

Quality Management in the Automotive Industry

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## Process Audit

**Potential Analysis**

**Product and Production Process Development**

**Product and Production Process Implementation**

**Series Production**

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**Potential Analysis**

**Product and Production Process Development**

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**Series Production**

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## Foreword

The VDA 6.3 process audit has been established for almost three decades as an important method for identifying strengths and weaknesses.

It involves analyzing and evaluating process capability during the product development and product implementation phase.

The characteristics of VDA 6.3 are:

- a structured approach to analyzing processes
- an evaluation and points system
- clear downgrading rules
- identification of specific product and process risks (questions marked with an asterisk, i. e. \*-questions)
- a clear presentation of the results of the process evaluation (A, B or C)
- worldwide comparability of the results for similar products and processes
- potential analysis for evaluating the suitability of new suppliers, locations, and technologies prior to awarding a contract
- a focus on the process and the product rather than on the system

The VDA 6.3 process audit is integrated into a company's QM system and contributes to the fulfillment of the requirements according to IATF 16949.

The VDA 6.3 process audit is part of the VDA 6.x family:

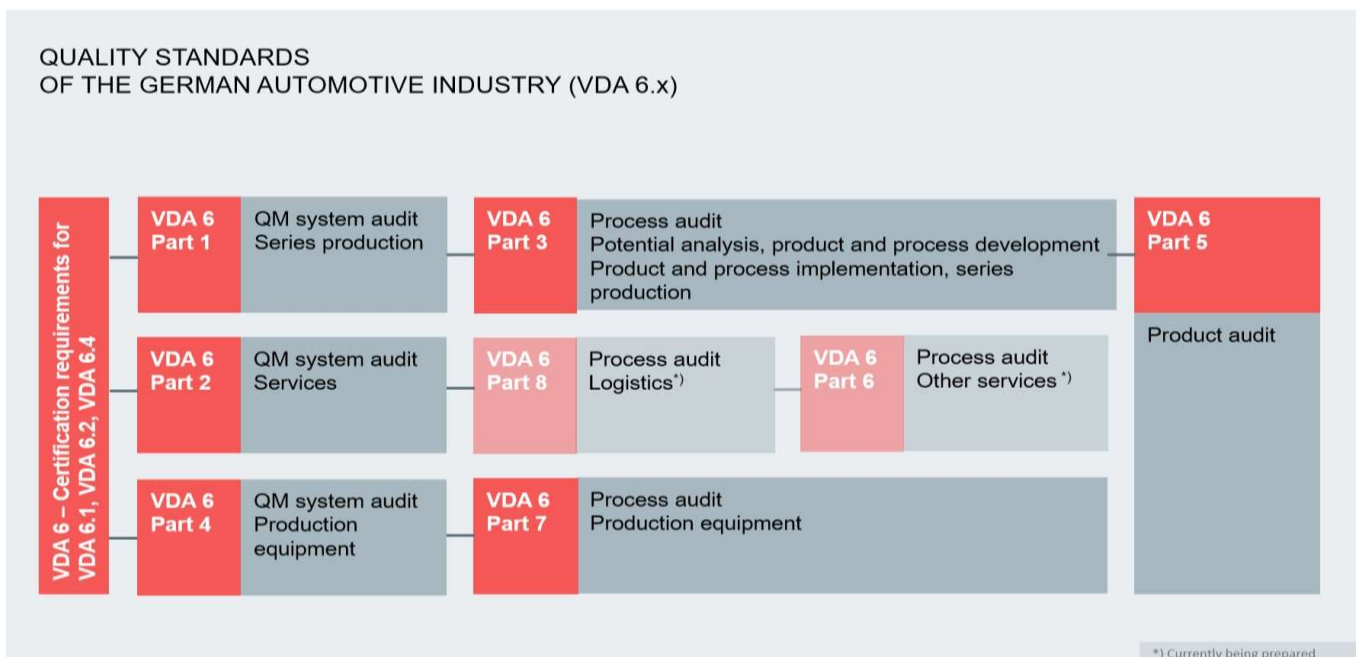


Figure 0-1: Overview of the volumes of the VDA 6.x family

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## 1 Notes on the revision

VDA 6.3 was published for the first time in 1998 and was revised in 2010, 2016 as well as 2023.

What has changed compared to the 2016 version?

- Software-related aspects have been considered in the questionnaire.
- The content of this volume was harmonized with further VDA methods, namely Automotive SPICE and maturity level assurance for new parts (VDA MLA).
- Requirements with regard to purchasing activities were added to P3 and P4.
- Notes on conducting remote audits were added.
- Chapter 4 ("Audit process") was deleted, as its contents are included in ISO 19011.
- Chapter 8 ("Process audit services") was completely deleted from the VDA Volume 6.3.
- Chapter 10 ("Best practice/lessons learned") was deleted.
- The evaluation of transport and parts handling (EU<sub>7</sub>) was omitted.
- In some cases, questions with special significance (\*-questions) were redefined.
- Some of the questions regarding the potential analysis were reallocated.
- A comprehensive online glossary for all VDA volumes is established.

What has remained the same?

- The classification system (A, B, C) for the overall assessment
- The structure of the questionnaire
- The evaluation model for the individual questions (10-8-6-4-0)
- The applicability of process elements P2-P7 according to figure 2-1
- The Turtle Model
- Previous downgrading rules

During the revision, the distinction between process and system audits was once again explicitly taken into account. The current IATF requirements have been observed.

For products with integrated (embedded) software, the interface between hardware and software has been strengthened. However, for a detailed evaluation of the software development, the Automotive SPICE® method should be used.

Due to the changes that have been made, the results of audits conducted according to the present volume are not directly comparable to the results of audits carried out in accordance with the previous edition from 2016.

## **2 Instructions for use**

### **2.1 Scope of the volume**

A process audit is a method for impartial analysis and evaluation of product development and implementation processes as well as their effectiveness.

Process audits can be used internally as well as externally throughout the entire product life cycle and fulfill the requirements specified in IATF 16949. Process audits are suitable for small or medium-sized companies as well as large corporations.

In general, this volume can be used throughout the entire product life cycle. In this regard, a distinction is made between:

- Potential analysis
- Product and production process development
- Product and production process implementation
- series production

When conducting process audits, the selection of process elements and the implementation period may vary.

During series production, the process audit serves to ensure regular monitoring of the series production processes and can also be used on an event-oriented basis.

The aim of the process audit is to determine whether the processes/process steps fulfill the process and product requirements and specifications. Any discrepancies detected are evaluated in accordance with a points system with regard to the process/product risk and are documented as audit findings. The objective is to determine to what extent potentially non-compliant products are to be expected based on the audit findings, as well as to identify the associated risks.

If any questions are added or deleted, or if any changes are made to the evaluation method, an audit cannot be considered a VDA 6.3 audit anymore, as the evaluation systems are not comparable any more.

Specific evaluation questions relating to sustainability, compliance with social standards, environmental protection, the conservation of resources, etc. are not included in the questionnaire. There are special audit standards as well as statutory and normative specifications for this. However, should the auditor identify obvious aspects which are not in compliance with the requirements of this process audit standard and/or which have a lasting negative effect on the

product characteristics, this should be documented and taken into account in the evaluation.

*Table 2-1: Differentiation between audit standards*

System audit standards	Process audit standards	Audit standards not related to quality
IATF 16949 ISO 9001 ISO 9004 VDA 6.1 VDA 6.2 VDA 6.4 Automotive cybersecurity management system audit (ACSMS)	<b>VDA 6.3</b> VDA 6.7 VDA 6.8 Automotive SPICE® Guidelines Automotive SPICE® for Cybersecurity	Environmental protection Occupational safety Fire protection Energy management Sustainability Animal welfare Supply Chain Act Social standards Human rights Data security Logistics

## 2.2 Integration into the product life cycle

The VDA 6.3 audit standard can be used throughout the entire product life cycle, from the selection of potential suppliers (P1 potential analysis) and the product and production process development (P2-P4) up to support during series production and follow-up support after production (P5-P7). Thanks to the modular structure of the volume, individual process elements can also be audited depending on the scope to be considered.

Figure 2-1 shows the possible use of the individual process elements according to VDA 6.3 and how they relate to VDA MLA and Automotive SPICE® standards.

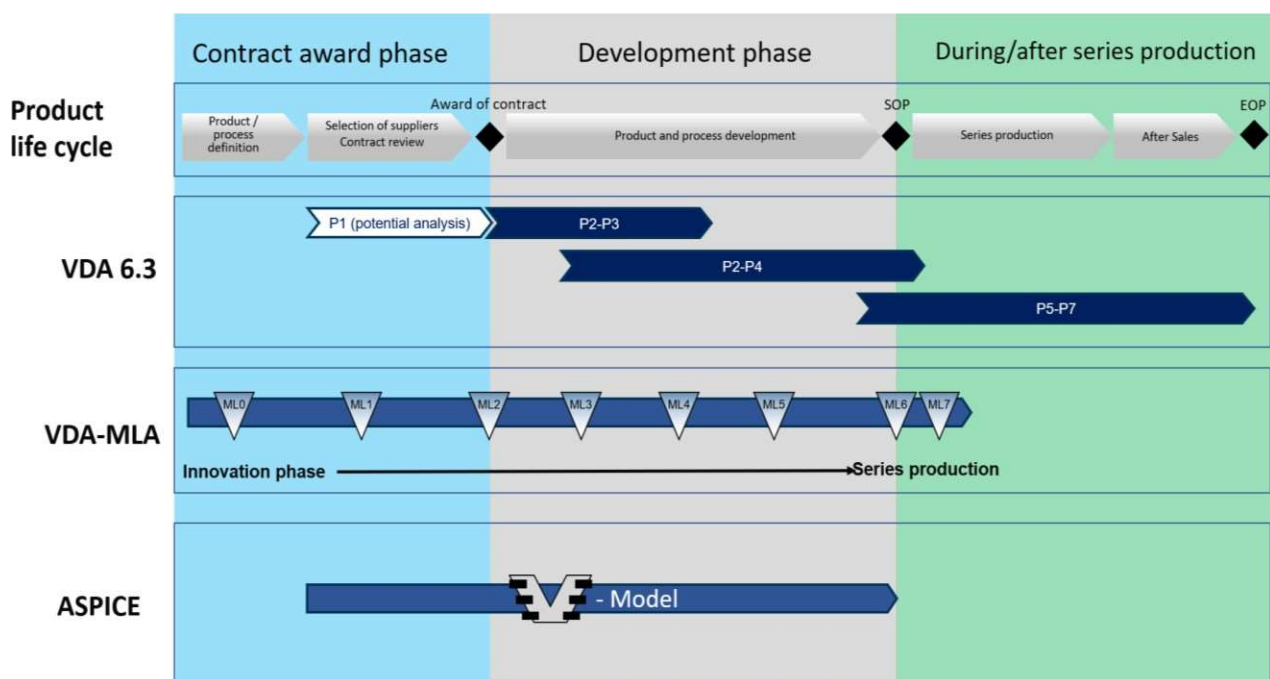


Figure 2-1: Possible use of the individual process elements

- P1: Potential analysis
- P2: Project management
- P3: Product and production process development planning
- P4: Implementation of product and production process development
- P5: Supplier management
- P6: Production process analysis
- P7: Customer care, customer satisfaction, service

For explanations regarding the potential analysis, see chapter 5.

The use of process elements P2 to P4 focuses on the phase of the product and production process development. Ideally, both process element P2 and process element P3 are used after contract award to analyze the planning activities.

Process element P4 can be used at a later time to analyze and evaluate the implementation of the planning activities in accordance with process element P3.

The breakdown of the process elements provides the opportunity to assess the planning activities as well as the implementation/realization in accordance with the requirements. From the contracting stage including SOP, the use of process elements P2 to P4 serves to identify maturity level and process risks early on.

Process elements P5 to P7 are ideally used at the time of the milestone SOP. This corresponds to maturity level ML 6 from VDA MLA. As part of series production, process elements P5 to P7 can be used to regularly monitor the series production processes and the processes after discontinuation of the series, or to support an event-based reactive process analysis.

In principle, each organization has the right to adapt the use of the process elements so as to meet their needs during product and production process development as well as production.

## 2.3 Differentiation between a potential analysis and a process audit

As can be seen from figure 2-1, a potential analysis (P1) can be carried out before a contract is awarded. The questionnaire, with a reduced scope, can be used to assess whether potential suppliers are suitable as series production suppliers. Given that these are potential suppliers, the audit must (if necessary) be based on other processes/products. However, these processes/products should be comparable to the product to be supplied. This procedure can be applied to the entire supply chain, taking into account the lead time to SOP.

## 2.4 Identification of process risks (risk analysis)

The effect of individual processes on the product is essential in the process audit. Consequently, the assessment must be made from the perspective of the relevant product risk. Potential process risks must therefore already be identified during the preparation for the audit in order to assess them adequately in the process audit itself.

A risk analysis can be carried out on the basis of the Turtle Model.

An example of the Turtle Model using process element P6 is shown below, but the model can be used for all process elements.

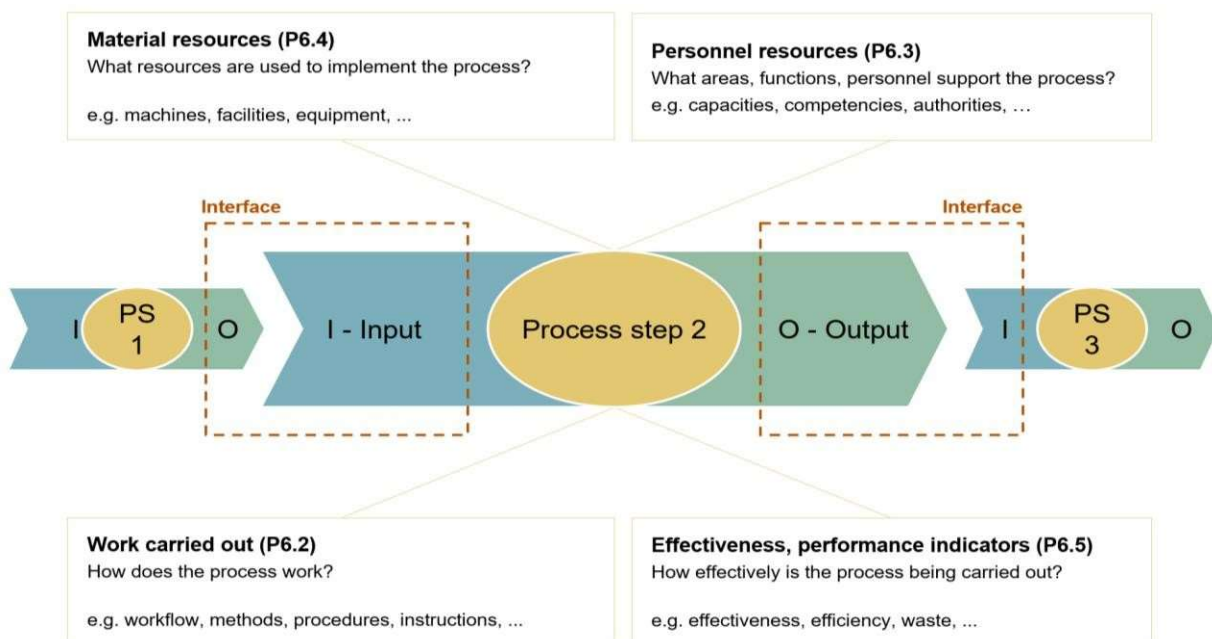


Figure 2-2: The Turtle Model



Firstly, it must be described what “input” (see questionnaire sub-element P6.1) is converted into an “output” (see questionnaire sub-element P6.6) by the process. In addition, the following questions are considered:

- How does the process work (work carried out, workflow, methods, procedures, instructions – see questionnaire sub-element P6.2)?
- What areas, functions and personnel support the process (personnel resources such as capacities, competencies, authorities, qualifications – see questionnaire sub-element P6.3)?
- Which tools are used to implement the process (material resources such as machines, tools, test equipment, facilities, other equipment – see questionnaire sub-element P6.4)?
- How effectively is the process carried out (effectiveness, performance indicators, efficiency – see process sub-element P6.5)?

As a second step, the potential risks in relation to the content of the Turtle elements are identified. The auditor as well as the audit team should make use of their process know-how to identify potential product and process risks that could affect product quality. These risks must then be analyzed and evaluated in the audit to ensure a reasonable degree of risk minimization. Based on the applied Turtle Model, it is possible to set priorities in a targeted manner.

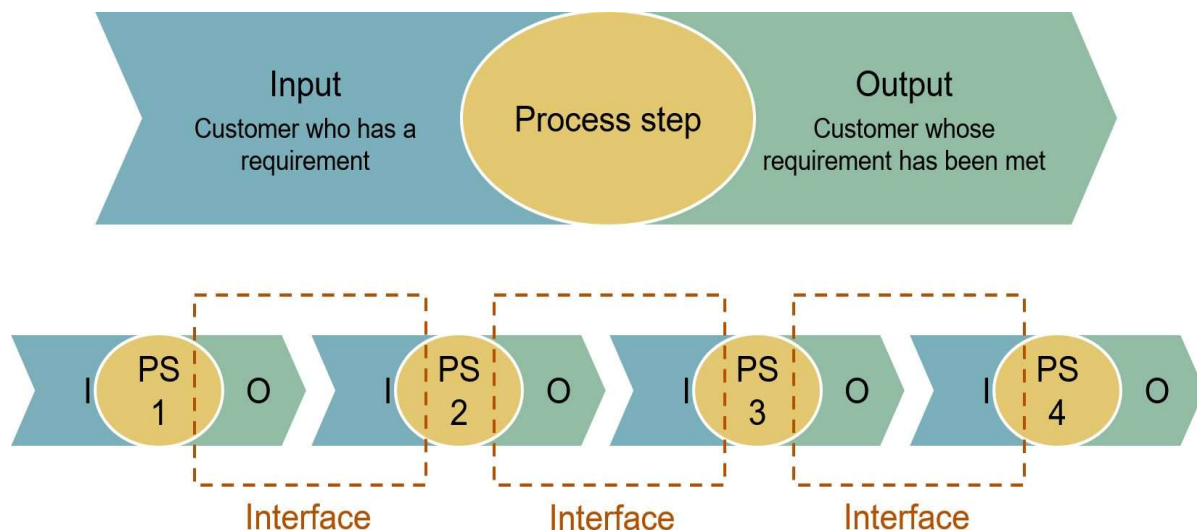


Figure 2-3: Schematic diagram of interlinked processes

The interfaces of the process steps have a significant influence on possible risks and therefore require a more in-depth analysis.

## **3 Requirements for process auditors**

### **3.1 Auditor qualification**

Auditor qualification is of vital importance when it comes to achieving the audit objectives. The quality and comparability of audit results are greatly influenced by the qualification of the auditors. In addition to the qualification criteria of each organization, the following minimum requirements, the requirements according to ISO 19011 as well as customer-specific and further external requirements should be taken into account. The organization 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 process auditors**

##### **Specialized knowledge**

- Good knowledge of quality tools and methods (e.g. VDA MLA, DoE, FMEA, FTA, PPA, SPC, SWOT, 8D Method)
- Knowledge of the relevant customer-specific requirements
- Knowledge of the relevant management system requirements (e.g. IATF 16949, DIN EN ISO 9001, VDA 6.1)
- Specific knowledge regarding the product and the process

##### **Evidence of specialized training**

- Successful participation in a VDA 6.3 training course (passing a test/obtaining a certificate of qualification)
- Knowledge of required quality tools and methods in the technology to be audited

##### **Professional experience**

A minimum of 3 years' professional experience (after 2 years' professional experience, in-house apprenticeship periods may be considered additionally), preferably in manufacturing companies within the automotive industry, including at least 1 year of experience in quality management.

### 3.1.2 Supplier auditors

#### Specialized knowledge

- Excellent knowledge of quality tools and methods (e.g. SPC, VDA Volume 5/MSA, FMEA, VDA MLA/APQP, VDA Volume 2/PPAP, 8D Method)
- If required, knowledge regarding software development processes and methods
- Auditor qualifications (negotiation, conflict management, audit procedure)
- Knowledge of the relevant customer-specific requirements
- Knowledge of the relevant management system requirements (e.g. IATF 16949, DIN EN ISO 9001, VDA 6.1)
- Specific knowledge regarding the product and the process

#### Evidence of specialized training

- Qualification as an auditor on the basis of DIN EN ISO 19011 (e.g. VDA Auditor qualification, 1st/2nd party auditor for DIN EN ISO 9001, IATF 16949, or VDA 6.1)
- Knowledge of required quality tools and methods in the technology to be audited
- Successful participation in VDA 6.3 training (successfully passing a written and an oral exam)
- Evidence of ability to apply the theoretical knowledge in practice (e.g. observation during audits/approval and witness audits)

#### Professional experience

A minimum of 5 years professional experience (after 3 years' professional experience in-house apprenticeship periods may be considered additionally), preferably in manufacturing companies within the automobile industry, including at least 2 years' experience in quality management.

### **3.1.3 Process auditors as external service providers**

External auditors are from independent, third-party organizations and carry out audits as a service for the organization.

#### **Specialized knowledge**

- Excellent knowledge of quality tools and methods (e.g. SPC, VDA Volume 5/MSA, FMEA, VDA MLA/APQP, VDA Volume 2/PPAP, 8D Method)
- If required, knowledge regarding software development processes and methods
- Auditor qualifications (negotiation, conflict management, audit procedure)
- Knowledge of the relevant customer-specific requirements
- Knowledge of the relevant management system requirements (e.g. IATF 16949, DIN EN ISO 9001, VDA 6.1)
- Specific knowledge regarding the product and the process

#### **Evidence of specialized training**

- Qualification as an auditor on the basis of DIN EN ISO 19011 (e.g. VDA Auditor qualification, 1st/2nd party auditor for DIN EN ISO 9001, IATF 16949, or VDA 6.1)
- Knowledge of required quality tools and methods in the technology to be audited
- Successfully passing an exam and obtaining a certificate within the scope of a VDA 6.3 training course
- Evidence of ability to apply the theoretical knowledge in practice (e.g. observation during audits/approval and witness audits)

#### **Professional experience**

A minimum of 5 years professional experience (after 3 years' professional experience in-house apprenticeship periods may be considered additionally), preferably in manufacturing companies within the automobile industry, including at least 2 years' experience in quality management.

## 3.2 Product/process-related knowledge of the auditors

The quality of an audit is determined to a large extent by the product/process-related knowledge of the auditors. There are various ways to gain this knowledge and to use it during an audit. This can for example be done by:

- Getting experts involved when evaluating product/process-specific aspects if the process auditor doesn't have the necessary expertise
- Auditors doing their own research prior to the audit, e.g. by consulting specialist literature, online forums and industry standards as well as knowledge databases
- Coordination with internal and external experts
- Drawing conclusions from previous audits

In order to systematically capture and expand this "expert knowledge" and to make it available to the auditors, it is recommendable to build up a knowledge database. The sources of such knowledge can for example be typical errors that have occurred or internal lessons learned. It must be ensured that information (from the customer, from the supplier, or from within the organization) remains confidential.

In addition, it should be noted that the resulting questions do not lead to additional requirements that go beyond the contractually agreed requirements.

Knowledge databases can for example be made available in the form of Wikis or process-related lists.

## 3.3 Code of conduct for auditors

- Process auditors must use their professional skills and judgment, 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 specialized methods, procedures and relevant standards. They must be familiar with the quality requirements for products as well as the specific process risks and the possible impact on the manufactured products.
- Process auditors must always 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 a lack of expertise.
- Process auditors are bound to secrecy regarding confidential information that they have acquired through their professional activities.

## **4 Notes on conducting remote audits**

Process audits according to the present VDA 6.3 audit standard are generally conducted on site.

Taking risks factors/influencing factors for auditors, auditees as well as products and processes into account, remote audits can in individual cases be carried out.

The organization conducting the audit bears overall responsibility for planning the scope/the elements of the audit and selecting the audit method, provided that the customer has not stipulated otherwise. It is recommendable to define a company-specific procedure for internal and external audits.

### **4.1 Definition of a remote audit**

“Remote audits” are defined in the ISO 19011 and can be carried out internally as well as externally.

### **4.2 Definition of a hybrid audit**

Hybrid audits are a combination of a remote audit and an on-site audit. In this regard, chapter 4.6 “Suitability of individual process elements/questions for conducting remote audits (process elements P2-P7)” must be taken into account.

### **4.3 Instructions for use**

Generally, remote audits cannot constitute a full process audit (P2-P7) in accordance with VDA 6.3. This is due to a lack of transparency during the audit process and due to technical, legal as well as data protection issues. The same applies to potential analyses (P1), which can only be carried out to a limited extent without a visit to the supplier’s premises. However, provided that risk factors / influencing factors are taken into account, hybrid audits can be considered full audits.

The “ $\frac{2}{3}$  rule” (see chapter 6.1) regarding the number of evaluation questions is still applied.

The privacy and confidentiality requirements remain the same, no matter whether a remote audit or an on-site audit is planned and conducted. In particular, taking pictures or making videos/audio recordings is not allowed unless both parties have given their express consent.

#### **4.4 Classification of the audit methods based on existing risk factors / influencing factors**

An audit may not lead to danger of life and limb (health) of the auditors/auditees because of conditions on site, which are known in advance.

When selecting a suitable audit method (on-site audit, remote audit, hybrid audit), the criticality of the product as well as the development / production process, the previous performance and aspects related to the location are particularly important. The following table provides an overview of the audit methods, including a classification of the risk factors/influencing factors.



**Table 4-1: Overview of audit methods, including a classification of the risk factors/influencing factors**

Type 1 High product/process risk	Type 2 Medium product/process risk	Type 3 Low product/process risk
High product criticality	Medium product criticality	Low product criticality
e.g. relevant to product safety, relevant to homologation, special characteristics (relevant to approval or safety)	e.g. special technical product characteristics, special characteristics (relevant to function)	-
High risks with regard to quality	Medium risks with regard to quality	Low risks with regard to quality
e.g. unknown processes, new products, high level of innovation	e.g. unknown location	e.g. products and processes are familiar, processes have already been audited
Performance	Performance	Performance
e.g. permanently negative KPIs	e.g. temporarily negative KPIs	e.g. acceptable KPIs
Maturity level	Maturity level	Maturity level
Product/process maturity level has not been reached, customer deadlines may not be met (VDA MLA red)	Product/process maturity level has not been reached (VDA MLA yellow)	Product/process maturity level has been reached (VDA MLA green)
On-site audit	Hybrid audit Part 1: Remote audit* Part 2: On-site audit	Remote audit*

\* Remote-Audits are possible as an alternative to an on-site audit

Remark: The most negative evaluation is the deciding factor when choosing the audit method.

## 4.5 Suitability of individual process elements/questions for conducting remote audits within the scope of the potential analysis (P1)

*Table 4-2: Overview of the audit questions for the potential analysis (P1) and their suitability for remote audits*

Question VDA 6.3	suitable	conditionally suitable	Question VDA 6.3	suitable	conditionally suitable
P2.1/P2.2*/P2.3 / P2.4/P2.6*	X		P6.4.1*		X
P3.2*/P3.4*	X		P6.4.2	(X)	
P4.1*	X		P6.4.3*		X
P4.3/P4.4*	X		P6.4.4		X
P5.1	X		P6.5.3*	(X)	
P5.5*/P5.6		X	P6.5.4	X	
P6.1.1/P6.1.5*		X	P6.6.2		X
P6.2.1		X	P6.6.3/P6.6.4*	(X)	
P6.2.2		(X)	P7.1	X	
P6.2.3*	X		P7.2	X	
P6.2.4*		X	P7.3*	X	
P6.3.1		(X)	P7.4*	(X)	

(x) = suitable/suitable to a limited degree, depending on product and process risks

## 4.6 Suitability of individual process elements/questions for conducting remote audits (process elements P2-P7)

*Table 4-3: Overview of the audit questions for process elements P2-P7 and their suitability for remote audits*

Questions VDA 6.3	suitable	conditionally suitable	Questions VDA 6.3	suitable	conditionally suitable
P2 - P4	X		P6.4.1*		X
P5.1/P5.2/ P5.3/P5.4*	X		P6.4.2		(X)
P5.5*		X	P6.4.3*		X
P5.6		X	P6.4.4		X
P5.7	X		P6.4.5		X
P6.1.1*		X	P6.5.1	X	
P6.1.2		X	P6.5.2		(X)
P6.1.3		X	P6.5.3*		(X)
P6.1.4		X	P6.5.4	X	
P6.1.5*		(X)	P6.6.1		X
P6.2.1		X	P6.6.2		X
P6.2.2		(X)	P6.6.3		(X)
P6.2.3*		(X)	P6.6.4*		(X)
P6.2.4*		X	P7.1	X	
P6.2.5		X	P7.2	X	
P6.3.1		(X)	P7.3*	X	
P6.3.2		(X)	P7.4*		(X)
P6.3.3		(X)	P7.5	X	

(x) = suitable/suitable to a limited degree, depending on product and process risks

## **5 Potential analysis (P1)**

### **5.1 Definition of a potential analysis**

A potential analysis is used to evaluate potential new suppliers. For existing suppliers, the potential analysis can be used in case of new locations, an introduction of new technologies or new products.

The supplier's potential to meet the requirements regarding the requested products and corresponding processes is assessed.

The analysis takes into account the supplier's experience and skills regarding the development and production of the scope of products requested, as well as their ability to fulfill customer-specific requirements for product and process implementation.

The assessment is based on existing processes for comparable products.

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

A potential analysis can also be carried out independently of a project in case of supplier changes or relocations.

In the event of relocations (components in series production, completed product development phase), the assessment is only based on the questions from process elements P2 to P4 related to the process development and P2 for the relocation project.

### **5.2 Prerequisites**

Given that no contractual relationship exists between the customer and the potential new suppliers during the inquiry and quotation stages, an agreement should be 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, an essential way to obtain information is to ask the prospective supplier to provide a self-assessment.

## 5.4 The process of conducting a potential analysis

The following diagram illustrates the process of conducting a potential analysis (P1). The evaluation questions in P1 are selected from process elements P2 to P7. An overview of the questions is provided in section 7.1.

The analysis of the supplier's processes is based on a comparable product/production process using the P1 questionnaire and, if required, knowledge databases relating to the scope of delivery under consideration.

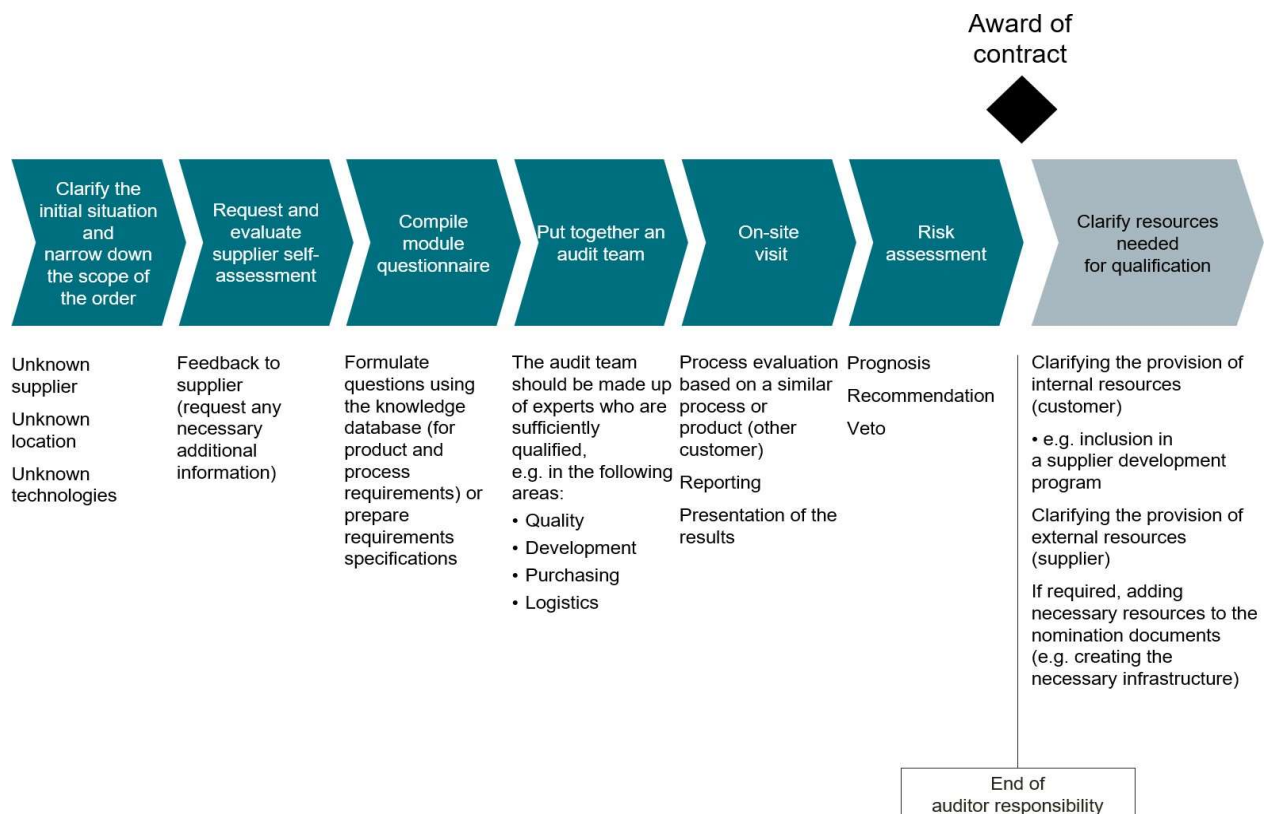


Figure 5-1: Process of conducting a potential analysis




## 5.5 Evaluation of a potential analysis

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”.

Each question is evaluated in terms of fulfillment of the respective requirement and the risk involved.




If a question is not evaluated (shown as n. e.), the reason for this must be stated. A maximum of 3 questions may be marked n. e. Otherwise, the results may no longer be comparable.

The assessment result is based on the traffic light system (“red”, “yellow” or “green”).

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 findings and the relevant evidence must be documented.

The overall assessment result of the potential analysis is calculated from the number of questions rated as red/yellow/green:

Classification		Evaluation based on questionnaire	
		Yellow	Red
Barred supplier		more than 12	one or more
Conditionally approved supplier		max. 12	none
Approved supplier		max. 6	none

A positive potential analysis result (“green”, “yellow”) does not necessarily lead to a contract being awarded.

A negative potential analysis result (“red”) excludes a contract award.

## Interpretation of results

**Green** = Fully approved supplier

The supplier has the potential to meet the customer's requirements to the extent required and may be considered for awarding a contract.

The customer can award a contract for the project, component or product group without restriction.

**Yellow** = conditionally approved supplier

With regard to the scope of products requested, a contract can only be awarded under certain conditions. In some cases, the supplier needs support from the customer in order to meet the requirements of the project. Under certain conditions, a limited approval for contract award may be given, e.g.:

- Restriction to a defined quantity (small-scale production)
- Restriction to a product/process with limited complexity
- Restriction to only a part of the requested scope of supply
- The supplier is included in a supplier development program

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

**Red** = barred supplier

It is not possible to award a contract covering the project, component or product group in question.

Note: In individual cases (e.g. if there is no alternative supplier), the management board can make the decision to award a contract. In this case, qualification measures must be initiated, and safeguarding measures must be initiated and implemented.

## **5.6 Follow-up activities after contract award**

The results of the potential analysis are used as input when planning the selection or implementation of methods (e.g. process audit, VDA MLA).

Once a contract has been awarded, the implementation of measures according to the action plan is mandatory.

The quality capability can only be validated (in terms of a release for series production) by means of a PPA process covering the customer-specific scope of delivery concerned. To achieve this, a process audit can be conducted within the scope of a process release.



## 6 Evaluating a process audit for material products

### 6.1 Evaluation of the individual questions

Each question is evaluated in terms of fulfillment of the respective requirements and the risk involved. For each question, 0, 4, 6, 8 or 10 points can be awarded. The number of points awarded is based on proven fulfillment of the requirements as well as the risk assessment regarding the product and the process.

Points	Assessment of compliance with the requirements
10	The requirements are fully met; conformity is ensured
8	The requirements are mainly++ met; minor non-conformity
6	The requirements are partially met; significant non-conformity
4	The requirements are inadequately met; major non-conformity
0	The requirements are not met

++) The term “mainly” means that there are only individual cases in which fulfillment of the requirements could not be proven, and there are no special risks.

The following table serves as a guideline for the appropriate allocation of points when evaluating the questions:

Points			
	Perspective of the process/process step	Perspective of the product	Perspective of the customer
10	Technical requirements and specifications for the process are fulfilled	No product defects, the product meets the technical standards	Requirements are completely met
8	Minor discrepancies in the process which do not affect compliance with the customer specifications or have an effect on the following process steps	Some product defects which do not influence the function, use or further process steps	Customer requirement is only met to a limited degree
6	The process does not always meet the defined requirements. This has an impact on the following process steps	Product non-conformities do not affect the function; however, the failure has a negative impact on the use of the product or on further process steps	Requirements are partially met; complaints are possible
4	The process does not meet the defined requirements. This has a significant impact on the customer or on the following process steps	Product non-conformities have an impact on the function. The failure leads to usage restrictions and has a significant impact on the following process steps	Requirements insufficiently met; customer is dissatisfied
0	The process is not suitable for ensuring compliance with the defined requirements	Product non-conformities, no function, the use of the product is considerably limited, further process steps are not possible	Not acceptable from the customer's point of view

If there are several findings for the assessment of a single question, the individual assessment which is associated with the highest risk is decisive for the assessment of the respective question.

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

If a question is not evaluated (n. e.), the reason for this must be stated.

At least  $\frac{2}{3}$  of the questions for each audited process element, sub-element or process step must be evaluated. In order to ensure comparability, the entire list of questions from the VDA 6.3 process element should be covered in full.

If corrective actions from previous audits are not implemented, this can also be regarded as a case of non-conformity, e.g. in the “cause analysis”, “implementation of measures”, “meeting customer requirements” questions.

### **Questions associated with a special product and process risk (\*-question)**

In the process elements, questions associated with special risks product and process risks are marked with an asterisk (\*-question). These special risks are already taken into account in the downgrading rules (see section 6.3). The evaluation is carried out in the same manner as for the remaining questions. Consequently, \*-questions are not evaluated more harshly than other questions.

## **6.2 Detailed evaluation and downgrading rules**

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

### **Process element**

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

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

### Exception: If there is more than one evaluation for a question

In process elements P3, P4 (separate evaluation of product and process development) and P6 (individual evaluation of each process step), there may be several evaluations for a single question. 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 replace the “**points awarded**” when calculating the level of compliance of a process element.

For each question, the total number “**possible points**” is 10 – regardless of the number of results per question.

### Sub-elements of P6

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

- E<sub>U1</sub> Process input
- E<sub>U2</sub> Work carried out
- E<sub>U3</sub> Personnel resources
- E<sub>U4</sub> Material resources
- E<sub>U5</sub> Efficiency
- E<sub>U6</sub> Process output

The evaluation of the sub-elements is carried out in the same manner as for the process elements and the exceptional case: more than one evaluation for a question.

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

### Individual process steps

The questions from P6 are used for the evaluation of the individual process steps. All questions from P6 can be answered for each process step. The compliance level E<sub>n</sub> of each process step can be calculated as follows:

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

### 6.3 Overall level of compliance and downgrading rules

Process elements for material products	
Project management (P2)	E <sub>P2</sub>
Planning of product and process development (P3)	E <sub>P3</sub>
Implementation of product and process development (P4)	E <sub>P4</sub>
Supplier management (P5)	E <sub>P5</sub>
Production process analysis (P6)	E <sub>P6</sub>
Customer care, customer satisfaction, service (P7)	E <sub>P7</sub>

The overall compliance level E<sub>G</sub> for the process audit is calculated as follows:

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

For process elements P3 and P4, product development (E<sub>P3</sub> product) and process development (E<sub>P3</sub> process) can be evaluated separately. To calculate the overall result for 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 evaluation of product and process development).

If during a specific audit, individual process elements from the overall questionnaire are evaluated, the result is calculated only on the basis of the evaluated process elements. It must be specified in the audit report which process elements have been used in the evaluation.

### Example P5/P6/P7

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

$$E_{G(P5P6P7)} [\%] = \frac{\text{Total **points awarded** for all evaluated questions from P5, P6 and P7 (E}_{P5}, E_{P6} \text{ and } E_{P7})}{\text{Total possible points for these questions}}$$

### Example P4

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

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

The designations  $E_{G(P5P6P7)}$  and  $E_{G(P4)}$  are used to easily identify the process elements evaluated.

### Overall level of compliance

The overall result is rounded to the nearest percentage point.

Classification	Level of compliance $E_G$ or $E_{G(P_n)}$ [%]	Description of the classification
<b>A</b>	$E_G \text{ or } E_{G(P_n)} \geq 90$	able to meet quality requirements
<b>B</b>	$80 \leq E_G \text{ or } E_{G(P_n)} < 90$	able to meet quality requirements to some extent
<b>C</b>	$E_G \text{ or } E_{G(P_n)} < 80$	not able to meet quality requirements

## Level of compliance for partial audits

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

## Downgrading rules

Results from the process elements, sub-elements of P6 or process steps have to be considered in the following downgrading rules and documented in the audit report.

### Reasons for downgrading from A to B even though the level of compliance 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 as having a level of compliance  $E_P$  or  $E_n < 80\%$
- A level of compliance  $E_{U1}$  to  $E_{U6}$  in one of the sub-elements of P6 is  $< 80\%$
- 4 points are awarded for at least one \*-question
- 0 points are awarded for at least one question in the process audit

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

- At least one process element (P2 to P7) or process step ( $E_1$  bis  $E_n$ ) is evaluated as having a level of compliance  $E_P$  oder  $E_n < 70\%$ .
- 0 points are awarded for at least one \*-question

When applying the downgrading rules (process element, sub-element or process steps), the individually calculated results  $E_{Pn}$ ,  $E_{Un}$  and  $E_n$  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 on the basis of individual process steps. Car manufacturers mainly use this procedure to classify the suppliers' quality capability. The evaluation of the suppliers' quality capability is thus restricted to product groups. This forms part of the preconditions for future contract awards.

Product group	Possible process steps			
Pressed and stamped parts	Stamping, drawing, forming	Galvanic plating	Painting	
Plastic injection moldings	Plastic molding		Painting	
Control devices	Fitting components	Soldering	Assembling	Functional check

**Note:** To evaluate process steps, additional process requirements should be generated from the organization's own knowledge databases.

In the evaluation matrix, the relevant process steps are allocated to the product group being evaluated.

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

$$E_{G(PG_n)} [\%] = \frac{\text{Total **points awarded** for the questions for the evaluated process elements } P_n \text{ (for each question in P6, the average value per question from the process steps for this PG is calculated}^{++})}{\text{Total **possible points** for the questions for the evaluated process elements } (^{++})}$$

<sup>++</sup> for explanations of "points awarded" and "possible points" see section: 6.2: Exception.

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 forms the basis of the auditor's work. The auditor selects the relevant process elements for the audit depending on the phase of the product life cycle (see section 2.2). Additional specific requirements can be added to the questions depending on the product/process risks identified.

The questions can be used for processes for material products and products with integrated (embedded) software as well as for auxiliary and process materials.

### Structure of the questionnaire

The questions for the process elements are structured as follows:

- Questions
- Minimum requirements relevant for assessment
- Examples for implementation

The “examples for implementation” provide a selection of potential applications. They should be selected on a product/process-specific basis and expanded, analyzed and evaluated when necessary.

The evaluation is carried out based on the questions in the “Minimum requirements relevant for assessment” list.

For the auditor, the audit consists of two mutually independent activities (see figure 6.1):

1. The auditor asks the auditee open questions to assess compliance with the requirements. The risks identified in the preparations for and during the audit are taken into account.
2. Based on the audit findings, the auditor uses closed questions to assess compliance with the requirements.

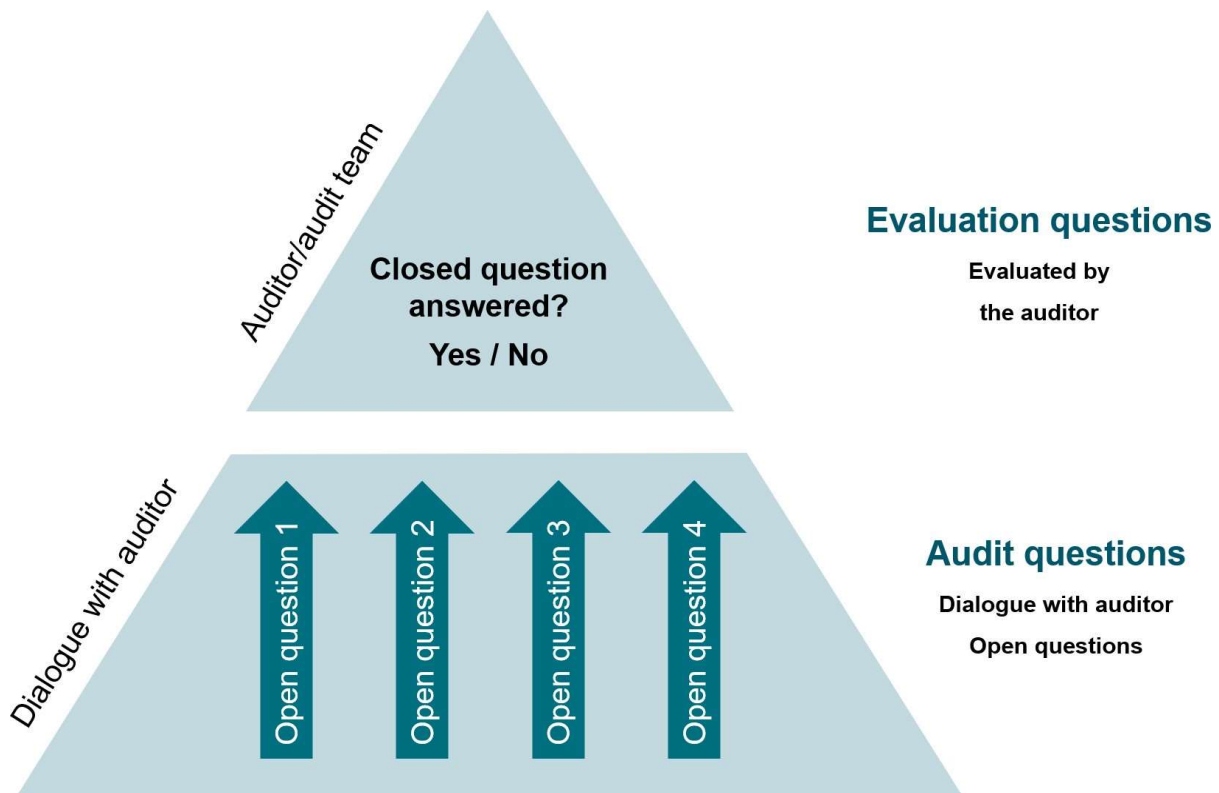


Figure 6-1: Audit pyramid

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 audited organization.

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

In addition to the VDA 6.3 questions listed in this volume, it is recommended that a knowledge database be created to store information about the risks associated with individual products and processes. The experience stored in the knowledge databases can be used in addition to the requirements relevant for the evaluation.

Based on the risk analysis described in section 2.4, identified risks must be checked against the questionnaire and integrated into the applicable questions.

## 6.6 Rules on conducting an audit

An audit can be stopped at the auditor's discretion, for example in the following cases:

- Refusal to disclose necessary information during the audit
- Obvious violations of the law
- Actively interfering with the auditor's work or putting the auditor in danger
- Refusal to grant access to areas that are relevant for the audit, despite prior agreement
- Insufficient preparation of the audit on the part of the organization
- Providing evidently false statements

The reason for stopping the audit must be stated. Audit findings obtained up to the point the audit was interrupted must be documented.

The organization conducting the audit decides whether a new audit should be carried out.

## 6.7 Repeat audit

It must be specified in which cases a repeat audit is necessary. Reasons for conducting a repeat audit can include, for example:

- A specified level of compliance is not reached
- Critical process that is associated with risks
- The requirements according to one or more \*-questions are not met (0 points)
- Potential analysis results in "red light"

The repeat audit must be carried out within a specified time frame. Within this period of time, the audited organization must initiate measures to effectively rectify the shortcomings.

The scope of the repeat audit must be the same as for the previous audit. Reducing the scope of the audit to a mere test of the effectiveness of the implemented measures is not permissible.

## 7 Questionnaire

### 7.1 Overview of questionnaire

		Potential analysis**
<b>P2</b>	<b>Project management</b>	
<b>2.1</b>	Has a project management strategy (including a project organization) been established?	<b>X</b>
<b>2.2*</b>	Are all resources required for project implementation planned and available, and are changes reported?	<b>X</b>
<b>2.3</b>	Is there a project plan that has been agreed upon with the customer?	<b>X</b>
<b>2.4</b>	Are the quality-related project activities being implemented and monitored for compliance?	<b>X</b>
<b>2.5</b>	Are the procurement activities of the project implemented and monitored for compliance?	
<b>2.6*</b>	Is change management within the project ensured by the project organization?	<b>X</b>

<b>P3</b>	<b>Planning product and process development</b>	
<b>3.1</b>	Are the specific product and process requirements available?	<b>X</b>
<b>3.2*</b>	Has the feasibility been comprehensively evaluated according to the identified product and process requirements?	<b>X</b>
<b>3.3</b>	Are the activities for product and process development planned in detail?	
<b>3.4*</b>	Have the procurement activities been planned, and are they monitored for compliance?	<b>X</b>
<b>3.5</b>	Have the necessary resources been taken into account for product and process development planning?	
<b>3.6</b>	Have the activities related to customer care/customer satisfaction/customer service and field failure analysis been planned?	

		Potential analysis**
<b>P4</b>	<b>Implementation of product and process development</b>	
<b>4.1*</b>	Are the activities from the product and process development plans implemented?	<b>X</b>
<b>4.2</b>	Are personnel resources available and are the personnel qualified to ensure the start of series production?	
<b>4.3</b>	Are the material resources available and suitable to ensure the start of series production?	<b>X</b>
<b>4.4*</b>	Are the required approvals and releases for product and process development available?	<b>X</b>
<b>4.5</b>	Have the planned procurement activities been implemented?	
<b>4.6</b>	Have the manufacturing and inspection specifications been derived from product and process development and are they implemented?	
<b>4.7</b>	Is a performance test carried out under series conditions for the series release?	
<b>4.8</b>	Have the processes for ensuring customer care/customer satisfaction/customer service as well as field failure analysis been established?	
<b>4.9</b>	Is there a controlled method for the project handover from development to series production?	

<b>P5</b>	<b>Supplier management</b>	
<b>5.1</b>	Are only approved suppliers used who are able to meet the quality requirements?	<b>X</b>
<b>5.2</b>	Are the customer requirements taken into account in the supply chain?	
<b>5.3</b>	Have target agreements for supplier performance been agreed upon and implemented?	
<b>5.4*</b>	Are the necessary releases available for purchased products and services?	

		Potential analysis**
<b>5.5*</b>	Is it ensured that the purchased products and services are of the agreed-upon quality?	<b>X</b>
<b>5.6</b>	Are incoming goods delivered and stored appropriately?	<b>X</b>
<b>5.7</b>	Are personnel qualified for their respective tasks and are responsibilities defined?	

<b>P6</b>	<b>Production process analysis</b>	
<b>6.1</b>	<b>What goes into the process?</b> <b>Process input</b>	
<b>6.1.1*</b>	Has the project been handed over from development to series production and is a reliable start guaranteed?	<b>X</b>
<b>6.1.2</b>	Are the necessary quantities/production batch sizes of primary materials available at the agreed upon time and at the correct storage location/work-station?	
<b>6.1.3</b>	Are primary materials stored appropriately and are the means of transport/packaging facilities suitable for the special characteristics of the incoming materials?	
<b>6.1.4</b>	Are the necessary identifications/records/releases available and allocated appropriately to the primary materials?	
<b>6.1.5*</b>	Are changes made to the product or process during series production tracked and documented?	<b>X</b>
<b>6.2</b>	<b>Are all production processes controlled?</b> <b>Process management</b>	
<b>6.2.1</b>	Are the requirements specified in the production control plan complete and are they fulfilled effectively?	<b>X</b>
<b>6.2.2</b>	Does a repeat release of production processes take place?	<b>X</b>
<b>6.2.3*</b>	Are special characteristics managed in production?	<b>X</b>
<b>6.2.4*</b>	Are non-released and/or defective parts managed?	<b>X</b>

		Potential analysis**
<b>6.2.5</b>	Is the flow of materials and parts secured against mixing/wrong items?	
<b>6.3</b>	<b>What functions support the process?</b> <b>Personnel resources</b>	
<b>6.3.1</b>	Are the employees able to fulfill their given tasks?	<b>X</b>
<b>6.3.2</b>	Do the employees know their responsibilities and authorizations regarding the monitoring of product and process quality?	<b>X</b>
<b>6.3.3</b>	Are the necessary personnel resources available?	
<b>6.4</b>	<b>What equipment is used to implement the process?</b> <b>Material resources</b>	
<b>6.4.1*</b>	Is the manufacturing equipment suitable to meet the customer's product-specific requirements?	<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 fulfillment of quality requirements be effectively monitored with the measurement and inspection equipment in use?	<b>X</b>
<b>6.4.4</b>	Do the work and inspection stations fulfill the requirements?	<b>X</b>
<b>6.4.5</b>	Are tools, equipment and inspection equipment stored properly?	
<b>6.5</b>	<b>How effectively is the process being carried out?</b> <b>Effectiveness and efficiency</b>	
<b>6.5.1</b>	Have targets been set for the manufacturing process?	
<b>6.5.2</b>	Is quality and process data collected in a way that allows for analysis?	
<b>6.5.3*</b>	In case of non-compliance with product and process requirements, are the causes analyzed and the corrective actions checked for effectiveness?	<b>X</b>
<b>6.5.4</b>	Are processes and products audited regularly?	<b>X</b>

		Potential analysis**
<b>6.6</b>	<b>What should the process accomplish? Process result (output)</b>	
<b>6.6.1</b>	Do the quantities/production batch sizes meet the needs and are they systematically directed to the next process step?	
<b>6.6.2</b>	Are products/components stored in an appropriate manner and are the means of transport/packaging facilities suitable for the special characteristics of the products/components?	<b>X</b>
<b>6.6.3</b>	Are the necessary records/releases retained?	<b>X</b>
<b>6.6.4*</b>	Are customer requirements met upon 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 the QM system, the product and the 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 ensured?	<b>X</b>
<b>7.4*</b>	If quality requirements are not met or if there are complaints, are failure analyses carried out and are corrective actions implemented effectively?	<b>X</b>
<b>7.5</b>	Are personnel qualified for their respective 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 (P1)



## 7.2 Project management (P2)

Process element P2: Project management	
P2.1 Has a project management strategy (including a project organization) been established?	
Minimum requirements relevant for assessment	Examples for implementation
<p>There is a project management process.</p> <p>An interdisciplinary project organization is specified.</p> <p>The responsibilities and authorizations of the project leader and team members are defined.</p> <p>The customer and the supplier have been informed who the contact persons are.</p> <p>The project organization and the associated escalation management meet the customer requirements.</p> <p>Escalation criteria (including escalation in supplier management) have been specified, and measures are derived in case of non-compliance with the specifications.</p> <p>Roles are defined in accordance with the development method or collaboration model (agile or not agile).</p> <p>Experiences (especially lessons learned) from ongoing or previous projects with a comparable scope of products are taken into account.</p> <p>Project risks have been identified, assessed, and have been mitigated by means of appropriate measures.</p>	<ul style="list-style-type: none"> <li>• The roles, tasks, competences and responsibilities of the project manager/technical experts have been defined</li> <li>• Project interfaces in multi-site projects</li> <li>• Organizational chart for the project</li> <li>• Composition of the project team</li> <li>• Evidence of qualifications</li> <li>• Special customer requirements regarding project management</li> <li>• In case of an agile approach: Definition of the escalation mechanism (e.g. the Scrum Master escalates to the Product Owner)</li> <li>• Contact persons/decision-makers in the escalation process have been defined</li> <li>• Records of milestone assessments, including measures</li> </ul>

<b>P2.2* Are all resources required for project implementation planned and available, and are changes reported?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The resource planning takes the customer requirements into account and is based on the project agreement.</p> <p>Resource planning for project team members has been established and implemented. The staff workload is taken into account.</p> <p>A review and (where necessary) an adjustment of the resource planning is carried out when changes occur (deadlines, scope of development performance etc.). 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 to the project organization (interface with customer) are reported.</p> <p>The resources for software-specific activities have been planned.</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, inspection and laboratory facilities)</li> <li>• Resource planning by the Scrum Master</li> <li>• Resource planning for integration and tests</li> </ul>

P2.3 Has project management been implemented and is there a project plan that has been agreed upon with the customer?	
Minimum requirements relevant for assessment	Examples for implementation
<p>The project plan meets the specific customer requirements.</p> <p>All internal and customer defined milestones are fully incorporated in the project plan.</p> <p>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 required maturity level is reached.</p> <p>If a statutory authorization procedure for a product is specifically required, the duration of this procedure is included in the project plan.</p> <p>In-house communication is ensured when changes are made to the project plan. Changes to the project plan which affect the customer are coordinated with the customer.</p> <p>Project changes that have an impact on the overall schedule have been taken in account in the escalation process (risk management).</p> <p>The critical path is generated from the project plan and takes account of the associated delivery items.</p> <p>Quality-related project activities as well as procurement activities must be part of the project plan. A separate, detailed plan can be referred to in the project plan.</p> <p>The plans must take prototypes and pre-launch parts into account.</p> <p>The scope of software required at the respective times has been planned.</p>	<ul style="list-style-type: none"> <li>• Project plan with milestones</li> <li>• Specific customer requirements regarding technologies and/or product groups</li> <li>• Customer project plan</li> <li>• Customer deadlines</li> <li>• Customer milestones</li> <li>• Targets set by the customer (measurements within the individual milestones)</li> <li>• Milestone assessments (reviews)</li> <li>• QM plan (e.g. from VDA MLA or APQP)</li> <li>• Country-specific certification requirements (ECE, SAE, DOT, CCC, INMETRO, KBA etc.)</li> <li>• Legal and regulatory approval processes relating to critical systems (environmental requirements, among other things)</li> <li>• Release planning regarding basic functions and milestones <ul style="list-style-type: none"> <li>• Software project plan</li> <li>• Software milestones</li> <li>• Basic Rollout Plan (BROP)</li> <li>• Feature Rollout Plan (FROP)</li> </ul> </li> <li>• Planning of the ASPICE assessment, including the definition of levels and the scope in accordance with the agreed customer requirements</li> </ul>

<b>P2.4 Have the quality-related project activities been planned, and are they monitored for compliance?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The quality-related project activities meet the specific customer requirements.</p> <p>Both product and process assurance measures are part of the quality-related activities.</p> <p>Verification and validation of the product and process requirements are included in the planning.</p> <p>The planning also addresses critical components and supply items (internal and external suppliers).</p> <p>The planning is regularly monitored for compliance and for target achievement.</p> <p>The quality-related activities relevant to software have been taken into account.</p>	<ul style="list-style-type: none"> <li>• Project plan</li> <li>• Customer milestones</li> <li>• Customer requirements with regard to quality plans</li> <li>• Quality plan (audits, reviews and VDA MLA)</li> <li>• Customer specifications</li> <li>• Specific software milestones</li> <li>• Reviews, e.g. of code and models</li> <li>• Test case creation and validation (verification?)</li> <li>• KPIs relevant to software (metrics, test coverage, level of test automation, rate of error reduction etc.)</li> <li>• Software-specific assessment planning and assessment levels</li> <li>• SW-Q release</li> <li>• Risk assessments (special characteristics, cyber security)</li> </ul>

<b>P2.5 Are the procurement activities of the project included in the project planning?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The supplier selection process and the target dates for contract awards are contained in the project plan for all types of suppliers.</p> <p>The suppliers of plants, machines, tools, measuring and inspection systems as well as the service providers are integrated in the planning.</p>	<ul style="list-style-type: none"> <li>• Project plan</li> <li>• Milestone plan</li> <li>• Make-or-buy decision</li> <li>• Service providers (e.g. development, laboratories, maintenance, software)</li> </ul>

<p>The deadlines for contract awards, supplier milestones and release are included in the planning and are coordinated so as to match the overall schedule.</p>	
<p><b>P2.6* Is change management within the project ensured by the project organization?</b></p>	
<p><b>Minimum requirements relevant for assessment</b></p>	<p><b>Examples for implementation</b></p>
<p>Change management within the project meets the customer's specific requirements.</p> <p>Changes (initiated by the supplier, internally or by the customer) must be evaluated. If necessary, the project plan must be adapted. This evaluation must include the risk assessment for product quality as well as the deadlines.</p> <p>Suppliers are actively involved in change management.</p> <p>It must be ensured that specified design freezes are observed. Exceptions must be agreed upon between the customer and the supplier and must be documented.</p> <p>All changes must be documented.</p> <p>The persons responsible for change management are defined for the customer, internally and to suppliers.</p>	<ul style="list-style-type: none"> <li>• Change management</li> <li>• Process description</li> <li>• Schedules</li> <li>• Change forms</li> <li>• Change history for the product and the process</li> <li>• Evaluation of changes</li> <li>• Approvals of changes</li> <li>• Software: Change request, change management</li> <li>• Change due to fault elimination, changes to the architecture and the requirements</li> </ul>

## 7.3 Product and process development planning (P3)

Process element P3: Product and process development planning	
P3.1 Have the product/process-specific requirements been specified?	
Minimum requirements relevant for assessment	Examples for implementation
<p>The functional and non-functional requirements, including the customer's requirements as well as statutory and regulatory requirements that apply to the product (and software) to be developed as well as to the production process have to be determined.</p> <p>The organization must identify and take into account the product and process requirements known from previous experience.</p> <p>Special characteristics must be identified on the basis of the organization's own requirements, customer requirements, statutory and regulatory requirements, manufacturing technology and characteristics that arise from the purpose/use of the product.</p> <p>Customer requirements regarding the selection of suppliers or primary materials must be documented.</p> <p>In case of suppliers appointed by the customer (directed suppliers), interface agreements are available.</p> <p>The customer's requirements regarding the documentation and release of Free and Open Source Software (FOSS) must be taken into account.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Requirements regarding the interfaces between hardware and software (products with integrated/embedded software)</li> <li>• Inquiry and contract documents, including requirement specifications</li> <li>• Traceability concept</li> <li>• Ordering and inspection requirements</li> <li>• Catalog of characteristics/reference samples</li> <li>• Product/process characteristics, including characteristics regarding functional safety</li> <li>• Purchasing conditions</li> <li>• Logistics requirements (packaging, JIT, JIS, on consignment)</li> <li>• Quality agreements, including QM-specific requirements</li> <li>• Schedules</li> <li>• Portals/information platforms on the Internet</li> <li>• Lessons Learned</li> <li>• Environmental aspects, recycling requirements</li> <li>• Capability requirements</li> <li>• Requirements regarding release</li> </ul> <p><b>Product development</b></p> <ul style="list-style-type: none"> <li>• Specifications, drawings</li> </ul>

## Process element P3: Product and process development planning

### P3.1 Have the product/process-specific requirements been specified?

Minimum requirements relevant for assessment	Examples for implementation
	<ul style="list-style-type: none"><li>• Software specifications</li></ul> <b>Process development</b> <ul style="list-style-type: none"><li>• Requirements regarding facilities, tools and inspection equipment as well as workplace and test station layout</li><li>• Requirements regarding handling, packaging, storage and identification</li><li>• Requirements for identification, configuration and ensuring correct installation of the software</li></ul>

<b>P3.2* Has the feasibility been comprehensively evaluated according to the product and process requirements?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>An interdisciplinary procedure for evaluating feasibility (including potential production locations) must be used.</p> <p>All determined product/process-specific requirements (technology, function, quality, logistics, software, etc.) must be checked for feasibility.</p> <p>Material and personnel resources must be considered in the feasibility study.</p> <p>The results of the feasibility study must be available before tendering.</p> <p>The feasibility of critical purchased parts must be ensured.</p> <p>If customer requirements cannot be fulfilled, the customer must be notified or non-conformities approved by the customer prior to the contract being awarded.</p> <p>A flash concept is available for programming at the plant and updates in the field (if required).</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Customer requirements and standards</li> <li>• Schedules, time frame</li> <li>• Regulations, standards, legislation, environmental impact</li> <li>• Requirements from product liability</li> <li>• Traceability concept</li> <li>• Buildings, premises</li> <li>• CAM, CAQ</li> <li>• Product/process innovation</li> <li>• Interdisciplinary feasibility analysis (for example, sales, development, purchasing, production planning, production, QM planning, logistics)</li> </ul> <p><b>Product development</b></p> <ul style="list-style-type: none"> <li>• Laboratory/test equipment</li> <li>• Parallel software development / prototyping</li> </ul> <p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Capacity monitoring</li> <li>• Availability of primary materials</li> <li>• Manufacturing options, manufacturing locations</li> <li>• Equipment, tools, production/inspection equipment, auxiliary materials, laboratory facilities, means of transport, containers, storage</li> </ul>



<b>P3.2* Has the feasibility been comprehensively evaluated according to the product and process requirements?</b>	
	<ul style="list-style-type: none"> <li>• Variant management, flash concepts</li> </ul>

<b>P3.3 Are the activities for product and process development planned in detail?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>When planning the product and process development, the level of detail depends on the component, software and complexity of the process.</p> <p>In the development phase, suitable risk mitigation measures must be used for product and process development assurance, so that the product meets the required operational conditions when goes into series production (function, reliability, safety).</p> <p>In case of product and process innovations, there is a fallback concept.</p> <p>Risk analyses are part of the planning.</p> <p>The inspection planning concept includes the requirements regarding series production, product audits and requalification.</p> <p>The schedules contain all information regarding product and process development (including deadlines and duration, milestones according to the overall project plan, performance testing, PPA date, software standards...).</p> <p>The methods and evidence for development release meet the customer requirements and clarification must be sought with the customer if non-conformities occur.</p> <p>The software engineering process has been specified and meets the customer's requirements.</p> <p>The software development progress must also be taken into consideration in the planning, such that the required software functions are tested and available at the required point in time.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Overall project plan including all deadlines</li> <li>• Customer requirements</li> <li>• Customer schedule</li> <li>• Lead times</li> <li>• Risk mitigation measures (including backup strategy and cybersecurity)</li> <li>• (QFD, FMEA, HARA etc.)</li> <li>• Prototype/pre-launch planning</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 product and process development, including packaging</li> <li>• Spare parts concept</li> </ul> <p><b>Product development</b></p> <ul style="list-style-type: none"> <li>• Reliability testing, functional testing, trial plan</li> </ul>

**P3.3 Are the activities for product and process development planned in detail?**

- Deadlines for development phase samples
  - Requirement analysis
  - Architecture design
  - Implementation
  - Test
  - Artifacts of agile project management (product backlog, sprint backlog, increment, definition of ready, definition of done, sprint planning, DevOps)
  - Release planning
- Process development**
- Tool deadlines (parts from production tools),
  - Inspection planning, inspection equipment planning, maintenance planning including spare parts management

<b>P3.4* Have the procurement activities been planned, and are they monitored for compliance?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>Selection criteria are defined to ensure that the selected suppliers are able to meet the quality requirements.</p> <p>A potential analysis has been planned or has been carried out for new suppliers not appointed by the customer, new locations or new technologies.</p> <p>The scope of the planning activities after contract award is based on the risk classification of the purchased products/services.</p> <p>There are clear rules for the communication of customer requirements along the supply chain.</p> <p>Customer requirements also include requirements arising from the drawing, the parts, software or component specifications, the delivery quantity, the deadlines, QM agreements and applicable regulations.</p> <p>Agreements regarding suppliers appointed by the customer (directed suppliers) are defined on a project-specific basis.</p> <p>The activities in terms of purchasing plants, machines, tools, measuring and inspection equipment as well as services have been determined and planned (selection, contract award, verification and approval).</p> <p>The progress of the supplier activities (such as contract awards, deadlines, customer and supplier milestones) is monitored.</p>	<p><b>Product / process development</b></p> <ul style="list-style-type: none"> <li>• Supplier selection criteria</li> <li>• VDA 6.3 potential analysis and/or comparable method for software</li> <li>• VDA 6.3 audit planning</li> <li>• Management (supplier development, forwarding customer requirements) of the suppliers, PPA procedures, failure analysis, quality, warranty, communication</li> <li>• Interface agreement (services according to DIA or interface agreement)</li> <li>• List of suppliers for the project, including service providers (e.g. development, laboratories, maintenance, software)</li> <li>• Risk classification for the scope of supply of the project and the activities derived (VDA MLA)</li> <li>• Third-party software</li> <li>• Criteria for the release of FOSS</li> </ul>

P3.5 Have the necessary resources been taken into account for product and process development planning?	
Minimum requirements relevant for assessment	Examples for implementation
<p>The required resources for the project have been determined and documented.</p> <p>Capacity for the implementation of prototypes and prototype construction, pilot production, performance tests and series production must be planned.</p> <p>Resource planning is regularly adapted to changes in the project and potential bottlenecks must be addressed.</p> <p>When introducing new technologies and products, consistent employee training must be planned, and it must be ensured that the necessary infrastructure is created.</p> <p>Means of transport for in-house transportation, such as packaging and special load carriers have been planned and the relevant quantities have been determined.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Planning of staff training, customer service (0km and field), among other things</li> <li>• Qualification matrix</li> <li>• CAx equipment</li> <li>• Availability of qualified personnel for the respective tasks</li> <li>• Budget, infrastructure, e.g. buildings, inspection equipment (hardware and software), laboratory equipment, machines, plants etc.</li> <li>• Capacity planning for all resources</li> <li>• Performance test, Run@Rate, 2-day production, stress test</li> <li>• Provision and distribution of software</li> <li>• Tool chain planning (software development tools)</li> </ul> <p><b>Product development</b></p> <ul style="list-style-type: none"> <li>• Test/inspection/laboratory facilities (internal and external)</li> <li>• Resources for planning and conducting tests as well as fixing bugs</li> <li>• Resources for installing the software on the hardware (e.g. flashing, coding, programming)</li> </ul> <p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Production locations, tools, production and inspection equipment, infrastructure</li> </ul>

<b>P3.6 Have the activities for customer care/customer satisfaction/customer service and field failure analysis been planned?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The customer requirements are taken into account in the concept for parts supply across the product life cycle, including spare parts supply.</p> <p>Contingency plans to continually ensure series supply must be included in the concept.</p> <p>The analysis process for 0-km and field complaints has been planned for the scope of delivery and the supply chain. The customer requirements regarding field failure analysis are taken into account.</p> <p>Interfaces to the complaints process have been planned.</p> <p>An access control concept for software has been established and is maintained.</p> <p>An analysis of all stakeholders has been carried out. Communication and escalation paths have been specified.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Investment planning</li> </ul> <p><b>Product development</b></p> <ul style="list-style-type: none"> <li>• Interfaces to analysis centers for customer complaints, including the relevant software</li> <li>• Access for diagnosis</li> <li>• Access control lists</li> </ul> <p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Inspection planning for standard and stress testing</li> <li>• Triggering criteria are defined</li> <li>• NTF process</li> <li>• Spare parts supply concepts</li> <li>• Contingency plans</li> </ul>

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

Process element P4: Implementation of product and process development	
P4.1* Are the actions from the product and process development plans implemented?	
Minimum requirements relevant for assessment	Examples for implementation
<p>Product and process development activities defined in the development planning are implemented in such a way as to ensure that the operational conditions are met (function, reliability, safety).</p> <p>The risk analysis (e.g. FMEA, HARA) is conducted on a multidisciplinary basis and is continuously revised in accordance with the progress of the project. Defined measures are implemented in accordance with the planning and are checked for effectiveness.</p> <p>Special characteristics are defined and identified in the relevant documents (FMEA etc.), and measures are implemented to ensure conformity.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Methods to minimize risk (e.g. FMEA, HARA, FTA)</li> <li>• Design of experiments (e.g. DoE, Shainin, Taguchi...)</li> <li>• Poka-Yoke principles</li> </ul> <p><b>Product development</b></p> <ul style="list-style-type: none"> <li>• Test planning</li> <li>• Assembly test and system test</li> <li>• A, B, C, D samples</li> <li>• Endurance tests</li> <li>• Environmental simulation test (e.g. salt spray test)</li> <li>• Automotive SPICE assessments in accordance with the planning</li> <li>• Code, software release management</li> <li>• Traceability, fallback concept</li> <li>• Variant management</li> <li>• Analysis of requirements, architecture design, implementation and test in accordance with the planning</li> </ul> <p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Control plan/inspection plan</li> </ul>

P4.2 Are personnel resources available and are the personnel qualified to ensure product and process implementation?	
Minimum requirements relevant for assessment	Examples for implementation
<p>A staff schedule must be available.</p> <p>The employees' tasks, responsibilities and authorizations are defined and allocated. This also applies to the staff of external service providers. Appropriate evidence must be available.</p> <p>It must be ensured that needs assessments is carried out regularly during product and process development with regard to potentially emerging bottlenecks and additional requirements.</p> <p>Qualified personnel are available during all phases of product and process implementation, and the requirements regarding the series production personnel have been derived.</p> <p>Processes that have been outsourced must be taken into account.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Customer requirements</li> <li>• Requirements profile for the relevant jobs</li> <li>• Determination of the need for training</li> <li>• Evidence of training</li> <li>• Knowledge of methods</li> <li>• Knowledge of foreign languages</li> <li>• Software development: Qualified software testers, integration managers, etc.</li> <li>• Agile development due to qualified roles (DevOps Manager, Release Train Manager, etc.)</li> </ul>

P4.3 Are the material/immaterial resources available and are they suitable to ensure product and process implementation?	
Minimum requirements relevant for assessment	Examples for implementation
<p>A process to determine resources has been implemented.</p> <p>The provision of resources refers to the availability of buildings, measuring and inspection equipment, laboratory equipment, machinery, plants, IT systems and infrastructure as well as their utilization.</p> <p>Processes that have been outsourced must be taken into account.</p> <p>Regular needs assessment must be carried out during product and process development with regard to potentially emerging bottlenecks and additional requirements.</p> <p>Material/immaterial resources are available for all phases of product and process implementation, and the requirements for series production have been derived.</p> <p>Equipment for in-house transport, such as packaging and special load carriers, has been defined and is available in sufficient quantities.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Customer requirements</li> <li>• Technical interface to the customer and suppliers</li> <li>• ERP systems</li> <li>• Supporting processes, e.g. from logistics and IT</li> </ul> <p><b>Product development</b></p> <ul style="list-style-type: none"> <li>• Resources for verification and validation</li> <li>• Test setups, e.g. Hardware in the Loop (HIL), test boards, evaluation boards</li> <li>• Development tools, provision of the tool chain for software development</li> </ul> <p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Facility planning</li> <li>• Facility layout</li> <li>• Release of plants and machines, line clearance</li> <li>• Quantities and throughput times</li> <li>• Transport routes</li> <li>• Transport, containers, storage</li> <li>• Capacity before the start of series production (initial stock)</li> </ul>



<b>P4.4* Are the required proofs of capability and releases for product and process development available?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The releases and proofs of capability are available for all items, assemblies, software versions and purchased products/services in accordance with development schedules.</p> <p>The capability of the measuring and inspection equipment has been proven.</p> <p>The material data has been confirmed and released.</p> <p>The measures from the risk analyses (e.g. FMEA, HARA) have been included in the product and process implementation, and their effectiveness has been confirmed.</p> <p>In case of products with integrated (embedded) software, the software-related aspects according to VDA Volume 2 have to be taken into account.</p> <p>The production process and product approval (PPA) must be available on the agreed date. The tolerances of process parameters for the production of special characteristics have to be verified.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• PPA results, in particular confirmation of conformity with statutory and regulatory requirements</li> <li>• PPA results for purchased products and services</li> <li>• Development releases from customers</li> </ul> <p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Process parameters and their tolerances</li> <li>• Confirmed logistics concept (e.g. suitability of packaging through sample shipping)</li> <li>• Proofs of capability</li> <li>• Capacity studies</li> <li>• Plant and tool releases</li> </ul> <p><b>Software</b></p> <ul style="list-style-type: none"> <li>• Recommendations for use (release notes) for each release</li> <li>• Release of third-party software and FOSS in accordance with customer requirements</li> <li>• Provision of test results and test evaluations</li> </ul>

#### P4.5 Have the planned procurement activities been implemented?

Minimum requirements relevant for assessment	Examples for implementation
<p>The planned procurement activities have been implemented. This includes risk assessments, the project plan, the maturity level, releases and observing deadlines.</p> <p>The planning activities according to the risk classification have been implemented; measures have been derived and their implementation is monitored.</p> <p>The required proofs of capability and releases (process and product release) for the purchased products and services are available in accordance with the project schedule. The material data has been confirmed and released.</p> <p>The relevant project-specific customer requirements have been taken into account.</p> <p>The processes for ensuring customer care/customer satisfaction/customer service as well as field failure analysis have been established.</p>	<ul style="list-style-type: none"> <li>• PPA release</li> <li>• FMEA, HARA</li> <li>• VDA 6.3 audit, potential analysis etc.</li> <li>• Releases, evidence and performance tests in accordance with the coordinated PPA procedure</li> <li>• NTF process, triggering criteria for stress tests have been defined</li> <li>• Spare parts supply concepts</li> <li>• Contingency plans</li> <li>• Interface agreement (services according to DIA or interface agreement)</li> <li>• Sub-supplier management by auditee for off-the-shelf components, engineering assignments (no personnel leasing)</li> <li>• Reference to the ASPICE Acquisition Process Group, ACQ2, ACQ.3, ACQ.4</li> </ul>

<b>P4.6     Are the manufacturing and inspection specifications derived from product and process development and are they implemented?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The manufacturing and inspection specifications contain all inspection characteristics from product and process development (including special characteristics). These must take into account all the components, assemblies, sub-assemblies, and materials, including the processes for manufacturing the products.</p> <p>The results of the risk analysis are considered (e.g. FMEA, HARA).</p> <p>A production control plan is available.</p> <p>It must be available throughout the prototype phase (if required by the customer), the pre-launch phase and the series production phase.</p> <p>The scope and the elements of product audits and requalification tests have been defined.</p> <p>Maintenance specifications are available.</p> <p>All test cases are described in accordance with the test levels and the customer requirements (e.g. V-Model).</p> <p>The software functions required at the respective times are released.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Risk analyses</li> </ul> <p><b>Product development</b></p> <ul style="list-style-type: none"> <li>• Product audit plan</li> <li>• Requalification planning</li> </ul> <p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Inspection instruction</li> <li>• Work instruction</li> <li>• Reaction plans</li> <li>• Production release (first and last piece, repeat release)</li> <li>• In-line inspections</li> </ul> <p><b>Software</b></p> <ul style="list-style-type: none"> <li>• Requirements for ensuring correct installation of the software</li> <li>• Release criteria in the production test</li> </ul>

P4.7 Is a performance test carried out under series conditions for the series release?	
Minimum requirements relevant for assessment	Examples for implementation
<p>A performance test must be carried out under series conditions to confirm that the required quantity can be produced for the customer with the resources used, within the specified period of time and in accordance with the specifications.</p> <p>If the performance test fails to confirm this, measures must be defined.</p> <p>The installation of the software in the components must be taken into account when determining the cycle times/throughput times.</p> <p><i>Note:</i> 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 product development!</p>	<p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Series production conditions: e.g. tools, plants, cycle time, personnel, production and inspection specifications, measuring and inspection equipment</li> <li>• Customer requirements</li> <li>• Performance test, Run@Rate</li> <li>• Determination of minimum quantities (production peak and agreed flexibility)</li> <li>• Series production maturity of equipment and facilities (measurement report)</li> <li>• Staff concept for series production</li> <li>• Packaging requirements</li> </ul> <p><b>Software</b></p> <ul style="list-style-type: none"> <li>• Flash times, including test, ROM programming</li> </ul>

<b>P4.8 Have the processes for ensuring customer care/customer satisfaction/customer service as well as the field failure analysis been established?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The customer requirements regarding the supply of parts throughout the product life cycle are established in the processes.</p> <p>The planned processes for the continuous series supply including safety margins for emergencies are available.</p> <p>The analysis process for 0-km and field complaints is established for the scope of delivery. The customer requirements regarding field failure analysis are taken into account.</p> <p>The requirements for the analysis capability at the site have been agreed with the customer.</p> <p>If external sites are used for analysis, the interfaces are defined and evidence of the availability of the required equipment and capacity is available.</p> <p>New technologies and products are also taken into account in customer support.</p> <p>The employees designated for these processes are qualified. The infrastructure is available.</p> <p>Processes for product monitoring in the field have been specified.</p> <p>There must be processes for error analysis and diagnosis (embedded software in control unit).</p> <p>If agreed, processes for over-the-air (OTA) software updates have been specified.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Inspection equipment for standard and stress tests</li> <li>• Triggering criteria are defined</li> <li>• Inspection plans for failure analysis</li> <li>• NTF process</li> </ul> <p><b>Process development</b></p> <ul style="list-style-type: none"> <li>• Qualification matrix and evidence of training</li> <li>• Inspection equipment</li> <li>• Service agreements with external analysis sites</li> <li>• Spare parts supply concepts</li> <li>• Contingency plans</li> </ul>

P4.9* Is there a controlled method for the project handover from development to series production?	
Minimum requirements relevant for assessment	Examples for implementation
<p>There is a process for transferring work results from the project to series production.</p> <p>The activities specified in the project plan have been implemented. Deadlines have been set for aspects that are still to be clarified, and responsible persons have been appointed.</p> <p>Successful internal release and customer release is a prerequisite for a series delivery release. Measures resulting from internal and external releases are implemented on time.</p> <p>Personnel are available in accordance with the planning and are qualified.</p> <p>The material resources for series production are available in accordance with the planning.</p> <p>Measures to secure the production start-up have been specified and introduced.</p> <p>For products with integrated (embedded) software, the results from development (including intermediate results and their documentation) are recorded.</p> <p>The industrialization is ensured.</p>	<p><b>Product/process development</b></p> <ul style="list-style-type: none"> <li>• Customer requirements</li> <li>• PPA records</li> <li>• Handover protocols/checklists with handover criteria, acceptance reports</li> <li>• Parts history</li> <li>• Key production figures such as OEE, ppm, reject rate, etc.</li> <li>• Experiences from the ongoing project</li> <li>• Personnel resources (production staff, process engineers, maintenance, etc.)</li> <li>• Material resources (machines and plants, buildings, access routes, inspection facilities, load carriers, packaging, etc.)</li> <li>• Change log, Release Note</li> <li>• Industrialization of software: includes flashing software onto the control unit in series production and coding</li> </ul>

## 7.5 Supplier management (P5)

Process element P5: Supplier management	
P5.1 Are only approved suppliers used who are able to meet the quality requirements?	
Minimum requirements relevant for assessment	Examples for implementation
<p>In series production, it must be ensured that only approved suppliers are used. The relevant approval criteria have been defined.</p> <p>When selecting suppliers and in order to assess their ability to meet quality requirements, a process audit must be planned and carried out depending on the risk classification of the component.</p> <p>Evaluations of the quality performance of existing suppliers have been taken into consideration.</p> <p>Risks in the supply chain (internal/external) have been identified, evaluated and mitigated using suitable measures.</p> <p>In case of suppliers appointed by the customer (directed suppliers), interface agreements are taken into consideration.</p>	<ul style="list-style-type: none"> <li>• Defined criteria for the selection of suppliers</li> <li>• QM agreements</li> <li>• In case of criteria that have not been met: evidence of measures being implemented in order to mitigate risks</li> <li>• Assessment of the suppliers' ability to meet quality requirements, e.g. by means of KPI (ppm, delivery performance), escalation level</li> <li>• Self-Assessment, audit results of the suppliers</li> <li>• ASPICE assessment results</li> <li>• VDA 6.3-Process Audit</li> <li>• VDA 6.3-Potential Analysis</li> </ul>

<b>P5.2 Are the customer requirements taken into account in the supply chain?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The communication of customer requirements must be regulated and traceable.</p> <p>Change management must also be taken into account during series production.</p> <p>In case of suppliers appointed by the customer (directed suppliers), interface agreements are taken into consideration.</p>	<ul style="list-style-type: none"> <li>• Requirements from: drawings, components, software or component specifications, milestone plans, QM agreements or other valid standards</li> <li>• Special characteristics</li> <li>• Requalification requirements</li> <li>• Forwarding of complaints, including measures</li> <li>• Statutory and regulatory requirements</li> </ul>

<b>P5.3 Have targets for supplier performance been agreed upon, and is the achievement of these targets regularly assessed?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>Target agreements regarding delivery performance must be made with all direct suppliers and must be implemented.</p> <p>Supplier performance must be checked and evaluated within defined periods and according to defined criteria.</p> <p>If the agreed targets are not met, measures must be defined and their implementation including deadlines must be monitored.</p> <p>In case of suppliers appointed by the customer (directed suppliers), interface agreements are taken into consideration.</p>	<ul style="list-style-type: none"> <li>• Measurable targets: Delivery quantity, punctuality, failure rate, PPM, special deliveries, rejects, lead times for complaints</li> <li>• Escalation criteria according to QM agreements</li> <li>• Evidence of measures (development programs) being implemented in case of suppliers that do not meet the required delivery performance</li> </ul>



<b>P5.4* Are the necessary releases available for purchased products and services?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>Prior to using new or changed products/processes in series production, a release must be available for all purchased products and services as agreed upon with the customer.</p> <p>In case of suppliers appointed by the customer (directed suppliers), interface agreements are taken into consideration.</p>	<ul style="list-style-type: none"> <li>• Report regarding the coordination of the PPA procedure</li> <li>• PPA reports</li> <li>• Reference parts for the PPA procedure</li> <li>• Boundary sample</li> <li>• Product and process changes in the supply chain</li> <li>• Release agreement for small series and individual needs</li> </ul>

<b>P5.5* Is it ensured that the purchased products and services are of the agreed-upon quality?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>To monitor the quality of purchased products and services, inspections are carried out, documented and evaluated in accordance with the inspection planning.</p> <p>If the quality requirements are not met, a standard complaints process is followed.</p> <p>Inspection and measuring equipment for purchased products and services must be sufficiently available and must be stored appropriately. Inspection stations must be laid out appropriately (e.g. climate control, lighting conditions, cleanliness, and protection against damage and contamination).</p>	<ul style="list-style-type: none"> <li>• Released inspection procedure</li> <li>• Sample size (e.g. Skip Lot)</li> <li>• Boundary sample</li> <li>• PPM evaluations, 8D reports</li> <li>• Improvement programs</li> <li>• Material certificates in accordance with DIN EN 10204</li> <li>• Gauges/fixtures</li> <li>• Drawings/specifications</li> <li>• Ordering and packaging specifications</li> </ul>

**P5.6 Are incoming goods delivered and stored appropriately?**

<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>Primary materials and load carriers must be stored in accordance with their release status so that they cannot be damaged or mixed.</p> <p>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 evidence shown.</p> <p>“Suspicious”/quarantined materials must be clearly labeled protected against unauthorized access.</p> <p>FIFO/FEFO (shelf-life requirements) and batch traceability must be ensured when the materials are further processed. This equally applies to residual quantities.</p> <p>Material stock figures in the warehouse management system match the quantities actually in stock.</p> <p>The storage conditions fulfill the product requirements.</p>	<ul style="list-style-type: none"><li>• Packaging</li><li>• Labeling (traceability/inspection status/use status)</li><li>• Quarantine stores; quarantine areas</li><li>• Batch-related use</li><li>• Climatic conditions</li><li>• Protection against damage/contamination/corrosion</li><li>• Order and cleanliness</li><li>• Precautions to prevent mixing/mistakes</li></ul>

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

Minimum requirements relevant for assessment	Examples for implementation
<p>The responsibilities, tasks and authority the employees have in their relevant work areas must be specified.</p> <p>The employees are qualified in accordance with the job profile.</p> <p>Qualification requirements must be determined in relation to the tasks, and qualifications must be planned and carried out accordingly.</p> <p>Knowledge of previous complaints (including corrective actions) is available for purchased products and services.</p>	<ul style="list-style-type: none"> <li>• Knowledge of specifications, product characteristics, customer requirements and production processes</li> <li>• Standards</li> <li>• Statutory and regulatory requirements</li> <li>• Packaging requirements</li> <li>• Quality procedures</li> <li>• Job description / description of tasks and function</li> <li>• Qualification matrix</li> <li>• Qualification of supplier auditors</li> </ul>

## 7.6 Production process analysis (P6)

Process element P6: Production process analysis	
<b>P6.1</b> What goes into the process? Process input	
<b>P6.1.1</b> Has the project been handed over from development to series production and is a reliable start guaranteed?	
Minimum requirements relevant for assessment	Examples for implementation
<p>The project handover to series production has been documented according to the specified criteria.</p> <p>The responsibilities for the entire handover process are specified and acknowledged. Unresolved issues are followed up on, and the necessary measures are implemented on schedule.</p> <p>A complete production process and product release (PPA) including the documentation required must take place before the first production shipment.</p> <p>Measures to secure the production start-up have been implemented on the basis of a risk analysis.</p> <p>Tools, transport and series packaging, inspection and measuring equipment are available in the necessary quantities.</p> <p>Analysis options for failure analysis are available</p> <p>The product software corresponds to the latest release versions.</p>	<ul style="list-style-type: none"> <li>• Handover reports</li> <li>• Defined measures and implementation schedule</li> <li>• Production release report</li> <li>• Releases for all plant components and tools in 6.1.2</li> <li>• PPA documents, including customer approval and reference parts regarding the PPA procedure</li> <li>• Waivers</li> <li>• Released software versions</li> <li>• Examples for securing the production start-up: Higher inspection frequency, additional inspections, Resident,</li> <li>• Safe launch concept</li> </ul>

**P6.1.2 Are the necessary quantities/production batch sizes of production materials available at the agreed upon time and at the correct storage location/work-station?**

Minimum requirements relevant for assessment	Examples for implementation
<p>The production material must be of the agreed quality and must be provided in the correct quantity and the correct packaging, 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 primary materials are provided as needed, taking into account the order quantity/lot size in accordance with the logistics concept.</p> <p>The reuse of residual quantities, separated parts, reworked parts, reused parts from product audits, inspected items, etc. and their traceability must be clearly defined.</p> <p>Regulations for reintroducing parts from outsourced processes (e.g. sorting service) must be available.</p>	<ul style="list-style-type: none"> <li>• Production material includes, for example:</li> <li>• Software, packaging, load carriers, parts and components, raw material, series packaging for delivery to the customer, operating, auxiliary and process materials</li> <li>• suitable means of transport</li> <li>• Defined storage locations and stock levels</li> <li>• KANBAN, Just in time/Just in sequence, FIFO/FEFO</li> <li>• Revision / change status of materials and software</li> <li>• Special requirements regarding components and containers (e.g. ESD protection, humidity, temperature, residue)</li> </ul>

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

Minimum requirements relevant for assessment	Examples for implementation
<p>Packaging requirements must be consistently taken into account/fulfilled.</p> <p>During manufacture and in-house transport and also when being transported to and from service providers, suitable transport units must be used to protect the products from damage and contamination.</p> <p>Storage areas/work-stations/containers must be appropriate for the tidiness and cleanliness required for the material. Cleaning cycles are defined and monitored.</p> <p>The supply of 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 must be monitored by means of appropriate methods</p> <p>Operating and auxiliary materials for plants and machinery that have a direct effect on the product/product quality must be monitored accordingly.</p> <p>Materials, operating and auxiliary materials must be protected against environmental and climatic influences.</p>	<ul style="list-style-type: none"> <li>• Stock quantities</li> <li>• Storage conditions</li> <li>• released special and standard transport containers</li> <li>• Protection against damage to the material</li> <li>• 5S</li> <li>• Over-filling (storage areas and containers)</li> <li>• Maximum and minimum storage times, specified interim storage times, FIFO/FEFO</li> </ul>

**P6.1.4 Are the necessary labels/records/releases available and allocated appropriately to the materials?**

Minimum requirements relevant for assessment	Examples for implementation
<p>Released materials must be clearly identifiable. The release identification on bundles/batches/load carriers/parts must be defined.</p> <p>It must be ensured that only released materials/parts are forwarded to production/the next production stage and used.</p> <p>Traceability from the sub-supplier to the customer must be guaranteed according to a defined traceability concept.</p> <p>Customer requirements as well as statutory and regulatory requirements regarding labeling are taken into account.</p>	<ul style="list-style-type: none"> <li>• Customer requirements regarding labeling and traceability</li> <li>• Labeling of released parts/materials (stickers, labels, issue slips, VDA label, DMC, etc.)</li> <li>• Records of approvals</li> <li>• Traceability system</li> <li>• Documentation of waivers (number, duration, type of identification, etc.)</li> <li>• Stock management systems</li> </ul>

<b>P6.1.5* Are product or process changes during series production tracked and documented?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>Changes to the product and the production process are implemented in accordance with the change management described. Changes to the product and process are agreed upon with the customer, approved and released (including software changes) in accordance with customer requirements. A PPA must be carried out. The history of change statuses must be fully traceable.</p> <p>The correct, released version of the material / software must be used.</p> <p>After changes have been made, it must be checked whether the risk analyses need to be updated.</p>	<ul style="list-style-type: none"> <li>• Trigger matrix in accordance with VDA Volume 2 or customer specifications</li> <li>• Documented release of a change</li> <li>• Cross-functional evaluation prior to changes</li> <li>• Change history/parts history (also for software)</li> <li>• Design and process FMEA</li> <li>• Operation management in case of changes</li> <li>• Pre-production</li> <li>• Unique software identifier, software integrity (build number, hash key)</li> </ul>



Process element P6: Production process analysis	
P6.2 Are all production processes controlled? Process management	
P6.2.1 Are the requirements in the production control plan complete and have they been effectively implemented?	
Minimum requirements relevant for assessment	Examples for implementation
<p>The production and inspection documents are complete and are based on the production control plan.</p> <p>The data relating to released machinery/tools/aids must be noted in the production control plan and/or the manufacturing and inspection documents.</p> <p>The documents must be accessible close to the work-station.</p> <p>Required measures (reaction plan) for process disturbances are described in the production control plan and are implemented and documented.</p> <p>Process parameters influencing product characteristics/quality must be fully stated.</p> <p>Tolerances must be stated for process parameters and inspection characteristics.</p> <p>The control limits in process control charts are defined, identifiable and plausible.</p> <p>Non-conformities and initiated measures regarding process requirements and inspection characteristics must be documented.</p> <p>Conditions governing rework are specified, assess as part of the risk analysis and secured within the process (parts identification; repeat inspection etc.).</p>	<ul style="list-style-type: none"> <li>• Inspection characteristics, inspection equipment, inspection methods, inspection frequencies, inspection cycles and requalification</li> <li>• Data regarding machines/tools/aids (identification numbers), process parameters and tolerances (pressure, temperatures, times, speeds etc.)</li> <li>• Work instructions (including reworking)</li> <li>• Inspection instruction</li> </ul>

### P6.2.2 Are production processes released?

Minimum requirements relevant for assessment	Examples for implementation
<p>A process-specific release inspection for first piece/last piece and repeat release was carried out and documented.</p> <p>A release is necessary for the product and the process and must be carried out and documented by authorized employees using acceptance criteria. Non-conformities and initiated measures are documented.</p> <p>At the time of release, the necessary reference and boundary samples must be available.</p> <p>Criteria for triggering a repeat release must be defined e.g. after an interruption of production.</p> <p>If production is continued after the collection of inspection parts, these products must be accessible until the inspection parts are released.</p>	<ul style="list-style-type: none"><li>• Release of a batch, including repeat release</li><li>• First piece /last piece and repeat release</li><li>• Tooling diagrams/reference parts/installation parts (e.g. defect identification)</li><li>• Possible triggering criteria for a repeat release:<ul style="list-style-type: none"><li>○ Production interruption (e.g. night time in two-shift operations, tool changes, material/batch/product change)</li><li>○ Repair, tool change,</li><li>○ changed setting data</li></ul></li><li>• Release of reworked parts</li></ul>

**P6.2.3\* Are special characteristics controlled in production?**

Minimum requirements relevant for assessment	Examples for implementation
<p>Special product characteristics specified by the customer and the organization as well as defined process parameters are marked in the production control plan and systematically monitored.</p> <p>Records of non-compliances and corrective actions are maintained. Non-compliances affecting the characteristics of the product must be approved by the customer.</p> <p>Records regarding special characteristics are available. The duration and type of archiving of these records are specified and meet the customer's requirements.</p>	<ul style="list-style-type: none"><li>• Drawings</li><li>• Labeling indicating the customer-specific special characteristics, e.g.: D/TLD, DS, DZ, R, S, F</li><li>• Process FMEA</li><li>• Production control plan</li><li>• SPC evaluations</li><li>• Quality control charts</li><li>• Proofs of capability</li><li>• Proof of inspection process capability</li><li>• Inspection results</li><li>• Process parameter records</li></ul>

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

Minimum requirements relevant for assessment	Examples for implementation
<p>Suspect parts and defective parts must be separated, labeled, recorded or (when necessary) safely removed from the production process.</p> <p>These parts must either be directly marked or marked on their container.</p> <p>Authorized personnel decide on the further use of potentially defective products.</p> <p>The scope (including inspection and release) of permissible rework is described in work instructions.</p> <p>Quarantine stores and quarantine areas must be clearly labeled. Accidental or unauthorized use of restricted parts must be excluded.</p>	<ul style="list-style-type: none"><li>• Labeling indicating the product status</li><li>• defined scrap/rework-stations in production</li><li>• Quarantine stores and quarantine areas, clearance areas</li><li>• Documentation regarding rejects, rework and repair</li><li>• Authorizations</li></ul>

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

<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>A mix-up of materials or the use of wrong materials, software or components must be ruled out.</p> <p>Appropriate measures must be taken to ensure that any mix-ups of parts or any use of wrong parts/in-correct installation of parts is detected early on.</p> <p>The process and/or inspection status of parts must be clearly visible.</p> <p>The reuse of residual quantities, separated parts, re-worked parts, reusable parts must be clearly defined. Traceability is ensured.</p> <p>Regulations for reintroducing parts from outsourced processes must be available.</p> <p>Setting masters, setup and reference parts must be labeled and protected against accidental use.</p>	<ul style="list-style-type: none"><li>• Process FMEA</li><li>• Poka Yoke actions</li><li>• Checks and inspections in production facilities</li><li>• Traceability of batches</li><li>• FIFO/FEFO</li><li>• Kanban</li><li>• Removal of invalid labeling</li><li>• Value stream analysis</li><li>• Sorting service</li><li>• Unique software identifier, software integrity (build number, hash key)</li></ul>

## Process element P6: Production process analysis

### P6.3 With which personnel resources is the process implemented?

#### Personnel resources

#### P6.3.1 Are the employees able to fulfill their given tasks?

Minimum requirements relevant for assessment	Examples for implementation
<p>For each task/job, the corresponding requirements profile has been specified. The employees' qualification is in line with the requirements profile. If this is not the case, a qualification scheme must be put in place.</p> <p>Instructions, trainings and inductions provided to the employees as well as proofs of qualification are documented.</p> <p>Proof of special qualifications required for the relevant job must be provided.</p> <p>In case of changes to processes, trainings/instructions are provided and documented.</p> <p>The requirements also apply to temporary employees.</p>	<ul style="list-style-type: none"><li>• Evidence of qualifications</li><li>• Training plan</li><li>• Initial training plan, including evidence</li><li>• On-the-job training</li><li>• Qualification matrix</li><li>• Knowledge about the product and failures that have occurred</li><li>• Handling of measuring equipment</li><li>• Interpretation of control charts</li><li>• Training/instructions regarding occupational safety</li><li>• Training in special characteristics</li><li>• Suitable evidence of qualification (e.g. welding certificate, vision test results, hearing test results)</li></ul>

**P6.3.2 Do the employees know what responsibilities and authority they have regarding the monitoring of product and process quality?**

<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The employees' responsibilities, duties and authority are described and implemented.</p> <p>The employees know the consequences of incorrect execution of work. The tasks/functions of the product are known. It is also known what happens when they are no longer guaranteed.</p> <p>Employees receive regular information on the current standard of quality achieved and are informed about customer complaints.</p> <p>The requirements also apply to temporary employees.</p>	<ul style="list-style-type: none"> <li>• Work/inspection instructions</li> <li>• Job descriptions</li> <li>• Setup release, first piece inspection, last piece inspection</li> <li>• Authority to stop and start the process</li> <li>• Escalation protocol</li> <li>• Product training</li> <li>• Product safety/product liability training</li> </ul>

**P6.3.3 Are the necessary personnel resources available?**

<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>There is a staff schedule for all shifts. The staff schedule takes into account the required number of qualified employees.</p> <p>Rules exist for supporting areas that are not continually in use (e.g. laboratory, measurement room).</p> <p>Fluctuations in customer orders and workforce absences (e.g. illness, holidays, training) are taken into account in the staff schedule.</p> <p>The requirements also apply to temporary employees.</p>	<ul style="list-style-type: none"> <li>• Shift plan</li> <li>• Evidence of qualifications</li> <li>• Qualification matrix</li> <li>• documented absence management rules</li> <li>• Staff schedule</li> <li>• Mentors</li> </ul>

Process element P6: Production process analysis	
P 6.4 What material resources are used to implement the process? Material resources	
P6.4.1* Is the manufacturing equipment suitable to meet the customer's product-specific requirements?	
Minimum requirements relevant for assessment	Examples for implementation
<p>It must be demonstrated that the processes are implemented in accordance with the customer requirements using the existing production facilities, and that the resulting products meet the customer specifications.</p> <p>The production facilities, machines and plants must be able to comply with the specified tolerances for the respective product and process characteristics.</p> <p>Parameters and software that influence the process are protected against unauthorized access.</p> <p>Process capability must be determined for selected product and process characteristics, and proof of capability must be provided.</p> <p>The process capability must meet internal requirements as well as customer requirements. The minimum requirement for process capability is <math>C_{pk} \geq 1.33</math>. In case of characteristics where a certain capability is required but proof of capability cannot be obtained, 100% inspection is required.</p>	<ul style="list-style-type: none"> <li>• Proof of machine/process capability</li> <li>• Monitoring of key process parameters (e.g. pressure, time, temperature)</li> <li>• Capability of replacement tools</li> <li>• Feed and removal systems</li> <li>• Reproducibility of gages, fixtures etc.</li> <li>• Cleanliness requirements</li> <li>• Configuration management, ensuring provision of software in accordance with the unique identifier, software integrity (build number, hash key)</li> </ul>

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

Minimum requirements relevant for assessment	Examples for implementation
<p>Preventive and/or predictive maintenance activities (maintenance, inspection and repair) are defined and implemented for all installations, equipment, machines and tools based on the risk.</p> <p>Scheduled and unscheduled maintenance activities that have been carried out are documented and analyzed with regard to potential improvement measures.</p> <p>Resources needed to carry out necessary maintenance activities are available.</p> <p>A process for the analysis and optimization of down-time, machine utilization and tool life is implemented effectively.</p> <p>The availability of replacement parts is ensured.</p> <p>Tools undergo tool management which includes the following:</p> <ul style="list-style-type: none"> <li>• Tool history including all changes and tool life</li> <li>• Operational status</li> <li>• Labeling of tools</li> </ul> <p>These requirements also apply to external service providers.</p>	<ul style="list-style-type: none"> <li>• Production-related logistical equipment, such as forklift trucks</li> <li>• Maintenance and servicing schedules</li> <li>• TPM Total Productive Maintenance</li> <li>• Key processes and bottle-neck machines</li> <li>• Technical documentation provided by the manufacturer</li> <li>• Preventative tool exchange programs for units subject to increased wear</li> <li>• Tool operation sheet</li> <li>• Operational status of tools, e.g. operational, not operational</li> <li>• Labeling of tools, e.g. property of the customer, tool no., index</li> </ul>



**P6.4.3\* Can compliance with quality requirements be effectively monitored with the measuring and inspection equipment in use?**

Minimum requirements relevant for assessment	Examples for implementation
<p>The inspection equipment and measuring systems used are suitable for the intended purpose and handling in production. They are included in the production control plan.</p> <p>Confirmed results of capability studies are available for the inspection equipment and measuring systems used.</p> <p>Inspection and measuring equipment is labeled. The validity status is monitored.</p> <p>A process for periodic monitoring of inspection equipment and measuring systems is established and implemented.</p> <p>In case of non-conformity, an assessment of potential risks in relation to the process, the product and the customer is carried out. Measures have been defined and are implemented effectively.</p> <p>Auxiliary equipment for inspection equipment and measuring systems that have an influence on the measurement result are monitored in the same way.</p>	<ul style="list-style-type: none"> <li>• Measuring system analysis</li> <li>• Test process capability</li> <li>• Replacement measuring equipment</li> <li>• Software integrity check</li> <li>• Calibration status (inspection sticker, barcode, engraving, etc.)</li> <li>• Reference parts</li> </ul>

#### P6.4.4 Do the work and inspection stations fulfill the requirements?

Minimum requirements relevant for assessment	Examples for implementation
<p>Workplace and ambient conditions are appropriate for the products and the work carried out, in order to prevent or eliminate contamination, damage, mix-ups of parts and the use of wrong parts.</p> <p>This also applies to rework, sorting and inspection stations that have been permanently or temporarily set up.</p> <p>The layout of the work station is adapted to the work to be carried out.</p>	<ul style="list-style-type: none"><li>• Cleanliness and tidiness, 5S</li><li>• Lighting</li><li>• Noise pollution</li><li>• Climate control</li><li>• Clean rooms</li><li>• ESD</li><li>• Layout of the work station</li><li>• Surroundings/handling of parts at the work station</li><li>• Occupational safety</li></ul>

#### P6.4.5 Are tools, devices and inspection equipment stored properly?

Minimum requirements relevant for assessment	Examples for implementation
<p>Tools, devices and test equipment must be stored properly.</p> <p>It is ensured that the equipment is stored in such a way as to be protected against damage and environmental effects.</p> <p>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 in such a way as to be protected against damage, e.g. collision protection</li><li>• 5S Method</li><li>• Defined storage location, e.g. markings on the floor</li><li>• Transparent warehouse management</li></ul>

Process element P6: Production process analysis	
How effectively is the process being carried out? Effectiveness and efficiency	
P6.5.1 Have targets been set for the production process?	
Minimum requirements relevant for assessment	Examples for implementation
<p>Process-specific targets are defined, monitored and communicated.</p> <p>Customer requirements are taken into account when setting targets.</p> <p>A regular comparison between specified targets and actual results is made and documented.</p>	<ul style="list-style-type: none"> <li>• Key production figures, e.g. quantities produced; quality metrics, throughput times, defect costs, process effectiveness figures, plant and machine availability)</li> <li>• First time through quality, First pass yield</li> <li>• Reduction of waste (e.g. rejects and rework, energy and process materials)</li> </ul>

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

<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>The quality and process parameters required to demonstrate product conformity (target values) are defined and documented. The actual data is recorded and evaluated.</p> <p>Special incidents are documented.</p> <p>The recorded data can be allocated to a product and process, the data is available, legible, accessible and archived as specified. Traceability requirements are met.</p> <p>The collected data is analyzed, and appropriate improvement measures are initiated.</p> <p>The potential for improvement must be continuously determined based on findings relating to quality, costs, and services.</p>	<ul style="list-style-type: none"><li>• Control charts</li><li>• Check sheet</li><li>• Types of errors/error frequencies</li><li>• Rejects/rework</li><li>• Process data sheet with parameter changes</li><li>• Shift/machine log</li><li>• Cycle times, throughput times</li><li>• Fault message (e.g. plant standstill, power outage, program error message)</li><li>• Output/availability</li><li>• Blocking message/sorting actions</li><li>• Traceability</li></ul>

**P6.5.3\* If product and process requirements are not met, are the causes analyzed and the corrective actions checked for effectiveness?**

Minimum requirements relevant for assessment	Examples for implementation
<p>If product and process requirements are not met, immediate actions are taken to fulfill the requirements, until it has been proven that the corrective actions have been effective. The employees are familiar with these immediate corrective actions.</p> <p>Suitable methods are implemented to analyze the causes.</p> <p>Repeat errors are recorded. A more detailed analysis of the causes must be carried out accordingly.</p> <p>Corrective actions are derived, their implementation is monitored and the effectiveness verified,</p> <p>The production control plan and the risk analysis are updated as needed.</p> <p>Non-conformities that affect the characteristics of the delivered product are communicated to the customer.</p>	<ul style="list-style-type: none"> <li>• 8D method</li> <li>• Cause and effects diagram</li> <li>• Taguchi, Shainin</li> <li>• 5W method</li> <li>• Process capability analysis</li> <li>• Design and process FMEA</li> <li>• Waivers/concessions</li> <li>• Additional dimensional, material, functional and endurance testing</li> </ul>

#### P6.5.4 Are processes and products audited regularly?

Minimum requirements relevant for assessment	Examples for implementation
<p>The audit program for process and product audits is based on customer requirements as well as specific risks. And is implemented.</p> <p>The process and product audits carried out are suitable to identify specific risks and weaknesses.</p> <p>If non-conformities are detected during an audit, the causes are analyzed. Corrective actions are derived, their implementation is monitored and the effectiveness is verified.</p> <p>Non-conformities that affect products which have already been delivered are communicated to the customer.</p>	<ul style="list-style-type: none"><li>• Specifications</li><li>• Special characteristics</li><li>• Audit program including scheduled and event-based audits</li><li>• Frequency of audits</li><li>• Audit results, audit reports, action plans</li><li>• Auditor qualification</li><li>• Scope of the audit, e.g.: P5, P6, P7</li><li>• Labeling, packaging</li><li>• Change status of individual parts and software</li></ul>

Process element P6: Production process analysis	
P6.6 What should the process accomplish? Process result (output)	
P6.6.1 Do the quantities/production batch sizes match needs and are they systematically directed to the next process step?	
Minimum requirements relevant for assessment	Examples for implementation
<p>Products must be forwarded to defined storage/holding points using suitable means of transport.</p> <p>The order quantity/batch size must be taken into account, so that only the required quantity of products is moved to the stipulated storage/holding point.</p> <p>The current state of the component (OK part, re-worked part, reject, etc.) must be evident from the labeling (component, container etc.).</p> <p>The change status must be clearly indicated.</p> <p>It is ensured that only OK parts move on to the next production process step.</p> <p>Rules are put in place for returning residual quantities, including the recording of the quantities as well as further processing.</p>	<ul style="list-style-type: none"> <li>• KANBAN</li> <li>• FIFO/FEFO</li> <li>• JIT/JIS</li> <li>• Storage management</li> <li>• Production quantities tailored to the customer's needs</li> <li>• Technical cleanliness</li> </ul>

**P6.6.2 Are products stored in an appropriate manner and are the means of transport/packaging facilities suitable for the special characteristics of the products?**

Minimum requirements relevant for assessment	Examples for implementation
<p>The products must be protected from damage by suitable storage and packaging.</p> <p>Internal and customer-specific packaging instructions are known and are implemented. This also applies to released replacement packaging.</p> <p>The storage areas/containers must meet the requirements with regard to cleanliness.</p> <p>Specified storage times must be monitored.</p> <p>Products must be protected against environmental and climatic influences during storage and shipment.</p> <p>These requirements apply to the handling during the production process as well as during shipment.</p> <p>It is ensured that there are no product risks in the transport chain, e.g. due to parts handling, transport routes, commissioning, outdoor storage areas (internal/external).</p>	<ul style="list-style-type: none"> <li>• Protection from damage</li> <li>• For electronic components: ESD protection</li> <li>• Technical cleanliness</li> <li>• Cleanliness, tidiness, 5S, over-filling (storage areas, containers)</li> <li>• Monitoring of storage times/storage quantity (maximum/minimum storage times, specified interim storage times)</li> <li>• Specifications regarding the cleaning of packaging</li> <li>• Sufficient amount of packaging</li> </ul>



**P6.6.3 Are the necessary records/releases retained?**

Minimum requirements relevant for assessment	Examples for implementation
<p>The release of the products as well as the relevant evidence is documented.</p> <p>Waivers/concessions are documented. The documentation must cover the period and/or quantity of parts involved.</p> <p>Internal specifications and customer requirements regarding the documentation of rework and repair are fulfilled.</p> <p>The traceability of products is ensured.</p> <p>The customer's requirements with regard to archiving are fulfilled.</p>	<ul style="list-style-type: none"><li>• Customer specifications</li><li>• Customer's requirements for archiving time limits</li><li>• Archiving requirements/regulations (e.g. EDP, paper, fire protection, legibility)</li><li>• Parts history</li></ul>

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

Minimum requirements relevant for assessment	Examples for implementation
<p>The customer-specific requirements regarding the final product (delivery reliability, quality targets, quality performance etc.) are known. The fulfillment of these requirements is continuously monitored, assessed and documented.</p> <p>In case of non-conformities, the causes are analyzed, and measures are defined and implemented.</p> <p>Products are labeled, stored and shipped in accordance with the customer requirements.</p> <p>In case of waivers/concessions, products and packaging are labeled accordingly.</p> <p>Internal specifications as well as customer requirements regarding the labeling of reworked or repaired products are observed.</p> <p>The handling of supplied products is regulated.</p> <p>Customers should be informed of delivery stops which affect them, and the further procedure should be coordinated with them.</p>	<ul style="list-style-type: none"><li>• Quality agreements with the customer</li><li>• Packaging specification</li><li>• Target agreements</li><li>• Shipping audit</li><li>• Customer specifications regarding labeling (e.g.: VDA label)</li><li>• Labeling in cases of waivers</li></ul>

## 7.7 Customer satisfaction/customer care/service (P7)

Process element P7: Customer care/service	
P7.1 Are all requirements related to the QM system and product conformity fulfilled?	
Minimum requirements relevant for assessment	Examples for implementation
<p>The internal and customer-specific requirements regarding the QM-system and its further development are fulfilled. The processes within the organization (including the outsourced processes) and along the supply chain are taken into account.</p> <p>Requalification tests are carried out in accordance with the customer requirements</p> <p>Customer requirements for the return of parts and their recycling must be fulfilled.</p> <p>Proof of conformity with necessary national and international regulations is available.</p>	<ul style="list-style-type: none"> <li>• Quality agreements with the customer</li> <li>• Requalification concept, e.g. product audits carried out, functional tests, endurance tests</li> <li>• Certification of the QM system</li> <li>• Proof of conformity, e.g. parts that are subject to type approval, CCC, ECE, DOT, certificates, inspection reports</li> </ul>

P7.2 Is customer service guaranteed?	
Minimum requirements relevant for assessment	Examples for implementation
<p>It must be ensured that competent contact persons are available for the various areas in the customer's organization.</p> <p>Communication is ensured in accordance with the customer specifications.</p> <p>Product monitoring in the field is ensured.</p> <p>Access to customer portals in accordance with the customer-specific agreements is ensured, and the required data is up to date/maintained.</p>	<ul style="list-style-type: none"> <li>• Knowledge regarding product use</li> <li>• Knowledge of problems with the product and complaints regarding the product or transport</li> <li>• Fulfillment of new requirements</li> <li>• Notification of improvement measures</li> <li>• World-wide customer service</li> <li>• The customer is informed in the case of non-compliance with the requirements</li> <li>• Required data (e.g. Certificates, contact data)</li> </ul>

<b>P7.3* Is the supply of parts guaranteed?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>Concepts (including contingency concepts to ensure that products/parts can continue to be supplied) are available and up to date. The processes within the organization (including the outsourced processes) and along the supply chain must be taken into account. This also includes immaterial products such as software, etc.</p> <p>Risks and their impact on the customer have been taken into account.</p> <p>Procedures must be in place which guarantee that the organization informs the customer immediately when supply shortages are detected. The information must include the expected duration and extent of the shortages, the reason and the measures which have been initiated.</p> <p>The customer's requirements regarding the supply of spare parts must be fulfilled during the series production phase as well as afterwards.</p>	<ul style="list-style-type: none"> <li>• Contingency plans (e.g. alternative production, suppliers, packaging, 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> <li>• Involvement of the suppliers in spare parts supply</li> <li>• Provision of software updates</li> </ul>

<b>P7.4* In case of complaints, are failure analyses carried out and corrective actions implemented effectively?</b>	
<b>Minimum requirements relevant for assessment</b>	<b>Examples for implementation</b>
<p>A complaints process that meets the customer requirements is followed in case of 0-km and field complaints.</p> <p>Analysis procedures must be defined. The necessary personnel and material resources are available to ensure punctual processing. The deadlines agreed upon with the customer must be met. In case of non-conformities, the customer has to be informed.</p> <p>In case of field complaints, a field failure analysis must be carried out according to the customer requirements (e.g. VDA Field Failure Analysis).</p> <p>In case of suppliers appointed by the customer (directed suppliers), interface agreements are taken into consideration.</p>	<ul style="list-style-type: none"> <li>• Process for processing complaints and field failure analysis process</li> <li>• Internal/external analysis facilities (laboratories, test and inspection facilities, personnel)</li> <li>• Use of problem-solving methods (8D)</li> <li>• Flow of information to the customer in the case of non-conformities</li> <li>• Knowledge databases, lessons learned</li> <li>• Quality control loop</li> <li>• Risk analysis (e.g. FMEA, HARA)</li> <li>• Access to the necessary release documents (e.g. PPA)</li> </ul>

P7.5 Are personnel qualified for their respective tasks and are responsibilities defined?	
Minimum requirements relevant for assessment	Examples for implementation
<p>It must be determined which responsibilities, duties and authorizations each employee has in their respective field of work.</p> <p>Training needs must be determined and implemented individually, based on the tasks.</p> <p>The employees are familiar with the product and the consequences of incorrect execution of work for the supply of parts and the quality of the final product.</p>	<ul style="list-style-type: none"> <li>• Organizational chart and escalation procedures</li> <li>• Evidence of knowledge of: the product/the specifications/ special customer requirements</li> <li>• Standards/legislation (product liability)</li> <li>• Intended 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, "5 Whys" method)</li> <li>• Knowledge of foreign languages</li> </ul>

## 8 Glossary and list of abbreviations

Definitions and terms from the VDA publications are provided in the overarching online glossary of the VDA QMC:

<https://vda-qmc-learning.de/module/glossar/glossar.php>

Abbrevia- tion	Explanation
AIAG	Automotive Industry Action Group
aSPICE	automotive SPICE (Software Process Improvement and Capability Determination)
CAX	Computer-Aided x
CMMI	Capability Maturity Model Integration
DIN	German Institute for Standardization (Deutsches Institut für Normung e. V.)
E <sub>Dn</sub>	Compliance level of the service process element (D2, D3, ..., D7)
ESD	electrostatic discharge
E <sub>G</sub>	Overall compliance for the Process Audit
E <sub>G(PGn)</sub>	Overall compliance for each product group
E <sub>n</sub>	Compliance level of a process step
E <sub>Pn</sub>	Compliance level of a process element (P2, P3, ..., P7)
E <sub>U1</sub>	Sub-element of P6 or D6: Process Input
E <sub>U2</sub>	Sub-element of P6 or D6: Work carried out
E <sub>U3</sub>	Sub-element of P6 or D6: Personnel resources
E <sub>U4</sub>	Sub-element of P6 or D6: Material resources
E <sub>U5</sub>	Sub-element of P6 or D6: Efficiency
E <sub>U6</sub>	Sub-element of P6 or D6: Process output
OK	OK
IEC	International Electrotechnical Commission
Inmetro	National Institute of Metrology, Standardization and Industrial Quality
ISO	International Organization for Standardization
n.e.	not evaluated
NOK	Not OK

Abbrevia- tion	Explanation
P1	Process element: Potential analysis
P2	Process element: Project management
P3	Process element: Product and process development planning
P4	Process element: Implementation of product and process development
P5	Process element: Supplier management
P6	Process element: Production process analysis
P7	Process element: Customer care, customer satisfaction, service
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
SAE	Society of Automotive Engineers
VDA	Verband der Automobilindustrie e. V.



## 9 Downloads

Given that the tables and figures can only be presented to a limited extent in the print form, we have provided you with PDF downloads under the following link: [www.vda-qmc.de/downloads](http://www.vda-qmc.de/downloads)

The downloads are available free of charge.

A supplier self-assessment form is also available on the download page.

### **Login details:**

Username:       prozessaudit

Password:       vda\_6.3

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

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

You may also order via this homepage.

Reference:

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