Auditing Management Systems: Process & Product

Why to do Audits?

- Assess the System, Product and Process requirements in supply chain
- Achieve Customer Requirements
- Verify conformance of manufacturing processes
- Evaluate the risks, inputs, outputs at each process stage to manufacture a product
- Evaluate product and process maturity from pre-series (Product Development Cycle) to mass production
- Audits are key drivers for continuous improvement process
- Compliance with international Automotive Industry Standards

Agenda

- Key Terms and definitions
- Principles of auditing
- IATF 16949 Requirement for Internal Audits
- Customers Approach for Process Audit
- Managing an Audit Programme
- Process Flow for the Management of an audit Programme - ISO 19011
- Process Audit VDA 6.3
- Auditor Qualification
- Potential analysis
- Process audit for material products
- Product Audit

Key Terms and definitions

Audit
Systemic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Audit Scope
Extent and boundaries of an audit. *Physical and virtual locations, functions, organizational units, activities and processes, as well as the time period covered.*

Audit Criteria
Set of requirements used as a reference against which objective evidence is compared. *Requirements may include policies, procedures, work instructions, legal requirements, etc.*

Objective Evidence
Data supporting the existence or verity of something. *Obtained through observation, measurement, test, generally consists of records, statements of fact, etc.*

Risk
Effect of uncertainty. *An effect is a deviation from the expected – positive or negative*

Principles of auditing

The principles below should help to make the audit an effective and reliable tool in support of management policies and controls, by providing information on which an organization can act in order to improve its performance.

Adherence to these principles is prerequisite for providing audit conclusions that are relevant and sufficient, and for enabling auditors, work independently from one another, to reach similar conclusions sin similar circumstances.

a) **Integrity**: the foundation of professionalism

b) **Fair presentation**: the obligation to report truthfully and accurately

c) **Due professional care**: the application of diligence and judgement in auditing

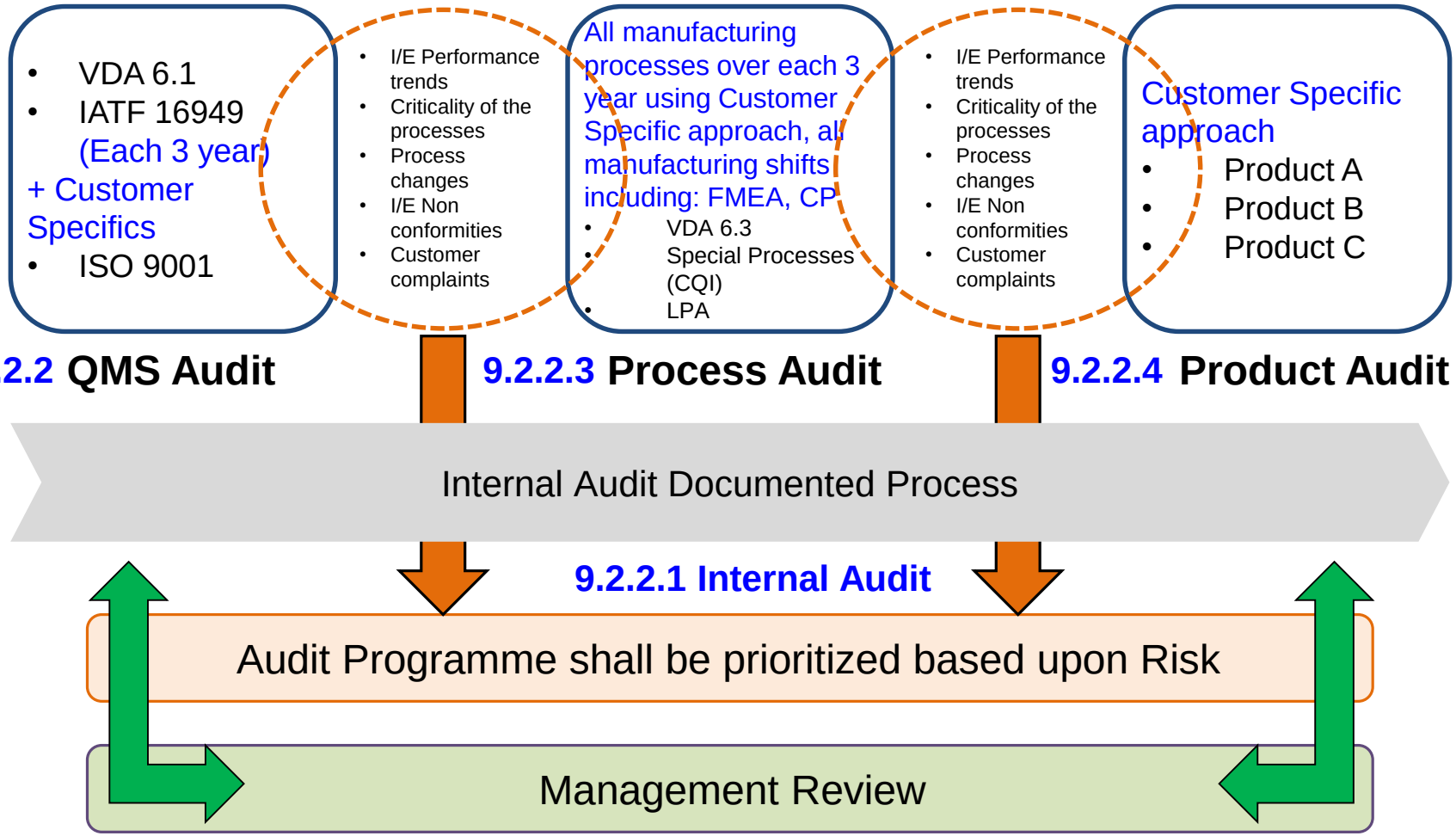
d) **Confidentiality**: security of information

e) **Independence**: the basis for the impartiality of the audit and objectivity of the audit conclusions

f) **Evidence-based approach**: the rational method for reaching reliable and reproducible audit conclusions in a systemic audit process

g) **Risk-based approach**: an audit approach that considers risks and opportunities

IATF 16949 Requirement for Internal Audits



Customers Approach for Process Audit

Layered Process Audit

GM IATF 16949 – Customer Specific Requirements

The Organization shall incorporate an internal layered process audit process to assess compliance to standardized processes.

In addition to LPA the organization shall audit specific manufacturing processes, applicability and effectiveness of these shall be determined utilizing the most current version CQI standard.

Manufacturing Process Audit

Ford IATF 16949 – Customer Specific Requirements

The Organization is responsible to ensure that all tiers of suppliers are assessed to the applicable Ford manufacturing process standards.

Assembly, Casting, Contamination, Electrical/ Electronics, Heat Treat, Machining, Plastic Molding, Plating and Coating, Welding / Brazing

Process Requalification

Specific Requirements of the BMW Group

Group Standard 90018-1 and Group Standard 90018-2 “Requalification of product and process at suppliers”

Published in b2b of the BMW Group.

Annual requalification is part of the contract with BMW Group and is an essential contribution in keeping and improving the quality level

VDA 6.3 Self Audit

Customer Specific requirements of the Volkswagen Group

VWAG requires yearly Supplier Self Audit acc. Formel-Q-Capability, this has valid time period of max. 12 months. Conducted by certified VDA 6.3 auditors

In case of D/TLD parts supplier to VWAG, a D/TLD Supplier Self Audit according to Formel-Q-Capability is required within every 12 months.

Special Processes

CQI-29 Brazing System Assessment, CQI-27 Casting System Assessment, CQI-12 Coating System Assessment, CQI-9 Heat Treat System Assessment, CQI-23 Molding System Assessment, CQI-11 Plating System Assessment, CQI-17 Soldering System Assessment, CQI-15 Welding System Assessment

Managing an Audit Programme

Organization Context

- Organizational Objectives
- Relevant external and internal issues
- The needs and expectations of relevant interested parties
- Information security and confidentiality requirements


Management System


Size


Nature


Complexity


Level of Maturity


Outsourced functions


Multiple locations/ sites


Higher Risks

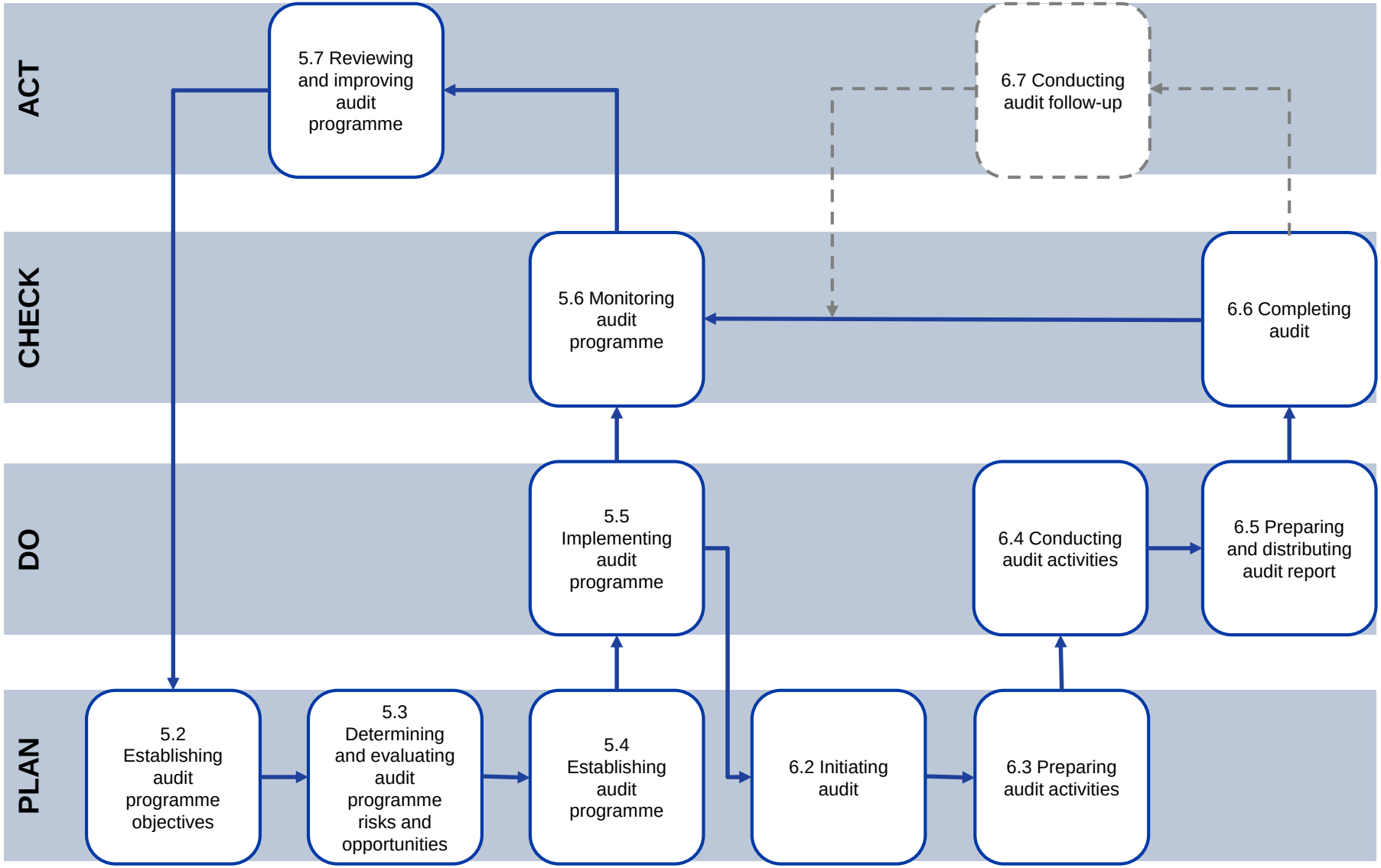

Level of Performance


Language

Audit Programme

- Audit Programme Objectives
- Audit Programme risks and opportunities
- Scope (extent, boundaries, locations)
- Schedule (number, duration, frequency)
- Audit type
- Audit criteria
- Audit methods employed
- Audit team members
- Relevant documented information

Process Flow for the Management of an audit Programme - ISO 19011



Process Audit VDA 6.3

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

The goal of the process audit is to check conformity of the processes and process steps to the requirements and specifications. Any deviation detected should be documented as an audit finding and evaluated based upon the product and/or the process risk.

The evaluation must consider what the resulting risks would be if the findings indicate non-compliant products.

Process Audit in Product's life cycle

Product Development Process Maturity (Progression) level and process risks evaluation

Regular Monitoring of the serial production and event orientated failure analysis and elimination

Customer

Issue Contract | **SOP**

Definition of Product & Process → Preselection of Suppliers; Potential Analysis → Product / Process Development → Serial Production → Customer Service (After Sales)

Supplier

Receive Order | **Issue Contract** | **SOP**

Offer Processing (Contract Review) → Product/ Process Definition → Preselection of Suppliers, Potential Analysis → Product/ Process Development → Serial Production → Customer Service After Sales)

VDA 6.3

- **Potential Analysis (P1)**
- **P2 / P3**
- **P2 – P4**
- **P5 – P7**
- **P5 – P7**

P2: Project Management
P3: Planning the product and process development
P4: Implementation of the product and process development
P5: Supplier Management
P6: Process analysis/ Production
P7: Customer support, Customer satisfaction, service

Audit Process Approach (Turtle diagram)

P2 – Project Management

P2.2 Resources available

a) Evidence of resource planning (taking another projects into account)
b) Resource planning for equipment
c) Resource planning for the project members is stablished and implemented
d) Budget for personnel and equipment (testing, laboratory) planned and released

P2.1 Cross functional team

a) Defined rolls, tasks, competence and responsibility of the project leader / project team, expert of technology
b) Project organizational chart
c) Composition of the project team
d) Team members qualifications
e) Responsibility and authority
f) Project organization and contacts are defined

a) Project plan meets customer specific requirements
b) All internal and customer defined milestones are fully incorporated in the project plan
c) Quality plan (MLA/ APQP)
d) Critical path from project plan
e) Changes coordinated with Customer
f) Prototype and preproduction plans
g) Product and process development
h) Detailed procurement activities

P2.3 Project Plan Definition

P2
Project Management

P2.5* Procurement Activities

a) Procurement activities implemented
b) List of suppliers for the project
c) Suppliers of service such as development, laboratories and maintenance.
d) Change management within the project meets the customer's specific requirements
e) Changes (initiated by Customer, in-house, or by Client) must be evaluated and if necessary the project plan must be adapted

P2.6* Change management ensured

P2.4 APQP Implemented

a) The advanced product quality planning meets customer specifics requirements
b) Project plan, Customer milestones and specifications
c) Verification and validation of the product and process requirements contained within the planning

P2.7 Escalation process established

a) The plan is regularly monitored for compliance and for target achievement
b) An escalation model (risk management) must be available for deviations in the project affecting the overall schedule

Audit Process Approach (Turtle diagram)

P3 - Planning the product and process development

P3.5 Infrastructure available

a) CAx equipment
b) Capacity planning for all resources
c) Test/ Inspection/ Laboratory equipment (Internal and external)
d) Production sites, tools, production and testing equipment
e) Availability of qualified personnel for respective tasks

P3.5 Qualified personnel available

a) Availability of qualified personnel for respective tasks
b) Employee training when introducing new technologies and products
c) Necessary infrastructure for customer service
d) Training plan
e) Qualification matrix

P3.1 Requirements

a) Specific process and product requirements available
b) Inquiry documents
c) Contract documents
d) Customer requirements
e) Legal requirements, purchasing conditions
f) Quality agreements, logistic requirements
g) Schedules, technical delivery conditions
h) Acces to customer portals
i) Experience with previous projects
j) Specifications, technical drawings, special characteristics

P3 Planing the product And process development

P3.2* Manufacturing Feasibility evaluated

a) Manufacturing feasibility evaluation (including purchasing parts)
b) Dates, timeframes
c) All determined product and process specific requirements (technology, function, quality, logistics, software)
d) Notification and deviations of customer requirments that can not be fulfilled

P3.3 Planified development activities

a) Planning of product and process
b) Overall schedule for product and process development
c) Lay out inspection and functional verification plans
d) Risks analysis (Product and process FMEA, QFD, Statistical testing plan, DOE, Shainin, Taguchi)
e) Logistics planning for all phases of the product and process development
f) Detailed planning for the reliability testing, functional testing, trial plan
g) Deadlines for the production trial run, tool timing plans, test equipment

3.4 Customer service, Support, satisfaction

a) Regular status checks on the progress of the development (reviews)
b) Inspection planning for standard and stress testing
c) Emergency plans

Audit Process Approach (Turtle diagram)

P4 – Implementation of the product and process development

P4.3 Resources available for series production

a) A process to determine resources
b) Test equipment, laboratory equipment, machinery, supporting processes
c) Facility lay out
d) Transport routes, containers, storage
e) Supporting processes, e.g. IT, logistics
f) Outsourced processes

P4.2 Human resources qualified

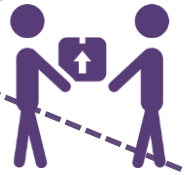
a) Personnel plan (pre-production, production start up and serial production)
b) Qualification to relevant tasks
c) Including external service providers
d) Needs assessments during P&P Development
e) Job profile
f) Knowledge of methods and foreign languages

a) P&P Development plan
b) FMEA (Reliability, safety, function)
c) Control plan/ inspection plan
d) Special characteristics
e) Testing plan (Prototype/ pre production)
f) Out-sourced products and services
g) Findings from Prototype/ pre production
h) Test equipmen

P4.1* Plans implemented

P4
Implementation of the Product and Process Development

P4.4* Approvals
P4.8* Handover



a) Test reports, protocols
b) Supporting docs (purchased parts)
c) Sampling results
d) Specifications/ DWGs
e) FMEA, Control Plan IMDs
f) Product testing
g) Conformity with legal requirements
h) Logistics concept
i) Proof of capability
j) Tool approvals
k) Transfer to series production

P4.5 Manufacturing and inspection specs
P4.7 Customer service

a) Risk analysis (FMEA/ FTA)
b) Process control plan (Prototypes, pre-series)
c) Lay out inspection and functional verification plan
d) Product audits
e) Specifications
f) Customer requirements
g) Handover protocols
h) Work instructions
i) Part history
j) Contingency plans

P4.6 Trial run

a) Production trial run
b) Cycle time
c) Intended production rate
d) Process capability study
e) Measurement reports

Audit Process Approach (Turtle diagram)

P5 – Supplier Management

P5.5* Quality of out-sourced products and services

a) Risk analysis (FMEA/ FTA)
b) Process control plan (Prototypes, pre-series)
c) Lay out inspection and functional verification plan
d) Product audits
e) Part history
f) Specifications
g) Customer requirements
h) Handover protocols
i) Work instructions

P5.7 Trained personnel

a) Job description
b) Responsibility and authority
c) Incoming Inspection, complaint processing, supplier management, supplier audit
d) Qualification requirements
e) Knowledge of previous complaints
f) Knowledge about product and process
g) Qualification matrix

P5.1 Approved suppliers

a) Supplier selection criteria
b) Qualification programme for suppliers
c) Evaluation of quality capability (QMS Audit, Process Audit A/ B/ C)
d) Potential analysis results
e) Prototype suppliers
f) Machinery, testing/ measurement equipment, tooling supplier
g) Outsourced service suppliers
h) Customer requirements/ Agreements
i) Engineering requirements
j) Legal Regulatory Requirements

P5
Supplier Management

P5.6 Received and stored

a) Packaging
b) Inventory control
c) Labeling (traceability,test status, work secuence, use status)
d) Quarantine areas
e) FIFO
f) Climatic conditions, protection against damage, contamination, corrosion
g) Terms of transport

P5.2 Customer requirements

P5.4* Approved outsourced products

a) Approved outsourced products and services before serial production of new/ changed products/ processes
b) PPA-Reports, PPAP
c) Proof of capability for special characteristics
d) Qualification test / reports
e) Change management
f) Approval of agreements

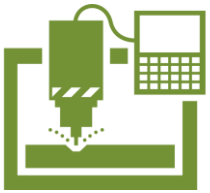
P5.3 Target agreements for supplier performance

a) Measurable targets for quality, delivery quantity, punctuality, PPM.
b) QM agreements
c) Escalation mechanisms
d) Avoidance of special trips
e) Reduction of rejects
f) Reduction of work in progress inventory

Audit Process Approach (Turtle diagram)

P6 – Process Analysis Production

P6.4 6.4.1*, 6.4.2, 6.4.3*, 6.4.4, 6.4.5,



a) Machine/ process capability for special characteristics/ process determining parameters
b) Warning deviations from limit specifications/ parameters
c) Capability of replacement tools
d) Cleanliness requirements, conditions for the work places
e) Lay out and condition of equipment, tools, fixtures and handling facilities under production requirements
f) Maintenance (Corrective, Preventive, Predictive, schedule, spareparts, metrics)
g) Tool management (Status, ownership, preservation, etc)
h) Calibration, MSA, reference components, set up parts

P6.3 6.3.1*, 6.3.2, 6.3.3

a) Training, qualification evidence
b) Qualification matrix
c) Initial training plan with evidence
d) Knowledge about the product and failures occurred
e) Handling of measurement and testing equipment
f) Training in special characteristics
g) Training in work safety, environmental aspects
h) Job descriptions
i) Shift plan, workforce scheduling

P6.1 6.1.1, 6.1.2, 6.1.3, 6.1.4, 6.1.5*

a) Project transfer to series production (PPAP, Sign off, etc)
b) Process and Product FMEA
c) Tools, test and measurement equipment
d) Parts/ components (Agreed quality, quantity, packing, time, place)
e) Defined store areas, Kanban, FIFO
f) Incoming materials release (to Customer specifications, requirements, legal)
g) Change management

P6
Process Analysis Production

P6.6 6.6.1, 6.6.2, 6.6.3, 6.6.4*

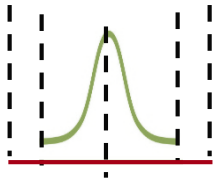
a) Parts forwarded to defined storage/ holding points
b) Kanban, JIT, FIFO
c) Special requirements for product preservation
d) Customer requirements
e) Quality agreements with the customer
f) Target agreements
g) Packaging instructions

P6.2 6.2.1, 6.2.2, 6.2.3*, 6.2.4*, 6.2.5

a) Work instructions
b) Control plan (test/ inspection documentation, frequencies, methods, qualifications)
c) Process parameters, Poka yoke
d) Control limits for process control charts
e) Inspection instructions
f) Release of reworked parts
g) First piece/ part release
h) Quality records
i) Product and Process FMEA
j) Special characteristics
k) Non conforming product management

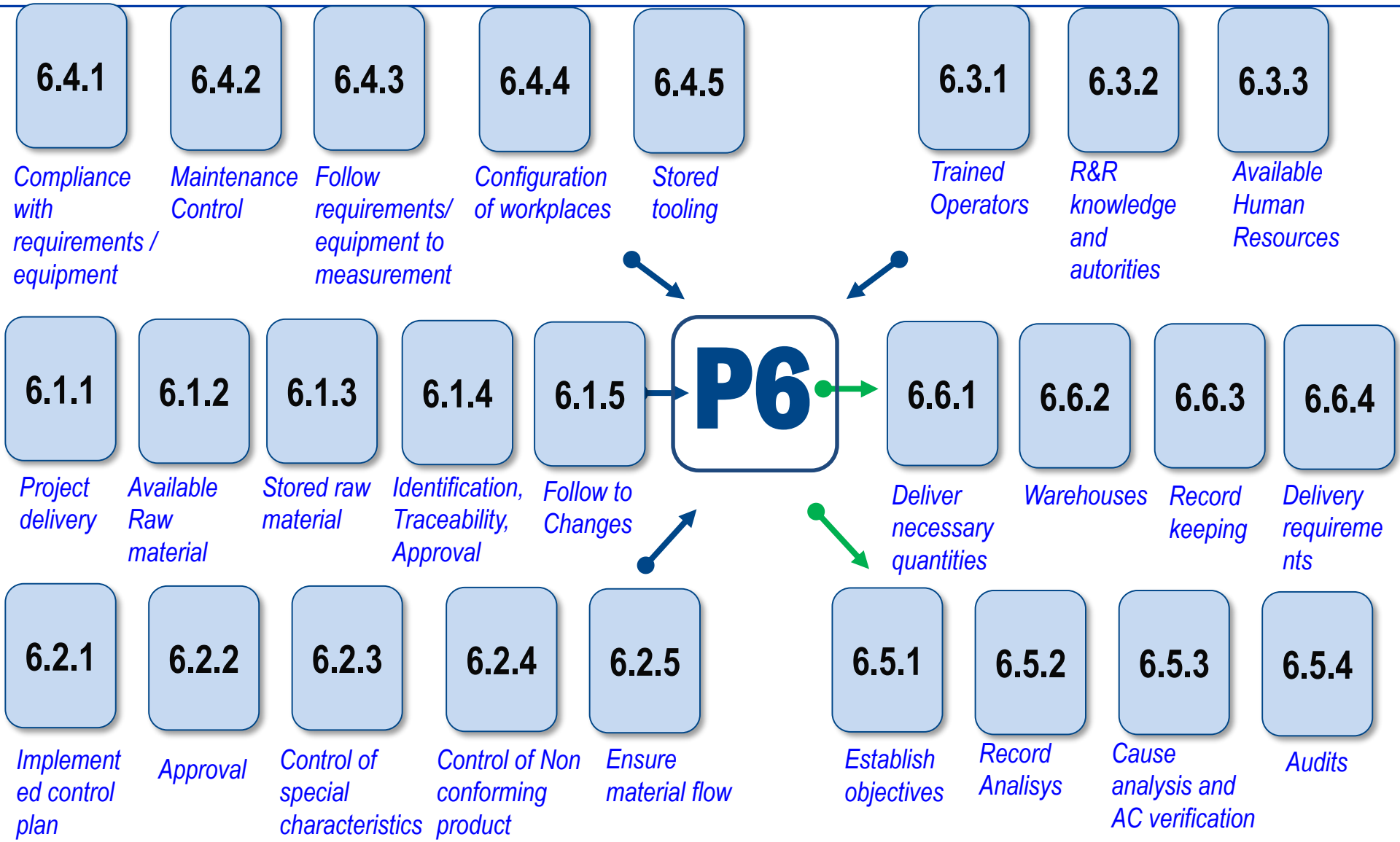
P6.5 6.5.1, 6.5.2, 6.5.3*, 6.5.4

a) Availability of instalations an machines
b) Number of parts produced per unit to time
c) Rework, scrap trends
d) Production runs with no reworking, first passes, first time thorugh quality, first pass yield
e) Quality metrics (failure rates, audit results)
f) Process capability
g) Control charts
h) Error costs
i) Pareto analyses
j) Root cause analysis
k) Process and product audit



Audit Process Approach (Turtle diagram)

P6 – Process Analysis Production



Identification of process risks

P7 – Customer support, customer satisfaction, service

P7.3* Parts supply

a) Concepts to ensure supplies are available and up to date
b) Contingency plans (e.g. for alternative production, supplier, transport)
c) Capacity and reaction time for sorting actions
d) Use of externally capacity
e) Communication regarding supply shortages
f) Escalation paths when introducing special actions
g) Blocking of parts

P7.5 Qualified personnel

a) Organizational chart
b) Evidence of knowledge of the product/ specifications/ customer requiremnts
c) Standards/ law (product liability)
d) Processing/ use
e) Failure analysis
f) Evaluation methods
g) Quality Techniques
h) Foreign language

a) Quality agreements with the customer
b) Lay out inspection and functional verification concept e.g. carried out products audits, function tests, endurance tests
c) Inclusion of sub-supplier for the supply of spare parts
d) Supply guarantee after serial production
e) Certification of QMS System

P7.1 Conform to Requirements

P7

Customer support, customer satisfaction, service

P7.1 Conform to Requirements

P7.2 Customer service

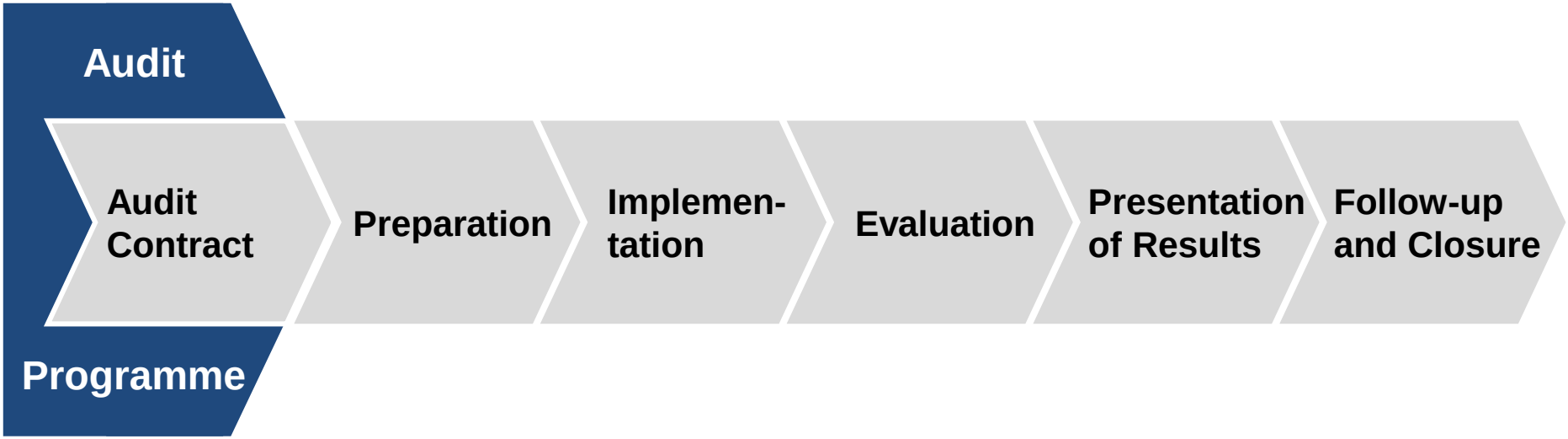
P7.4* Analysis and correction

a) Process for processing complaints, 8D Process
b) Internal and external analysis facilities (Laboratories, comprehensive testing facilities, personnel)
c) Use of problem solving methods
d) Performance tests
e) Flow of information to the customer by deviations
f) Quality control loop
g) Customer satisfaction metrics
h) FMEA
i) Access to necessary release documents
j) Testing concept for defective parts in field
k) Performance indicators for processing complaints

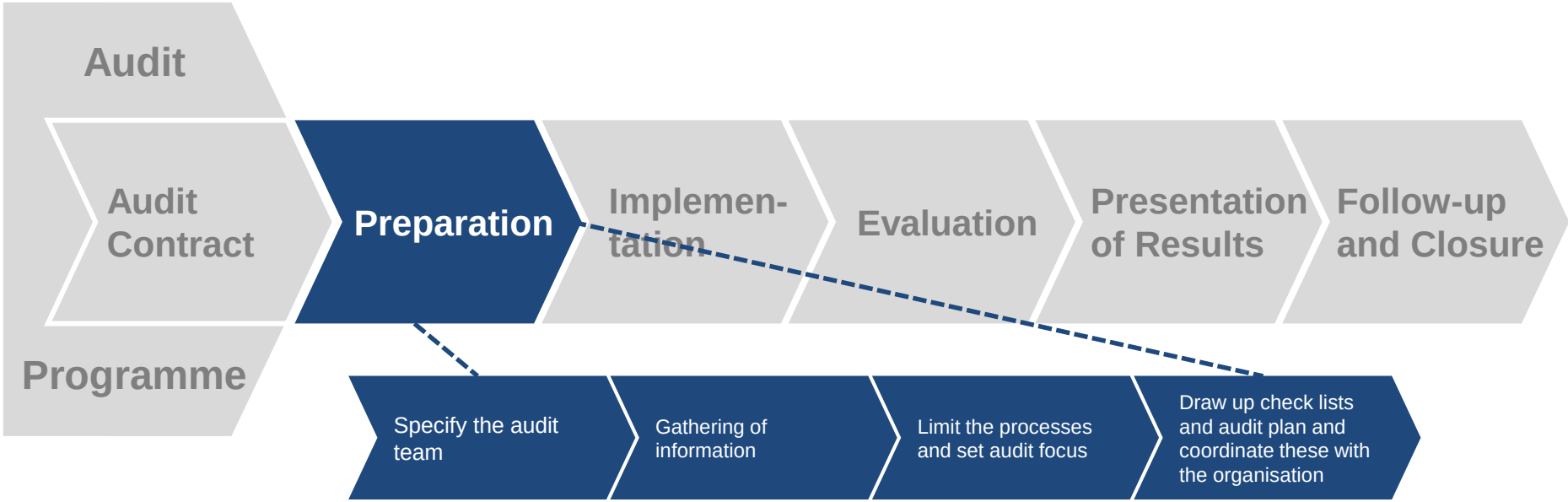
P7.2 Customer service

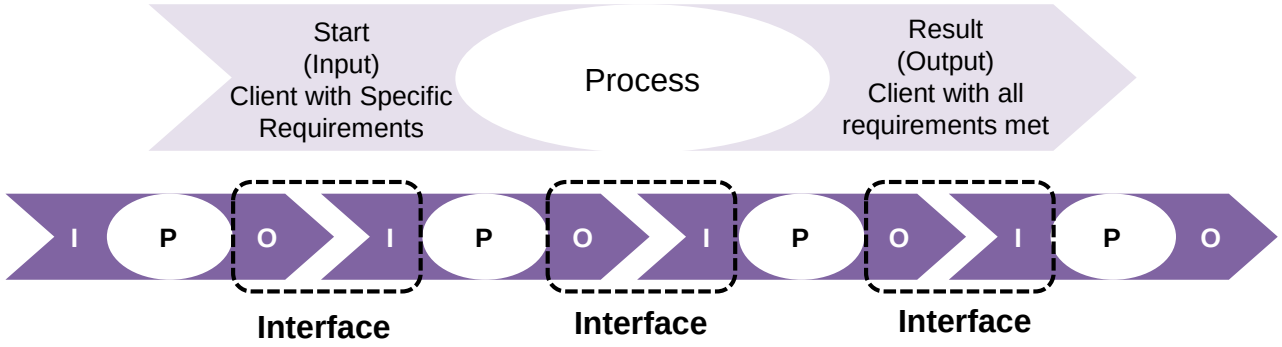
a) Knowledge of the product application
b) Knowledge of problems with product and complaints regarding the product or transport
c) Implementation of new requirements
d) Notification of improvement actions
e) World-wide customer service
f) Information from the customer by non-compliance with the requirements

Audit Process – VDA 6.3



Audit Preparation





Potential risks within the process must be determined as early as the preparations for the audit

Auditor Qualification

	Specialized Knowledge	Specialized Training	Professional Experience
 **Internal Auditor**	• Good Knowledge of quality tools and methods • Knowledge of the relevant Customer specific requirements • Knowledge of the relevant management system requirements • Specific knowledge regarding the product and process	• Successful participation in a VDA 6.3 training (pass mark in the knowledge test/ qualification certificate)	• A minimum of 3 years professional experience (from 2 years professional experience Company training periods may be considered additionally), preferably in manufacturing companies within the automobile industry, including at least one year experience in quality management
 **Supplier Auditor**	• Excellent knowledge of quality tools and methods • Auditor qualifications (negotiation, conflict management, audit procedure) • Knowledge of the relevant Customer specific requirements • Knowledge of the relevant management system requirements • Specific knowledge regarding the product and process	• Auditor qualification as EN ISO 19011 (e.g. VDA 6.3 – basic qualification, first / second party auditor for DIN EN ISO 9001, IATF 16949 or VDA 6.1) • Successful participation in a VDA 6.3 training (pass mark in the knowledge test/ qualification certificate)	• A minimum of 5 years professional experience (from 3 years professional experience Company training periods may be considered additionally), preferably in manufacturing companies within the automobile industry, including at least two years experience in quality management.

In addition Auditor code of conduct

Potential analysis

Questions selected from the process elements P2 – P7
P2 = 7, P3 = 2, P4 = 3, P5 = 5, P6 = 15, P7 = 4. **Total =36**

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.	

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

Award of contract

Clarify the initial situation and limit the contract	Request supplier self-evaluation and rate this	Compile questionnaire module	Specify the audit team	On site visit	Risk evaluation	Clarify resources needed for qualification
Unknown supplier Unknown facility Unknown technology	Feedtack to supplier (request any necessary additional information)	Create questions using the knowledge data-base (for product and process requirements or specifications	The audit team should be made up of experts in: • Quality • Development • Procurement • Logistics	Process evaluation based on a similar process or product (another Customer) • Report • Presentation of results	• Prognose • Recomendation • Veto	• Clarify the provision of internal resources (Customer), e.g. taking part in a supplier development programme • Clarify the provision of external resources in the nomination documents, e.g. construction of necessary infrastructure

End of auditor responsibility

Potential analysis

Fully Approved Potential Supplier

The contract award (nomination) for the Project, component or product group by the Customer is possible with out restriction.

Conditionally Approved Supplier

Only a conditional approval for a contract award can be given to minimize the risk:

- Restriction to a defined quantity (small-scale production)
- Restriction to a defined product
- Restriction to part-quantities of the overall enquiry
- The (Potential) supplier receives a trial order on probation
- The (Potential) supplier is included in a supplier development proram
- Special support from supplier development teams with careful on monitoring the progress of the project

The (Potential) supplier is barred

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

Process audit for material products

For Questions answered n/a reason must be stated, at least 2/3 of the questions must be answered.
If non-conformities from previous audit are repeated, the lack of implementation of corrective actions can also be regarded as a deviation

Points	Assessment of Compliance with requirements
10	Full Compliance with requirements
8	Requirements mainly++ fulfilled, minor deviations
6	Requirements partialy fulfilled; significant deviations
4	Requirements inadequally fulfilled, major deviations
0	Requirements not fulfilled

++ *The relevant requirements are met in most instances no special risks identified*

Immediate actions may be required depending on the risk findings

Overall level of compliance:

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

Rules for downgrading

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

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

- At least one process element (P2 to P7) or process step (E1 to E_n) is evaluated with a level of achievement E_G or $E_{G(Pn)}$ or E_n from < 80%.
- A level of achievement in one of the sub-elements of P6 is < 80%.
- At least one *-question is rated with 4 points.
- At least one question from the Process audit is rated with 0 points.

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

- At least one process element (P2 bisP7) or process step (E_1 bis E_n) is evaluated with a level of achievement E_G or $E_{G(Pn)}$ or E_n from < 70%.
- A level of achievement E_{U1} to E_{U7} in one of the sub-elements of P6 is < 70%.
- At least one *-question is rated with 0 points.

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

Product Audit

The product audit serves as management tool for the independent evaluation of products from the Customer’s viewpoint and to provide assurance against liability claims arising from deficiencies in products and property. It also indicates the potential for continuous improvement.

In a product audit the specified characteristics of the product are checked (e.g. conformance with the parts list, product dimensions, materials, functionality, reliability, packaging, identification) and known Customer expectations in a specified condition (e.g. packed, the product as new, after use, etc.)

Product Audit

Product Audits can be carried out at any stage in the manufacturing process

a. On semi-finished or finished items from an individual process
b. On components (e.g., a bolt, hose, crankcase, etc.)
c. On assembles such as a control unit, injection pump, auxiliary heater, motor, transmission, bodywork
d. On the complete vehicle

A product audit is not intended as:

a. A repetition of in-production inspection operations
b. A means of directed process control
c. General proof of the effectiveness of a quality management system

Objective and area of application

Difference between a product audit and other checks

	Product Audit Covered by the requirements of IATF 16949 and VDA 6.1	In-process checks (e.g., Monitoring process parameters, SPC, tensile strength, torques, etc…)	Requalification checks Covered by the requirements of IATF 16949, Section 8.6.2
Purpose	1. To identify the potential for improvements 2. To play the role of the Customer (internal & external) regarding the finished product 3. To take account of items relevant to the Customer (e.g., consider feedback from field) 4. To prove reliability requirements 5. To prove the interplay of product characteristics (function check) 6. To demonstrate characteristics not checked in the production control plan 7. To demonstrate product characteristic which may influence customer satisfaction 8. To demonstrate product characteristics checked via equivalents in in-process checks 9. To demonstrate packing and labeling	Process Control IATF 16949, Section 8.5.1.3 – Verification of job set-ups The organization shall: a) Verify job set-ups when performed, such as an initial run of a job, material change over, or job change that requires a new set-up d) Perform first-off/ last-off part validation, as applicable	A layout inspection and a functional verification to applicable customer engineering material and performance standards.
Frequency of execution	To the internal audit program and as required	To the production control plan Based on the production order	To the production control plan Repeated periodically, generally at longer intervals
Documentation/ evaluating results	Test/ inspection results Audit report Part of the management review	To the production control plan	To the production control plan Requalification document
Contents	An evaluation of product quality to an internal requirement which at least covers customer requirements	Part of the contract with the customer	Part of the contract with the customer

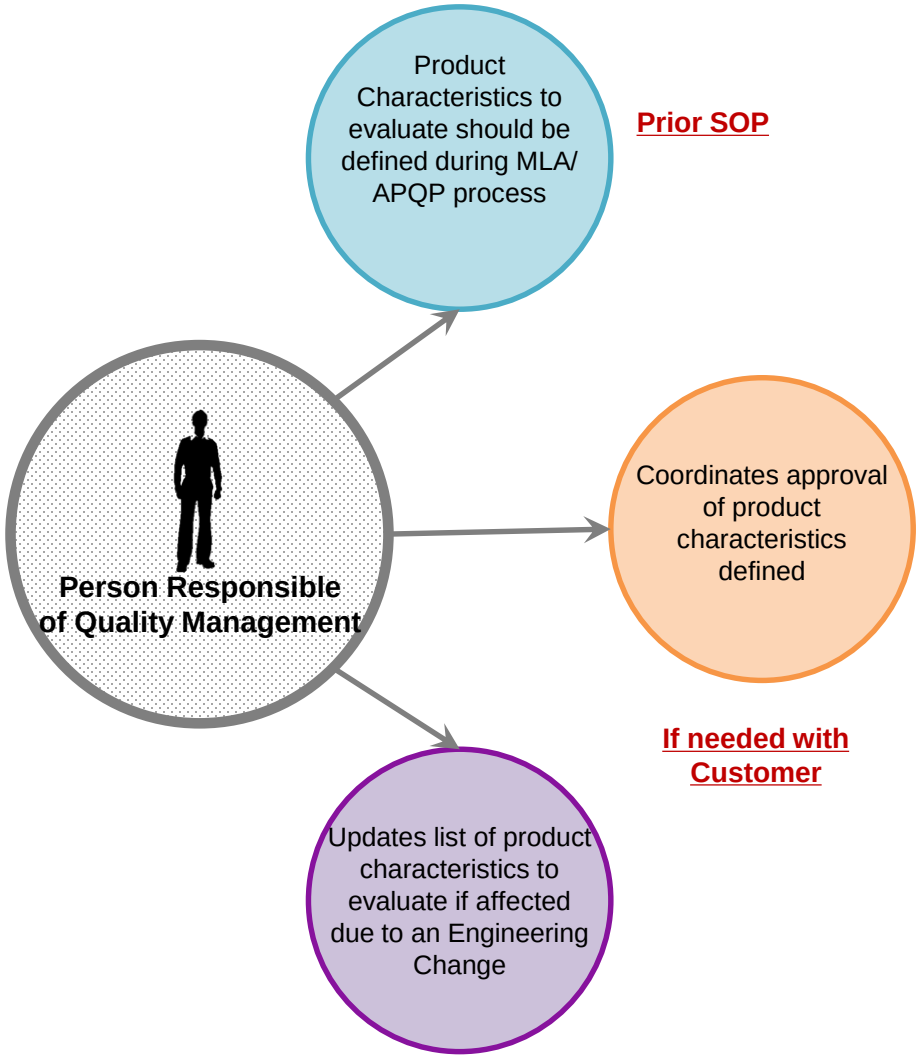
Carrying out a product audit

- With the development of the Audit Programme, the product characteristics to review are defined:

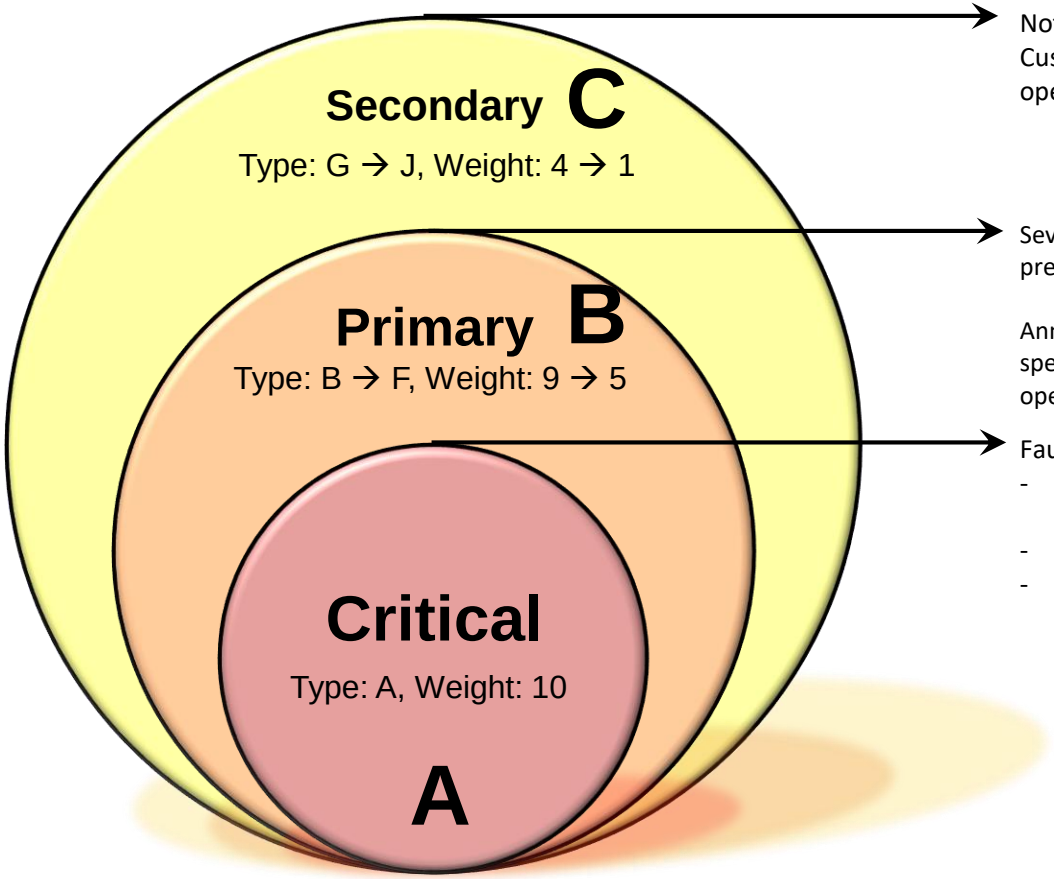
  a) *Material*
  b) *Dimensions*
  c) *Appearance (and other attributive characteristics)*
  d) *Functionality*
  e) *Packaging*
  f) *Identification (labeling)*

- Review product characteristic requirements in technical documentation, such as:

  a) *Drawings*
  b) *Customer Requirements*
  c) *Customer Agreements*
  d) *Packaging standards*
  e) *Control Plan*
  f) *Testing and inspection specifications*
  g) *FMEAs*
  h) *International standards (ISO, ASME, SAE, etc…)*
  i) *Regulations*



Examples of failure categories



Noticeable concern, will be not satisfactory by the Customer. Customer concern and functional issues in operation are to be expected with higher frequency.

Severe nuisance, deficiency, significantly outside predetermined standards.

Annoying, Customer complaints are expected, specification deviation, disturbance of the Customer operation is possible

Fault will certainly result in Customer complaints
- Safety risk, violation of legal regulations, breakdown
- Product cannot be sold / function not fulfilled
- Extreme Surface appearance complaints

Examples of failure categories

Fault Category	Fault description/ effect	Immediate action	Follow-up action
A	Fault will certainly result in customer complaints. - Safety risk, violation of legal regulations, breakdown, - Product cannot be sold / function not fulfilled - Extreme surface appearance complaints	- Quarantining / Sorting of available stocked parts - Information to receiving plants and risk assessment - Corrective actions on the manufacturing / inspection process & if necessary 100% inspection; - Intensified inspection on processes and on finished products; if necessary 100% inspection before shipment; - Permit requested from Engineering - Further measures to be Agreed with the Customer receiving plant (see Formel Q Konkret)	- Continued analysis of process / inspection activities - Development & implementation of corrective measures - Proving of Process Capability and Zero defects - Effectiveness verification of implemented measures - If necessary, change of Specification.
B	Severe nuisance, deficiency, significantly outside predetermined standards. Objectional, annoying, customer complaints are expected, specification deviation, disturbance of the customer operation is possible.		
C	Noticeable concern, will be critised by the customer. Customer concern and functional issues in operation are to be expected with higher frequency.	- Information to receiving plants for coordination of actions	

Examples of failure categories

MATRIX TO DETERMINE THE TYPE AND WEIGHT FACTOR, DEPENDING ON ITS EFFECTS											
EVALUATION CRITERIA		CONSEQUENCE OF FAILURE									
	Failure weight. Type of failure	10 A	9 B	8 C	7 D	6 E	5 F	4 G	3 H	2 I	1 J
	Failure classification	Critical failure	Main failure		Main Failure			Secondary Failure		Secondary Failure	
	Consequences of the function	Failure that endangers life	Totally detrimental usability		Greatly diminished usability (including comfort)			Totally detrimental usability (including comfort)		No detrimental usability	
	Customer reaction	Very harmful (Security)	Very harmful (Function)		The customer always feels upset or angry			The customer hardly feels upset		None	
	Probability of claim	Out of doubt	Very high	Median	Very high	High	Median	Little	Very Little	Unlikely	
	Consequences of the failure	Transgression of the law. - Units return action	- Stay in the way. - May cause damage to other construction parts		You must go to the workshop. Reliability in doubt. Poor quality in the delivery of units			Possibly faults are eliminated in guarantee by quality image		None	
	Reaction in the next step in production	Scrap	- Great danger of damage to machine and tools. - Mounting difficulties. - Rework, caused mostly scrap		They can damage machines and tools. Greater rework in assembly, which may cause failures. Rework, Caused, Waste			Eventually a little more work		None	

Questions