compliance with the requirements
10	Full compliance with requirements
8	Requirements mainly <sup>++</sup> fulfilled; minor deviations
6	Requirements partially fulfilled; significant deviations
4	Requirements inadequately fulfilled; major deviations
0	Requirements not fulfilled

<sup>++</sup> The term "mainly" means that the relevant requirements are met in most instances and no special risks have been identified.

The following table illustrates the appropriate allocation of points for the evaluation of the questions for services:

Points	Evaluation of the performance of the individual requirements		
	Risk assessment from the perspective of the process / process step; specific	Risk assessment from the perspective of the service	Systematic view; abstract
10	Technical requirements and specifications for the process are fulfilled.	The service meets the specified requirements / standards	Requirements are completely met
8	Small deviations in the process which do not affect compliance with the customer specifications or have an effect on following process steps.	The service mostly meets the specified requirements and produces no serious service defects or incidents for the customer	Requirements are mainly fulfilled, minor deviations.

6	The process does not always meet the defined requirements. This has an impact on the customer or following process steps.	The service is faulty or disturbs the customer processes. This can be corrected with additional work / expense	Requirements are partially met; larger deviations
4	The process does not meet the defined requirements and has a significant impact on the customer or following process steps.	The service is not conform or disturbs the customer processes. This cannot be completely corrected with additional work / expense	Requirements insufficiently met: serious deviations
0	The process is not capable of ensuring compliance with the defined requirements	Full failure of the service. The requirements of the service are not met.	Requirements are not met

The auditor may require immediate actions depending on the risk of the findings.

If a question is not answered (n.a.), a reason for this must be stated. At least 2/3 of the questions for each evaluated process element, sub-element or process step must be answered. To ensure comparability the entire list of questions from the VDA 6.3 process element should be covered in full.

If non-conformities from previous audits are repeated, the lack of implementation of corrective can also be regarded as a deviation: e.g. “cause analysis”, “implementation of measures”, “meeting customer requirements”.

#### Questions involving special product and process risk (\* Question):

In the process elements, questions involving special risks in terms of product and process are identified by an asterisk (\*). The specific risks in the \* questions are already taken into account by the classification rules (see section 8.8.3). The evaluation is carried out analogously to the remaining questions, this means, \* questions are not evaluated more severely than other questions.

## 8.8.2 Detailed Evaluation and Downgrading Rules

### Process Element

The compliance  $E_{Dn}$  of a process element (P2, P3, ..., P7) is calculated as:

$$E_{Dn} [\%] = \frac{\text{Total points awarded for the relevant questions}}{\text{Total possible number of points for the relevant questions}}$$

### Exception: When more than one result is given for a question

In process elements S6 several process steps for each question may produce multiple results. In this case the arithmetic mean of all results for the question must be calculated. In calculations following this step, the average is rounded to two decimal places.

These averages are used in place of “**total points**” when calculating the compliance of a process element. For each question only 10 points may be awarded for the **total possible** number of points – regardless of the number of results per question.

The calculation of the sub-elements is carried out in the same manner as the process elements using the exception: more than one result is given for a question.

### Sub-elements of D6

In the process element D6 the following sub-elements are evaluated:

- $E_{U1}$  Process Input
- $E_{U2}$  Process management
- $E_{U3}$  Personnel resources
- $E_{U4}$  Material resources
- $E_{U5}$  Efficiency
- $E_{U6}$  Process Output

The assessment of the sub-elements is analogous to the evaluation of a single process element and the special case: consideration of several results per question.

$$E_{Un} [\%] = \frac{\text{Total points awarded for the relevant questions in the sub-elements}}{\text{Total possible number of points for the relevant questions in the sub-elements}}$$

## Individual Process Steps

The questions from D6 are used for the evaluation of the individual process steps. All questions from D6 can be answered in each process step. The performance level  $E_n$  of each process step can be calculated as follows:

$$E_n [\%] = \frac{\text{Total points awarded for the D6 questions for this process step}}{\text{Total possible number of points for the D6 questions for this process step}}$$

## Application of the downgrading rules

These results (process element, sub-element of D6, or process step) are considered in the downgrading rules, but not used as intermediate results to calculate the percentage of the overall results.

## 8.8.3 Overall Level of Performance

Process elements for Services	
Project management (D2)	$E_{D2}$
Planning the service development (D3)	$E_{D3}$
Implementation of the service (D4)	$E_{D4}$
Supplier management (D5)	$E_{D5}$
Providing the service (D6)	$E_{D6}$
Customer care, customer satisfaction, service (D7)	$E_{D7}$

The overall performance  $E_G$  for the process audit is calculated as follows:

$$E_G [\%] = \frac{\text{Total points from all evaluated questions from } E_{D2}, E_{D3}, E_{D4}, E_{D5}, E_{D6} \text{ und } E_{D7}}{\text{Total of all possible points from these questions}}$$

If during the audit individual process elements from the questionnaire are used, the result is calculated based only on the evaluated process elements. Which process elements have been used in the evaluation must be made clear in the audit report.



### Overall level degree of performance:

Classification	Level of achievement $E_G$ or $E_{G(Dn)}$ [%]	Description of the classification
A	$E_G \text{ or } E_{G(Dn)} \geq 90$	Quality capable
B	$80 \leq E_G \text{ or } E_{G(Dn)} < 90$	Conditionally quality capable
C	$E_G \text{ or } E_{G(Dn)} < 80$	Not quality capable

### Level of performance for partial audits:

To classify the performance of a partial audit the calculated performance (e.g.  $E_{G(D5D6D7)}$  and  $E_{G(D4)}$ ) is compared to the benchmarks as given above (at least 80% for a “B” classification of conditionally quality capable or at least 90% for quality capable).

### Rules for downgrading

The following rules for downgrading are to be used and documented in the audit report:

#### Reasons for downgrading from A to B even though the level of achievement is $E_G$ or $E_{G(Dn)} \geq 90\%$

- At least one process element (D2 to D7) or process step ( $E_1$  to  $E_n$ ) is evaluated with a level of achievement  $E_G$  or  $E_{G(Dn)}$  or  $E_n$  from  $< 80\%$ .
- A level of achievement in one of the sub-elements of S6 is  $< 80\%$ .
- At least one \*-question is rated with 4 points.
- At least one question from the Process audit is rated with 0 points.

#### Reasons for the downgrading to C even though the level of achievement is $E_G$ or $E_{G(Dn)} \geq 80\%$

- At least one process element (P2 bis P7) or process step ( $E_1$  bis  $E_n$ ) is evaluated with a level of achievement  $E_G$  or  $E_{G(Dn)}$  or  $E_n$  from  $< 70\%$ .
- A level of achievement  $E_{U1}$  to  $E_{U7}$  in one of the sub-elements of P6 is  $< 70\%$ .
- At least one \*-question is rated with 0 points.

The overall result is rounded to the nearest percentage point. Similarly, when applying the downgrading rules (process element, sub-element or process step), the individually calculated results  $E_{Pn}$ ,  $E_{Un}$  are rounded to the nearest percentage point.

## 9 Assessment forms

### 9.1 Process Audit for Material Products

Audited Organisation/Supplier				VDA 6.3 Audit Report: Assessment of Quality Capability				Date 14.12.2016	
<b>Perfect Parts for Cars Ltd.</b>				Supplier Nr 000987-3		DUNS-Nr.: 12-345-6789		Contract No PA 12/2016	
Location Quality Street 1 88888 No Mistakes Town Germany				Contract issued by Ms. Wilde		Dpt. Procurement			
				Reason for contract Reevaluation of the awarded contract for bumpers					
<b>Audit results</b>				<b>Findings / Requirements:</b>					
<b>Process Elements Assessed</b>		<b>Assessment Index</b>	<b>Achieved</b>	<b>Summary of the audit carried out:</b>					
P2, P3		EG2, 3	95%						
<b>Evaluated Product Group</b>		<b>Prod. Nr.</b>	<b>E<sub>G</sub>(pGN)</b>						
				<b>During the audit the following significant findings were identified:</b>					
				<b>Conclusion:</b>					
				<b>Course of action:</b>					
				<b>Dates Action Plan</b>					
				Confirmation of Measures:		28.12.2016		Performance Test:	
								14.03.2017	
				Action: see action plan and/or immediate action					
<b>Last audit results / certificates</b>				<b>Participants:</b>					
<b>Certificate / Audit nr.</b>		<b>Date of issue</b>	<b>Carried out by</b>	<b>Result</b>	<b>Management:</b>				
ISO/TS 16049		30.06.2015	Certifier	Requirements met	<b>Organisation:</b>				
Self audit		10.10.2016	Internal	92% A	Management: Mr. Hagen				
ISO 14001		30.06.2015	Certifier	Requirements met	Plant manager: Mr. Rudolph				
Potential analysis		15.02.2014	Client X	YELLOW	Q-Manager: Mr. Schmack				
<b>Audit team:</b>				<b>Management:</b>					
Mr. Freundlieb Auditor		Mr. Schmack		QMIL		Management: Mr. Hagen			
Mr. Marx Co-Auditor		Mr. Säuberlich		ET		Plant manager: Mr. Rudolph			
Mrs. Schmidt SQA		Mr. Einsiedler		VT		Q-Manager: Mr. Schmack			
<b>Auditor:</b> Mr. Freundlieb				<b>Audit team leader:</b> Mr. Boettger					
				<b>Organisation Representative:</b> Mr. Hagen					

Overall level of Performance EG:

## Potential analysis (P1) as an extract from the VDA questionnaire

## Audit Report VDA 6.3

**Organisation / Supplier**      **Perfect Parts for Cars Ltd.**

Supplier Nr.: 123457/22

Date: 20.05.2017

**Location** No Mistakes Town

**Contract Nr:** POT 12345

Summary of Results				Overall Evaluation	Rules
0	0	0	0		
0	0	0	0		
0	0	0	3		
0	1		2		
Yellow	Red	Green			

Questions from the VDA 6.3 Questionnaire				Project X	Project Y	Project Z	Audit Results
<b>P2 Project Management</b>							
P2.1	Is a project management established with a project organisation ?	Green	n.b.	n.b.			
P2.2	Are all resources required for the project development planned and available	Green	Green	n.b.			
P2.3	Is there a project plan and has this been coordinated with the customer?	Green	Green	Green			
P2.4	Is the advanced product quality planning implemented within the project and monitored for compliance?	Green	Green	Green			
P2.5	Are the procurement activities of the project implemented and monitored for compliance?	Green	Green	Green			
P2.6	Is change management within the project ensured by the project organisation?	Green	Green	Green			
P2.7	Is there an escalation process established and is this effectively implemented?	Green	Green	Green			
<b>P3 Planning the product and process development</b>							
P3.1	Are the specific product and process requirements available?	Yellow	Red	Green			
P3.2	Can the manufacturing feasibility be evaluated according to the product and process requirements?*	Yellow	Yellow	Green			
<b>P4 Implementation of the product and process development</b>							
P4.1	Are the actions which were defined in the product and process development plan implemented?	Yellow	Yellow	GRÜN			
P4.3	Are the material resources available and suitable to ensure the start of the series production?	Yellow	Yellow	GRÜN			
P4.4	Are the required approvals and releases for the product and process development implemented?	Yellow	Yellow	GRÜN			
<b>P5 Supplier Management</b>							
P5.1	Are only approved and quality-capable suppliers used?	Yellow	Green	Green			
P5.2	Are customer requirements taken into account in the supply chain?	Yellow	Green	Green			
P5.4	Are the necessary releases available for out sourced products and services?	Yellow	Green	Green			
P5.5	Is the quality of the out-sourced products and services ensured?	Yellow	Green	Green			
P5.6	Are incoming goods stored appropriately?	Yellow	Green	Green			

<b>P6</b> Process analysis / production				
<b>P6.1</b> What goes into the process? Process input				
P6.1.1	Has the project been transferred from development to serial production and is	Green	Green	Green
<b>P6.2</b> Are all production processes controlled? (process management)				
P6.2.1	Are the specification of the control plan complete and have they been effectively	Green	Green	Green
P6.2.2	Is there a restart of production of manufacturing processes?	Green	Green	Green
P6.2.3	Are special characteristics managed in the production?	Green	Green	Green
P6.2.4	Are non-released and / or defective parts managed?	Green	Green	Green
<b>P6.3</b> What functions support the process? (personnel resources)				
P6.3.1	Are the employees able to fulfill their given tasks?	Green	Green	Green
P6.3.3	Are the necessary personnel resources available?	Green	Green	Green
<b>P6.4</b> What means are used to implement the process? (material resources)				
P6.4.1	Can the product-specific requirements from the customer be met with the material	Green	Green	Green
P6.4.2	Is the maintenance of the manufacturing equipment and tools controlled?	Green	Green	Green
P6.4.3	Can the quality requirements be effectively monitored with the measurement	Green	Green	Green
P6.4.4	Are the work and inspection stations appropriate for the needs?	Green	Green	Green
<b>P6.5</b> How effective is the process being carried out? Effectiveness, efficiency, waste avoidance				
P6.5.3	In the case of deviations from product and process requirements, are the causes analysed and the corrective actions checked for effectiveness?	Green	Green	Green
P6.5.4	Are processes and products audited regularly?	Green	Green	Green
<b>P6.6</b> What should the process produce? (process result / output)				
P6.6.2	Are products / components stored in an appropriate manner and are transported	Green	Green	Green
P6.6.4	Are customer requirements met at the delivery of the final product?	Green	Green	Green
<b>P7</b> Customer care / customer satisfaction / service				
P7.1	Are all requirements related to QM-System, product and process fulfilled?	Green	Green	Green
P7.2	Is customer service guaranteed?	Green	Green	Green
P7.3	Is the supply of parts guaranteed?	Green	Green	Green
P7.4	If there are deviations from quality requirements, are failure analyses carried out and corrective actions implemented effectively?	Green	Green	Green

## 10 Best Practice / Lesson Learned

### 10 Example of a supplier self-assessment

Supplier Self Assessment (SSA)						VDA QMC	
for procurement enquiry :						Date:	
Sourcing Nr. :		Parts-No. :		Parts Name:			
<p>The return of the supplier self assessment is an obligation (where appropriate with attachments). The details are exclusively related to the actual manufacturing site! Please return the completed form within a few days! - (If required please add in additional lines)</p>							
<b>1. General Data Supplier</b>							
Company name:		responsible:	Sales		Research&Develop.		Quality
		Name :					
		Tel. No. :					
		Mobile Phone :					
If available please provide former name of the company:		email:					
		Languages:	German		German		German
		English		English		English	
		Spanish		Spanish		Spanish	
		French		French		French	
Internet-Hompage:							
Address of Manufacturing site :			Address of Development Centre :				
Manufacturing Site-Index :							
DUNS-No:			DUNS-No:				
Turnover p.A (€):		Number of Employees:		Number of Employees Develop.		Number of Employees Quality:	
<b>1.1 General Information for the actual Supplier Programme :</b>							
Series Deliveries of quoted products/product groups from the manufacturing site:							
Parts / Products		Customers/Plant(s), Vehicle Types			annual volume	since	
<b>1.2 Assessment of Quality</b>							
(Cert. DIN/ISO 9000 / EN 29000 - Volume/VDA Bd.6 / QS 9000 / ISO TS 16949 (Please send the cover page of the last audit))							
Parts- / Product Groups		Company / Auditor		Cert. To	%	Grade	Date

### 1.3 Sub-Suppliers

Are there plans that relevant features, for e.g. functional- and quality relevant components will be bought from sub-suppliers and/or services of service suppliers will be used for the actual quoted project ? e.g. machining, assembly, painting

Yes	No

Parts- / Product Groups	Supplier/Company	Cert. To	%	Grade	Date

### 1.4 Tool Maker

Is there a tool making facility at the suppliers site?

Yes	No

Name and address of the tool maker:

Contact/ Tel. No. :


## 2. Development

### 2.1 Joint Venture Partner / Know-How-Cooperation

Company/Contact:	JV-Share(in %)	Know-How-Joint Venture	financial Joint Venture(s)
	Tel. No.:	Fax No.:	
Which components involve a JV or Know-How-Cooperation?			Partner:

### 2.2 Core Competencies

Core Competencies:


### 2.3 Research&Development Departments

Is the supplier capable to handle all aspects of research&development:

Yes	No

If not, which development work requires to be done elsewhere:

Operation	Partner / Organisation	Licens / Joint Venture

### 2.4 Project Management, Methods of Product Development

Does the supplier have the project management/development at the OEM site? (e.g. local engineering office)

Yes	No

If yes, contact and contact details:


Which Development- and Quality Methods are used by the supplier?

Yes	No

a) QFD Methods:

b) FMEA (Design FMEA, Process FMEA):

c) DOE Methods:

d) Others:


<b>2.5 CAD Engineering Systems?</b>		Yes	No
Does the supplier have CAD Systems?			
If yes, what systems are they:			
1.			
2.			
Is there a CAD-Data link to VW AG?			
If yes, what sort of link is in use?			
Does the supplier use simulation methods?			
If yes, what are the systems?			
1.			
2.			
3.			
<b>2.6 Innovation</b>		Yes	No
Does the supplier hold own patents?			
If yes, for which products or processes :		locally	Intern.
<b>2.7 Laboratory Equipment:</b>		Yes	No
Which equipment is available at the suppliers site?		available at site ?	
Which laboratory equipment is used externally?		Partner / Organisation	
<b>2.8 Test Equipment</b>		Yes	No
Which <b>functional test rigs</b> does the supplier maintain at the site?		available at site ?	
Which test rigs are used externally?		Partner / Organisation	
Which endurance test rigs are maintained at the site?		available at site ?	
Which endurance test rigs are used externally?		Partner / Organisation	
Which measurement- and analysis equipment does the supplier maintain?		available at site ?	
Which measurement- and analysis equipment is used externally?		Partner / Organisation	



<b>2.9 Test Facility/Prototyping</b>		Yes	No
Does the supplier maintain a test facility or prototyping on site?			
Which prototyping facilities are used internally?			
Which prototyping facilities are used externally?		Partner / Organisation	
<b>3. Other Informations</b>			
<b>3.1 Export</b>			
Which components are exported and for which customers? How much is the share for the net value of such products?			
Components:		Customers:	Product Net Value
<b>3.2 Comments / Attachments</b>			

[www.vda-qmc.com](http://www.vda-qmc.com)

## 10.2 Knowledge Database

Audit results are greatly influenced by the knowledge of the auditor regarding the product and process being evaluated. Asking relevant questions and evaluating the answers depends on this knowledge. There are different ways to build up this knowledge and use it in an audit. This is done for example by:

- The inclusion of product and process experts in the audit team
- Preparation by the auditor including literature research, online forums and industry standards.
- Discussion with in-house experts

It is recommended to systematically record, develop and store this information in the knowledge database and make this available for auditors. Sources of this knowledge are, for example, typical errors and lessons learned. The confidentiality of this information (from customers, suppliers or in-house) must be ensured.

It should be noted that questions resulting from this database must not present additional requirements that go beyond the requirements agreed upon in the contract.

This knowledge database can be made available e.g. in the form of wikis or process-related lists.

Knowledge database for process auditors  
(Listing and level of detail are examples)

Knowledge database for process auditors – Plastic injection moulded parts	
Input materials	Rate storage conditions of granules (temperature, humidity, batch separation).
	Examine pre-drying and conditioning. <ul style="list-style-type: none"><li>- For plastic <i>Type 123</i> pre-drying and conditioning is always required in the delivery requirements. <i>Details ...</i></li></ul>
	Note the maximum allowed amount of recycled material. <ul style="list-style-type: none"><li>- Recycled material is not permitted in the following plastics: ...</li></ul>

Knowledge database for process auditors - Plastic injection moulded parts		
Production process	Evaluate parameter monitoring (temperature, pressure, cycles, retention time). <ul style="list-style-type: none"><li>- Injection moulding processes often fluctuate. The constancy of the parameters is to be evaluated</li></ul>	
	Evaluate prototypes and tool releases. <ul style="list-style-type: none"><li>- If prototypes were taken from the development process the machines used in the serial production should be checked for comparable working parameters (holding pressure, temperature control etc.).</li></ul>	
	The temperature distribution in the machine is known to the supplier.	
Inspections	Sample parts <ul style="list-style-type: none"><li>- Observe the production start of the injection moulding machine before the first piece inspection</li><li>- How the sample is taken, test sequence and sample type may affect the parts (e.g. on the shrinkage characteristics).</li></ul>	
	Surface quality <ul style="list-style-type: none"><li>- If visual tests are being carried out rate the workplace (lighting etc.).</li><li>- Evaluate the reference samples (approval status, storage etc.).</li></ul>	
	Dimensional accuracy <ul style="list-style-type: none"><li>- Evaluate gauges or when appropriate fixture from measurement machines (position point, voltage-free etc.)</li></ul>	
Version:	Issued:	Released:

Knowledge Database for Process Auditors – Stamped and punched parts		
Input materials	Rate storage conditions of input materials. <ul style="list-style-type: none"><li>- Corrosion protection</li><li>- Damage-free surface</li></ul>	
	Material certificate <ul style="list-style-type: none"><li>- Evaluate material batches and material certificates.</li></ul>	
Production process	Damage-free parts and tools <ul style="list-style-type: none"><li>- Ensure there is no systematic damage.</li></ul>	
	Tool maintenance intervalls <ul style="list-style-type: none"><li>- Tool life monitoring, quantity monitoring</li><li>- Evaluate wear and tear in preventive maintenance</li></ul>	
	Tool design <ul style="list-style-type: none"><li>- Hardened surfaces</li></ul>	
Inspections	Visual examination (e.g. damage-free surface) <ul style="list-style-type: none"><li>- workplace evaluation (lighting)</li><li>- Boundary samples for surface quality (approval status, storage etc.)</li></ul>	
	Dimensional accuracy <ul style="list-style-type: none"><li>- Evaluate measuring equipment for serial inspections at the workplace and in the measurement laboratory.</li><li>- Check data collection and analysis (cp, cpk Levels)</li></ul>	
Version:	Issued:	Released:

# 11 Glossary

## 11.1 Terms and Definition

Term	Definition	Notes / References
<b>CAM</b> <b>Computer aided manufacturing</b>	CAM refers to the IT support for control and monitoring of production equipment and processes.	Source: Committee for Efficient Production (AWF)
<b>Capability of Measurement Processes</b>	The capability of measurement processes documents evidence that the measurement process used (device / apparatus, operator, environment etc) is suitable for a specific application.	VDA Volume 5
CAQ Computer aided Quality Assurance	CAQ System is the generic term for IT systems that are specifically developed to support quality management processes.	See VDA Volume: Standard Process for Handling Customer Complaints
<b>CCC</b> <b>China Compulsory Certificate</b>	A valid certification system in the People's Republic of China. Chinese safety certification system required for specified parts or system parts when they are imported or used within the Chinese market.	
<b>C<sub>mk</sub></b> <b>Machine Capability Index</b>	The machine capability shows how a machine is performing in relation to the tolerance limits for variance (capability corrected for position). This is calculated using mathematical and statistical methods and only the short time variance (scattering) is considered.	VDA Volume 6.4
<b>Conflict Management</b>	Conflict management is the containment and prevention of escalation due to conflicts of interest. It is about the systematic, deliberate and targeted approach to conflicts in audit situations.	
<b>Conformity Confirmation</b>	Confirmation of compliance with the requirements; Unlike certification only the actual status is evaluated. An ongoing monitoring programme does not take place.	
<b>Consignment</b>	Storage for products which remain in the ownership of the supplier until removal by the customer but are however, already owned by the customer.	
<b>Control Chart</b>	With the help of control charts the performance of processes is monitored and statistically significant non-random deviations can be detected. Control charts help to focus on the stability of a process.	DIN ISO 10004
<b>Control Cycle</b>	System which continuously compares its actual value with the desired value and can react to implement corrective changes.	See VDA Robust Production Process

Term	Definition	Notes / References
<b>C<sub>pk</sub></b> <b>Capability process index</b>	Statistical estimation of the result of a characteristic of a process that has been demonstrated to be controlled. A process is capable when the statistical parameters for variance and position in relationship to the setpoint and tolerance values meet the given criteria.	From EN ISO 21747: 2004-09
<b>Deviation Permit</b>	Risk assessment of parts that do not meet the specifications. It is assessed whether the parts can still be used. The permit allows the use of components that do not meet all the required steps and release specifications. A deviation permit / authorization can be granted only by authorized personnel and only in coordination with the customer. The deviation permit must be attached together with the action plan for the execution of the shortcomings of the PPF documentation. See PPF and deviation permit / authorisation	s.a. VDA Band 2
<b>DoE Design of Experiments</b>	The objective of this method is to vary factors that influence the process or the system experimentally to find an optimum (e.g. optimal combination of injector, mixture etc. to achieve the most fuel efficient combustion possible). The basis of the method is an experimental design using statistical methods to maximize the use of information from the experiments carried out.	See VDA Volumes 4 and Volume 11
<b>DOT Department of Transportation</b>	Department of Transportation in the USA. The DOT defines specific requirements for components and their labelling.	
<b>ECE Economic Commission for Europe</b>	Economic Commission for Europe within the United Nations. Sets standards requirements for components and related component labelling.	
<b>Embedded Software</b>	Embedded software is a part of a technical system and fulfils functions of the system.	See IEEE (Glossary of software engineering terminology)
<b>Error test pieces</b>	Monitoring the identification of defective parts using a part with known deviations from the specification see red rabbit.	
<b>Feasibility Study</b>	A feasibility study assesses at an early stage whether a requested product (part, component, modules, system, process) can be produced under series conditions to the specifications given.	VDA Volume 4
<b>FIFO</b> <b>First in first out</b>	FIFO refers to the method of using the oldest parts in stock before newer parts are used.	
<b>First Pass Yield</b>	Percentage of results that are correct in the first process run and do not require reworking (corresponds to first-time-through quality, straight running)	VDA volume: Robust Production Process
<b>First pass yield</b>	Percentage of results that are correct in the first process run and do not require reworking (corresponds to first-time-through quality, pass yield, straight running)	VDA volume: Robust Production Process

Term	Definition	Notes / References
<b>First time through quality</b>	Percentage of results that are correct in the first process run and do not require reworking (corresponds to first pass yield, straight running)	VDA volume: Robust Production Process
<b>FMEA Failure Mode and Effects Analysis</b>	The objective of an FMEA is the early identification of potential sources of error / weaknesses and mistakes. The consequences are evaluated in a methodical risk analysis that initiates prevention measures. The FMEA method prioritizes potential errors according to the criteria "importance for the customer" / "occurrence probability" / "detection probability".	VDA Volume 4
<b>FTA Fault Tree Analysis</b>	The fault tree analysis is a method for risk analysis for equipment and systems.	VDA Volume 4
<b>IMDS International Material Data System</b>	The IMDS is the material data system of the automotive industry. All materials used in the manufacturing of vehicles are collected, maintained analysed and archived within the IMDS. Through the use of the IMDS it is possible to fulfil the requirements of national and international standards, laws and regulations that are required by automotive manufactures and their suppliers.	See IMDS International Material Data System
<b>JIS Just in sequence</b>	Provision of parts with a large number of variants in the planned production sequence.	
<b>JIT Just in time</b>	The provision of parts or materials to the location they are needed in the production at the time they are required.	See VDA recommendation 5010
<b>KANBAN</b>	Method for reducing material stock in the production by using demand control according to the pull principal.	
<b>Layout Inspection and Functional Inspection</b>	A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review.	ISO TS 16949
<b>MSA Measurement System Analysis</b>	Evaluates the test process suitability (capability of measuring instruments and measuring systems) based on the product specifications. MSA is described in a publication published by the AIAG, in addition there are company specific requirements for measurement system analysis.	See AIAG, VDA Volume 5
<b>Negotiation</b>	The auditor uses discussion and questioning techniques such as active listening, giving feedback, summary, importance of body language and intercultural aspects.	
<b>NTF No trouble found</b>	NTF refers to the fact that a rejected part is analysed (standard test and load test) and no deviations from the specifications are found. The part is considered OK according to the findings and the complaint could not be validated. The cause of the error could not be identified.	See VDA Volume Field Failure Analysis

Term	Definition	Notes / References
<b>OEE</b> <b>Overall equipment effectiveness</b>	The OEE (Overall Equipment Effectiveness) is a measure of the effectiveness of a production system based on its availability factor, efficiency factor and quality factor.	
<b>Pareto Analysis</b>	Using the Pareto analysis priorities can be identified and visualised. In a Pareto analysis the characteristics (e.g. error, defective components, etc.) are sorted by frequency or importance.	See VDA Volume 4
<b>Parts History</b>	All changes that have been made to a numbered part and the associated manufacturing process are documented in the part history.	VDA Volume 2
<b>Pilot Lot</b>	Production of a component prior to series production.	
<b>Poka-Yoke principle</b>	System method for preventing mistakes	See VDA Robust Production Process
<b>Positioning parts</b>	Parts that are produced during the setup process or that are required for setting up the system (e.g. master-parts, red-rabbit). These parts are not suitable to be used by the customer.	
<b>PPA</b> <b>Production Process and Product Approval</b>	Release Procedure for series production (sampling), described in VDA Volume. 2	VDA Volume 2
<b>PPAP</b> <b>Production Part Approval Process</b>	The purpose of the PPAP is to determine whether the product complies with the design documents and specification requirements. Also see: APQP; PPF.	See AIAG; VDA Volume 2 VDA Volume Maturity Level Assurance for New Parts
<b>Ppm</b> <b>Parts per million</b>	Representation of the error component based on the number of 1 million produced or supplied parts.	
<b>Process risk</b>	All risks associated with the manufacturing process that could have an effect on the product quality. Deviations arising from the process and how they impact on the properties of the product.	
<b>Process Step</b>	Defined production step or production process as part of the overall process for the production of a product (e.g. machining, painting, plastic injection moulding)	
<b>Product group</b>	Similar products with a comparable manufacturing process	
<b>Product risk</b>	Risk that a product deviates from the specifications and the possible resulting effects e.g. to function, safety, installation.	
<b>Production peak</b>	The production peak is the number of units produced at maximal planned capacity.	
<b>Prototype</b>	Sample for or functional tests and reliability tests.	DIN 55350



Term	Definition	Notes / References
<b>QFD</b> <b>Quality Function Deployment</b>	QFD is a quality tool developed in Japan in the seventies. It is used to determine customer requirements and their direct implementation within the technical specifications. The methodological approach is based on a separation of the customer requirements (what) of the technical product features and functionality (how).	See VDA Volume 11 and Volume 4
<b>Quality assurance agreement</b>	A written quality assurance agreement providing all quality assurance measures for future deliveries between customers and suppliers. In this way the obligations regarding the quality of supply are regulated. Quality assurance agreements constitute a contractual agreement between customers and suppliers.	
<b>Red Rabbit</b>	Monitoring of error testing using a part with defined deviations from the specifications	
<b>Required Supplier</b>	When an organisation manufactures modules and must use parts from a supplier stipulated by the customer, then this supplier is a required supplier	VDA Volume 2
<b>Risk</b>	Risks must be anticipated and estimated (from their probability and extent of damage, often expressed in possible cost). Also to consider are the technical, economic, political and socio-cultural risks.	ISO 9001
<b>Risk assessment</b>	Risiken müssen vorausgesehen und abgeschätzt werden (aus Eintrittswahrscheinlichkeit und Schadenshöhe, oft in möglichen Kosten ausgedrückt). Zu beachten sind technische, wirtschaftliche, politische und soziokulturelle Risiken.	VDA Volume 11
<b>Shainin</b>	Test-based method (named after Shainin) used to identify relevant factors through the use of different measurement methods and experiments.	See: Quentin: Statistical test methods according to Shainin
<b>Skip Lot</b>	The method of sampling inspection in which some lots will be accepted within a group without examination if the results of the sampling tests at a specified number of immediately preceding lots, meet defined criteria.	ISO 2859-3
<b>SOP</b> Start of Production	Start of the serial production	VDA Volume 2
<b>SPC</b> Statistical process control	Statistical process control, improved with the help of statistical methods, the quality of production and service processes.	VDA Volume 4
<b>Start of Production</b>	The primary goal of the start of production phase is to convert a new product from the laboratory like conditions to a stable product series. This phase begins as soon as the integration of all product components in prototype is successful and ends with the ability to produce the desired quality and quantity.	Milling & Jürging. (2008). Start of Production in the Automotive Industry: Technical changes as a cause or symptom of initial difficulties?

Term	Definition	Notes / References
<b>Straight run</b>	Percentage of results that are correct in the first process run and do not require reworking (corresponds to first pass yield, first time through quality)	VDA volume: Robust Production Process
<b>Sustainability</b>	Sustainability in the business context includes the safeguard of requirements regarding environmental protection, occupational safety and social standards as well as long-term profit orientation.	
<b>Taguchi</b>	Test-based method (named after Taguchi) that helps design robust systems, products and processes.	see: Wu:Taguchi's Quality Engineering Handbook
<b>Validation</b>	Validation is the uses of objective evidence to confirm that the requirements which define an intended use or application have been met.	ISO 9000
<b>VDA Maturity Level Assurance for New Parts</b>	Continuous tracking of the maturity level of new parts in conjunction with an objective assessment of the product and production process maturity at agreed times during the product implementation process	See VDA Volume 2: Maturity Level Assurance for New Parts
<b>Verification</b>	Verification is the use of objective evidence to confirm that specified requirements have been met.	ISO 9000

## 11.2 List of Abbreviations

Abbreviation	
CAX	Computer-aided x
EDP	Electronic data processing
ESD	Electrostatic discharge
IEC	International Electrotechnical Commission
inkl.	Inklusive
Inmetro	National Institute of Metrology, Standardization and Industrial Quality
ISO	International Organization for Standardization
IT	Information Technology
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
SAE	Society of Automotive Engineers
VDA	German Automotive Industry Association

Some abbreviations are based on terms from the German Volume. These have not been translated because of their use in the calculations and assessment forms where one standard abbreviation is necessary. A summary of these abbreviations is given below.

Abbreviation	
D	Service or provision of service ( <u>D</u> ienstleistung in German)
P	Process Element ( <u>P</u> rozesselement in German)
E	Compliance level ( <u>E</u> rfüllungsgrad in German)
E <sub>Dn</sub>	Compliance level of the service ( <u>D</u> ) process element ( <u>n</u> )
E <sub>G</sub>	Overall compliance ( <u>G</u> from <u>G</u> esamterfüllungsgrad)
E <sub>G(Dn)</sub>	Overall compliance ( <u>G</u> ) of the service process element ( <u>Dn</u> )
E <sub>G(PGn)</sub>	Overall compliance ( <u>G</u> ) of the <u>p</u> roduct <u>g</u> roup <u>n</u>
E <sub>n</sub>	Compliance level ( <u>E</u> ) of each process step <u>n</u>
E <sub>Pn</sub>	Compliance level ( <u>E</u> ) of the <u>p</u> rocess element <u>n</u>
E <sub>u</sub>	Compliance level ( <u>E</u> ) of the sub-element u (u from <u>U</u> nterelement)
E <sub>un</sub>	Compliance level ( <u>E</u> ) of the specific sub-element n
n.a.	Not applicable (the specific question/process element is not relevant for the audit).
n.b.	Not rated (from <u>B</u> ewertet in German), the question/process element could have been audited but was not (not enough time, no process expert present etc).

## 12 Downloads

The content and forms for the download are still being prepared.

## 13 Overview Matrix

### For the Process Elements P2.1-P2.7

	P2.1	P2.2	P2.3	P2.4	P2.5	P2.6	P2.7
VDA Volume 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records							
VDA Volume 2 Quality Assurance for Supplies Production process and product approval PPA					x		
VDA Volume 3.2/3.3 (Part 1) Reliability Assurance of Car Manufacturers and Suppliers							
VDA Volume 4 Quality Assurance in the Process Landscape				x	x		
VDA Volume 5 Capability of Measurement Processes							
VDA Volume 6.x Quality Audit Fundamentals					x		
VDA Volume 7 Exchanging Quality Data QDX							
VDA Volume 16 Decorative surfaces of external fittings and functional parts in the internal and externals of Automobiles							
VDA Volume 19.x Technical Cleanliness							
VDA Volume Maturity Level Assurance for New Parts	x	x	x	x	x	x	x
VDA Volume Standard Process for Handling Customer Complaints							
VDA Volume Field Failure Analysis							
VDA Volume Customer-Specific QM Systems Requirements							
VDA Volume Robust Production Process					x		
VDA Volume Special Characteristics							
VDA Volume Minimising Risk in the Supply Chain					x		
VDA Volume Automotive SPICE							
AIAG APQP	x	x	x	x	x	x	x
AIAG/VDA FMEA				x	x		
AIAG PPAP					x		
AIAG MSA							

## For the Process Elements P3.1-P3.5

	P3.1	P3.2	P3.3	P3.4	P3.5
<b>VDA 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records</b>					
<b>VDA Volume 2 Quality Assurance for Supplies Production process and product approval PPA</b>					
<b>VDA Volume 3.2/3.3 (Part 1) Reliability Assurance of Car Manufacturers and Suppliers</b>			X		
<b>VDA Volume 4 Quality Assurance in the Process Landscape</b>	X	X	X		
<b>VDA Volume 5 Capability of Measurement Processes</b>					
<b>VDA Volume 6.x Quality Audit Fundamentals</b>					
<b>VDA Volume 7 Exchanging Quality Data QDX</b>					
<b>VDA Volume 16 Decorative surfaces of external fittings and functional parts in the internal and externals of Automobiles</b>	X	X			
<b>VDA Volume 19.x Technical Cleanliness</b>	X	X			
<b>VDA Volume Maturity Level Assurance for New Parts</b>	X	X	X	X	X
<b>VDA Volume Standard Process for Handling Customers' Complaints</b>	X	X			
<b>VDA Volume Field Failure Analysis</b>	X	X		X	
<b>VDA Volume Customer-Specific QM Systems Requirements</b>					
<b>VDA Volume Robust Production Process</b>			X	X	
<b>VDA Volume Special Characteristics</b>	X	X			
<b>VDA Volume Minimising Risk in the Supply Chain</b>		X			
<b>VDA Volume Automotive SPICE</b>					
<b>AIAG APQP</b>	X	X	X	X	X
<b>AIAG/VDA FMEA</b>	X	X	X		
<b>AIAG PPAP</b>					
<b>AIAG MSA</b>					

## For the Process Elements P4.1-P4.7

	P4.1	P4.2	P4.3	P4.4	P4.5	P4.6	P4.7
VDA 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records							
VDA Volume 2 Quality Assurance for Supplies Production process and product approval PPA				x		x	x
VDA Volume 3.2/3.3 (Part 1) Reliability Assurance of Car Manufacturers and Suppliers	x						
VDA Volume 4 Quality Assurance in the Process Landscape	x			x	x		
VDA Volume 5 Capability of Measurement Processes	x						x
VDA Volume 6.x Quality Audit Fundamentals							
VDA Volume 7 Exchanging Quality Data QDX							
VDA Volume 16 Decorative surfaces of external fittings and functional parts in the internal and externals of Automobiles							
VDA Volume 19.x Technical Cleanliness							
VDA Volume Maturity Level Assurance for New Parts	x	x	x	x	x	x	x
VDA Volume Standard Process for Handling Customers' Complaints	x				x		
VDA Volume Field Failure Analysis	x				x		
VDA Volume Customer-Specific QM Systems Requirements							
VDA Volume Robust Production Process	x	x	x	x		x	x
VDA Volume Special Characteristics							x
VDA Volume Minimising Risk in the Supply Chain							x
VDA Volume Automotive SPICE	x	x	x	x	x	x	x
AIAG APQP	x			x	x		
AIAG/VDA FMEA				x		x	x
AIAG PPAP	x						x
AIAG MSA			x				

## For the Process Elements P5.1-P5.7

	P5.1	P5.2	P5.3	P5.4	P5.5	P5.6	P5.7
VDA 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records				x			
VDA Volume 2 Quality Assurance for Supplies Production process an product approval PPA		x		x			
VDA Volume 4 Quality Assurance in the Process Landscape		x		x	x		
VDA Volume 6.x Quality Audit Fundamentals	x						
VDA Volume 16 Decorative surfaces of external fittings and functional parts in the internal and externals of Automobiles		x					
VDA Volume 19.x Technical Cleanliness		x					
VDA Volume Maturity Level Assurance for New Parts	x	x		x			
VDA Volume Standard Process for Handling Customer Complaints		x			x		
VDA Volume Robust Production Process			x				
VDA Volume Minimising Risk in the Supply Chain	x						
AIAG APQP		x		x			
AIAG/VDA FMEA		x		x	x		
AIAG PPAP		x		x			

## For the Process Elements P6.1,1-P6.1.5

	P6.1.1	P6.1.2	P6.1.3	P6.1.4	P6.1.5
VDA 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records				x	x
VDA Volume 2 Quality Assurance for Supplies Production process an product approval PPA	x				x
VDA Volume 4 Quality Assurance in the Process Landscape	x				x
VDA Volume 5 Capability of Measurement Processes					
VDA Volume 6.x Quality Audit Fundamentals					
VDA Volume 16 Decorative surfaces of external fittings and functional parts in the internal and externals of Automobiles					
VDA Volume 19.x Technical Cleanliness					
VDA Volume Standard Process for Handling Customers' Complaints					



<b>VDA Volume Robust Production Process</b>	<b>x</b>	<b>x</b>	<b>x</b>	<b>x</b>	<b>x</b>
<b>VDA Volume Special Characteristics</b>					
<b>AIAG/VDAFMEA</b>	<b>x</b>				<b>x</b>
<b>AIAG PPAP</b>	<b>x</b>				<b>x</b>
<b>AIAG MSA</b>					

## For the Process Elements P6.2.1-P6.2.5

	P6.2.1	P6.2.2	P6.2.3	P6.2.4	P6.2.5
<b>VDA 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records</b>			<b>x</b>	<b>x</b>	
<b>VDA Volume 2 Quality Assurance for Supplies Production process and product approval PPA</b>					
<b>VDA Volume 4 Quality Assurance in the Process Landscape</b>		<b>x</b>			
<b>VDA Volume 5 Capability of Measurement Processes</b>					
<b>VDA Volume 6.x Quality Audit Fundamentals</b>					
<b>VDA Volume 16 Decorative surfaces of external fittings and functional parts in the internal and external of Automobiles</b>		<b>x</b>			
<b>VDA Volume 19.x Technical Cleanliness</b>					
<b>VDA Volume Standard Process for Handling Customers' Complaints</b>					
<b>VDA Volume Robust Production Process</b>	<b>x</b>	<b>x</b>	<b>x</b>	<b>x</b>	<b>x</b>
<b>VDA Volume Special Characteristics</b>			<b>x</b>	<b>x</b>	
<b>AIAG/VDAFMEA</b>		<b>x</b>			
<b>AIAG PPAP</b>					
<b>AIAG MSA</b>					

## For the Process Elements P6.3.1-P6.4.5

	P6.3.1	P6.3.2	P6.3.3	P6.4.1	P6.4.2	P6.4.3	P6.4.4	P6.4.5
<b>VDA 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records</b>								
<b>VDA Volume 2 Quality Assurance for Supplies Production process an product approval PPA</b>								
<b>VDA Volume 4 Quality Assurance in the Process Landscape</b>							x	
<b>VDA Volume 5 Capability of Measurement Processes</b>						x		
<b>VDA Volume 6.x Quality Audit Fundamentals</b>				x				
<b>VDA Volume 16 Decorative surfaces of external fittings and functional parts in the internal and externals of Automobiles</b>				x			x	
<b>VDA Volume 19.x Technical Cleanliness</b>				x			x	
<b>VDA Volume Standard Process for Handling Customers' Complaints</b>								
<b>VDA Volume Robust Production Process</b>				x	x	x	x	x
<b>VDA Volume Special Characteristics</b>								
<b>AIAG/VDA FMEA</b>							x	
<b>AIAG PPAP</b>								
<b>AIAG MSA</b>						x		

## For the Process Elements P6.5.1-P6.6.4

	P6.5.1	P6.5.2	P6.5.3	P6.5.4	P6.6.1	P6.6.2	P6.6.3	P6.6.4
VDA 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records		x					x	x
VDA Volume 2 Quality Assurance for Supplies Production process and product approval PPA							x	x
VDA Volume 4 Quality Assurance in the Process Landscape		x	x			x		
VDA Volume 5 Capability of Measurement Processes								
VDA Volume 6.x Quality Audit Fundamentals				x				x
VDA Volume 16 Decorative surfaces of external fittings and functional parts in the internal and external of Automobiles						x		x
VDA Volume 19.x Technical Cleanliness						x		x
VDA Volume Standard Process for Handling Customer Complaints			x					
VDA Volume Robust Production Process	x	x	x	x	x	x	x	x
VDA Volume Special Characteristics								
AIAG/VDAFMEA		x	x			x		
AIAG PPAP							x	x
AIAG MSA								

## For the Process Elements P7.1-P7.5

	P7.1	P7.2	P7.3	P7.4	P7.5
VDA 1 Documentation and Archiving - Code of practice for the documentation and archiving of quality requirements and quality records	x				
VDA Volume 2 Quality Assurance for Supplies Production process and product approval PPA	x	x			
VDA Volume 4 Quality Assurance in the Process Landscape	x			x	
VDA Volume 6.x Quality Audit Fundamentals	x				
VDA Volume Field Failure Analysis				x	
VDA Volume Standard Process for Handling Customer Complaints			x	x	
AIAG PPAP	x	x			
AIAG/VDA FMEA				x	

## **Quality Management in the Automotive Industry**

The current issues of VDA publications covering quality management in the automotive industry (QAI) can be viewed in the Internet under <http://www.vda-qmc.de>.

You can also place orders on this home-page.

Available from:

**Verband der Automobilindustrie e.V. (VDA)  
Qualitäts Management Center (QMC)**

Behrenstraße 35  
10117 Berlin  
Germany

Telephone: +49 (0) 30 89 78 42-235  
Telefax: +49 (0) 30 89 78 42-605  
E-Mail: [info@vda-qmc.de](mailto:info@vda-qmc.de)  
Internet: [www.vda-qmc.de](http://www.vda-qmc.de)

Forms available from:

**Henrich Druck + Medien GmbH**

Schwanheimer Straße 110  
60528 Frankfurt am Main  
Germany

Telephone: +49 (0) 69 96 777- 0  
Telefax: +49 (0) 69 96 777-111  
E-Mail: [info@henrich.de](mailto:info@henrich.de)  
Internet: [www.henrich.de](http://www.henrich.de)



Qualitäts Management Center im  
Verband der Automobilindustrie