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**IATF 16949:2016
QMS**

Internal Auditing

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Welcome to

Internal Auditing training program

based on IATF 16949:2016

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Objective of this Program



To understand,

- § Accreditation and Certification process
- § Automotive Process Approach
- § Requirements of IATF 16949:2016 QMS

Agenda Day 1



- § 09.00 am Course Registration
- § 09:15 am Opening Session - Introduction
- § 09:30 am Session on Accreditation and Certification process
- § 11:15 am Tea Break
- § 11:30 am Session on Automotive Process Approach
- § 01:30 pm Lunch break
- § 02.00 pm Exercises on IATF 16949:2016 QMS Requirements
- § 03:45 pm Tea Break
- § 04.00 pm Session on IATF 16949:2016 QMS Requirements
- § 05.15 pm Question and Answer Session
- § 05:30 pm End of the Day

Agenda Day 2



- § 09.00 am Discussion on previous day's agenda.
- § 09:15 am Session on IATF 16949:2016 QMS Requirements
- § 11:15 am Tea Break
- § 11:30 am Session on IATF 16949:2016 QMS Requirements
- § 01:30 pm Lunch break
- § 02.00 pm Exercises on IATF 16949:2016 QMS Requirements
- § 03:45 pm Tea Break
- § 04.00 pm Session on IATF 16949:2016 QMS Requirements
- § 05.15 pm Question and Answer Session
- § 05:30 pm End of the Day

Agenda Day 3



- § 09.00 am Discussion on previous day's agenda.
- § 09:15 am Session on Auditing guidelines
- § 11:15 am Tea Break
- § 11:30 am Session on Auditing guidelines
- § 01:30 pm Lunch break
- § 02.00 pm Exercises on Auditing guidelines
- § 03:45 pm Tea Break
- § 04.00 pm Written Exam
- § 06:00 pm End of the Day

IATF 16949:2016 QMS

Accreditation and Certification Process



Accreditation and Certification Process



QMS Overview,

- § Journey of QMS – BS 5750...ISO 9001...QS 9000....ISO/TS 16949....IATF 16949
- § IAF (ISO 9001) and IATF (IATF 16949)
- § Technical Committee (TC 176) and Oversight Offices
- § Automotive Associations (JAMA, AIAG) and OEMs
- § Country specific Accreditation Bodies (NABCB, Dakks, ANAB)
- § Certification Bodies (TUV, BVQI, SGS, UL, DNV)
- § Certified Clients (OEMs and Suppliers)

Accreditation and Certification Process



IATF members Includes,

- § General Motors
- § Chrysler
- § Ford
- § BMW
- § Fiat
- § Peugeot
- § Volkswagen

Accreditation and Certification Process



IATF members Includes,

- § ANFIA – Italy (Associazione Nazionale Fra Industrie Automobilistiche)
- § AIAG – USA. (Automotive Industry Action Group)
- § CCFA – France (Comite des Constructeurs Francais d'Automobiles)
- § FIEV – France (Federation des Industries des Equipements pour Vehicules)
- § SMMT Ltd. – UK (Society of Motor Manufacturers and Traders Ltd.)
- § VDA – Germany (Verband der Automobilindustrie)
- § JAMA – Japanese Automotive Manufacturer's Association

Accreditation and Certification Process



Oversight offices of IATF,

- § ANFIA – ITALY - Associazione Nazionale Fra Industrie Automobilistiche
- § IAOB - US – International Automotive Oversight Bureau
- § IATF FRANCE – FRANCE
- § SMMT - UK– Society of Motor Manufacturers and Traders
- § VDA QMC – GERMANY

Accreditation and Certification Process



Indian Accreditation Bodies,

- § NABC – National Accreditation Board for Certification Bodies
 - § NABL – National Accreditation Board for Laboratories
 - § NABET – National Accreditation Board for Education and Training
- Every country specific Accreditation Body will be a part of IAF / IATF

Accreditation and Certification Process



Major Tasks of IATF,

- § Criteria for CB recognition
- § Certification Body Processes
- § Certification Auditor Qualification
- § Certificate Content Requirements

Accreditation and Certification Process



Major Tasks of Oversight Office,

- § Scheduling witness audits for CB
- § Monitoring the CB
- § Monitoring CB Auditors
- § CB Auditor Qualification and Training

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02-Dec-16

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Accreditation and Certification Process



Different Standards – Comparison,

ISO 9001:2015

QS 9000

ISO/TS 16949:2009

IATF 16949:2016

VDA 6.3 Process Audit



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Slide 16

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Certification Requirements,

- § Definition of Process – Manufacturing process
- § Definition of Automotive – QS 9000 and IATF 16949
- § Definition of Site – ISO 9001 and IATF 16949
- § Single Site and Multi Site Certification
- § Extended Work Bench
- § Remote Location
- § Remote Function

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Slide 17

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Certification Requirements,

- § Main Certificate and Sub Certificate - ISO 9001
- § Site Certificate - IATF 16949
- § LOC - Letter of Conformance – Provisional Certificate
- § Scope Statement and Exclusion – Design, manufacturing, assembly, supply and after sales service
- § On site and off site Man day requirement

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Certification Requirements,

- § Lead Auditor Qualification
(Industrial experience...process and product knowledge and QMS experience...implementation and audit experience)
- § Lead Auditor
- § Auditor
- § Trainee Auditor (Observer)
- § External Auditor
- § Technical Expert
- § Guide

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Certification Requirements,

- § Pre-assessment Audit
- § Stage 1 Audit – Adequacy Audit / Document Review Audit
- § Stage 2 Audit – Compliance Audit / Certification Audit
- § Audit Opening Meeting
- § Audit Closing Meeting
- § Audit Report to VETO

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Certification Requirements -

- § NC Closure by Client
- § VETO Approval
- § Certificate
- § Validity date and Audit due date
- § Surveillance Audits
- § Suspension and Termination
- § Recertification audits

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Applicable Standards -

- § Clients – ISO 9001, IATF 16949, ISO 14001
- § Auditors – ISO 19011, ISO 9000
- § Certification body – ISO 17021

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Accreditation and Certification Process



Customer Specific Requirements -

- § Specific Requirements of Customers for establishment and implementation of Quality Management System (CSR)
- § Identification, review, communication, awareness, establishment, implementation, effectiveness and compliance of CSR is a mandatory requirement of IATF 16949 QMS standard.
- § It's a responsibility of an Organization to identify, review, communicate, establish, implement, maintain and comply to Customer Specific Requirements.
- § OEM's (and Tier 1) have their own derived CSRs applicable for suppliers.

Any Questions?





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Automotive Process Approach

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Process Approach



Business Processes – (Engineering Industry)

- § Business Planning and Management Review
- § QMS and Internal Audit
- § Product Design and Development (Part Drawing and Engineering Specifications)
- § Process Design and Development (Establishment of 6M and E Resources)
- § Marketing and Sales
- § Production Planning and Production – Press work, Molding, Machining
- § Purchase and Stores
- § Outsourcing (Heat Treatment, Surface Coating)
- § Production
- § QA and Lab
- § Training
- § Maintenance and Tool Room
- § Packing and Dispatch
- § Customer Feedback

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Process Approach



Organization Business Process Mapping

- § Site specific Processes
- § Remote Function and Remote Location
- § Customer Oriented Processes, Management Processes and Support Processes
- § Sequence of Processes
- § Process Interaction (Interface of other processes)
- § Interested Parties
- § Internal and External Factors (Context of the Organization)

Process Approach



Process Analysis (Turtle)

- § Process Input and Process Output (PDCA)
- § Process Infrastructure, Utility, Hardware and Software Resource Requirement
- § Process Owner Competency Requirement (Generic skills, Soft skills and Technical skills)
- § Process Documents and Records Requirement
- § Process Interface (supporting processes)
- § Process Performance Objective (SMART – Effectiveness and Efficiency)
- § Interested Parties and Internal and External Factors
- § Process Risk, Effect, Escalation, Mitigation Plan, Contingency Plan



Any Questions?



IATF 16949:2016 QMS

Requirements Clause 1 Scope

IATF 16949:2016 QMS Requirements



1 Scope

This International Standard specifies requirements for a quality management system when an organization:

- a) Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

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1 Scope

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

IATF 16949:2016 QMS Requirements



1.1 Scope - automotive supplemental to ISO 9001:2015

This Automotive QMS Standard defines the quality management system requirements for the design and development, production and, when relevant, assembly, installation, and services of automotive-related products, including products with embedded software.

This Automotive QMS Standard is applicable to sites of the organization where manufacturing of customer-specified production parts, service parts, and/or accessory parts occur.

This Automotive QMS standard should be applied throughout the automotive supply chain.

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 33

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Requirements

Clause 2

Normative References



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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 34

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2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies.

For undated references, the latest edition of the referenced document (including any amendments) applies. ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

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2.1 Normative and informative references

Annex A (Control Plan) is a normative part of this Automotive QMS standard.

Annex B (Bibliography - automotive supplemental) is informative, which provides additional information intended to assist the understanding or use of this Automotive QMS standard.



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Requirements Clause 3 Terms and Definitions

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Slide 37

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

3.1 Terms and definitions for the automotive industry

Accessory part

Customer-specified additional component(s) that are either mechanically or electronically connected to the vehicle or powertrain before (or after) delivery to the final customer (e.g., Custom floor mats, truck bed liners, wheel covers, sound system enhancements, sunroofs, spoilers, superchargers, etc.)

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02-Dec-16

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Slide 38

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3.1 Terms and definitions for the automotive industry

Advanced product quality planning (APQP)

Product quality planning process that supports development of a product or service that will satisfy customer requirements; APQP serves as a guide in the development process and also a standard way to share results between organizations and their customers; APQP covers design robustness, design testing and specification compliance, production process design, quality inspection standards, process capability, production capacity, product packaging, product testing and operator training plan, among other items

Aftermarket part

Replacement part(s) not procured or released by an OEM for service part applications, which may or may not be produced to original equipment specifications

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 39

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3.1 terms and definitions for the automotive industry

Authorization

Documented permission for a person(s) specifying rights and responsibilities related to giving or denying permissions or sanctions within an organization

Challenge (master) part

Part(s) of known specification, calibrated and traceable to standards, with expected results (pass or fail) that are used to validate the functionality of an error-proofing device or check fixtures (e.g., Go / no-go gauging)

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 40

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3.1 Terms and definitions for the automotive industry

Control plan

Documented description of the systems and processes required for controlling the manufacturing of product (see Annex A)

Customer requirements

All requirements specified by the customer (e.g., technical, commercial, product and manufacturing process-related requirements, general terms and conditions, customer-specific requirements, etc.)

Customer-specific requirements (CSRs)

Interpretations of or supplemental requirements linked to a specific clause(s) of this Automotive QMS Standard

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3.1 Terms and definitions for the automotive industry

Error proofing

Product and manufacturing process design and development to prevent manufacture of nonconforming products

Escalation process

Process used to highlight or flag certain issues within an organization so that the appropriate personnel can respond to these situations and monitor the resolutions

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3.1 Terms and definitions for the automotive industry

Laboratory

Facility for inspection, test, or calibration that may include but is not limited to the following:
chemical, metallurgical, dimensional, physical, electrical, or reliability testing laboratory scope
controlled document containing

- § Specific tests, evaluations, and calibrations that a Laboratory is qualified to perform;
- § A list of the equipment that the laboratory uses to perform the above; and
- § A list of methods and standards to which the laboratory performs the above

Manufacturing

Process of making or fabricating

- § Production materials;
- § Production parts or service parts;
- § Assemblies; or
- § Heat treating, welding, painting, plating, or other finishing services

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 43

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3.1 Terms and definitions for the automotive industry

Manufacturing feasibility

An analysis and evaluation of a proposed project to determine if it is technically feasible to manufacture the product to meet customer requirements. This includes but is not limited to the following (as applicable): within the estimated costs, and if the necessary resources, facilities, tooling, capacity, software, and personnel with required skills, including support functions, are or are planned to be available

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 44

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3.1 Terms and definitions for the automotive industry

Multi-disciplinary approach

Method to capture input from all interested parties who may influence how a process is administered by a team whose members include personnel from the organization and may include customer and supplier representatives; team members may be internal or external to the organization; either existing teams or ad hoc teams may be used as circumstances warrant; input to the team may include both organization and customer inputs

No trouble found (NTF)

Designation applied to a part replaced during a service event that, when analyzed by the vehicle or parts manufacturer, meets all the requirements of a "good part" (also referred to as "No Fault Found" or "Trouble Not Found")

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 45

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3.1 Terms and definitions for the automotive industry

Outsourced process

Portion of an organization's function (or processes) that is performed by an external organization

Periodic overhaul

Maintenance methodology to prevent a major unplanned breakdown where, based on fault or interruption history, a piece of equipment, or subsystem of the equipment, is proactively taken out of service and disassembled, repaired, parts replaced, reassembled, and then returned to service

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 46

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3.1 Terms and definitions for the automotive industry

Predictive maintenance

An approach and set of techniques to evaluate the condition of in-service equipment by performing periodic or continuous monitoring of equipment conditions, in order to predict when maintenance should be performed

Premium freight

Extra costs or charges incurred in addition to contracted delivery

NOTE This can be caused by method, quantity, unscheduled or late deliveries, etc.

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 47

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3.1 Terms and definitions for the automotive industry

Preventive maintenance

Planned activities at regular intervals (time-based, periodic inspection, and overhaul) to eliminate causes of equipment failure and unscheduled interruptions to production, as an output of the manufacturing process design

Product

Applies to any intended output resulting from the product realization process

Product safety

Standards relating to the design and manufacturing of products to ensure they do not represent harm or hazards to customers

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 48

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3.1 Terms and definitions for the automotive industry

Production shutdown

Condition where manufacturing processes are idle; time span may be a few hours to a few months

Reaction plan

Action or series of steps prescribed in a control plan in the event abnormal or nonconforming events are detected

Remote location

Location that supports manufacturing sites and at which non-production processes occur

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 49

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3.1 Terms and definitions for the automotive industry

Site

Location at which value-added manufacturing processes occur

Special characteristic

Classification of a product characteristic or compliance with regulations, fit, function, product manufacturing process parameter that can affect safety or performance, requirements, or subsequent processing

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 50

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3.1 Terms and definitions for the automotive industry

Special status

Notification of a customer-identified classification assigned to an organization where one or more customer requirements are not being satisfied due to a significant quality or delivery issue

Support function

Non-Production activity (conducted on site or at a remote location) that supports one(or more) manufacturing sites of the same organization

Total productive maintenance

A system of maintaining and improving the integrity of production and quality systems through machines, equipment, processes, and employees that add value to the organization

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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 51

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IATF 16949:2016 QMS

Requirements

Clause 4

Context of the Organization



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02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 52

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4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

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4.1 Understanding the organization and its context

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

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4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

- a) The interested parties that are relevant to the quality management system;
- b) The requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

IATF 16949:2016 QMS Requirements



4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

- a) The external and internal issues referred to in 4.1;
- b) The requirements of relevant interested parties referred to in 4.2;
- c) The products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

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4.3 Determining the scope of the quality management system

The scope of the organization's quality management system shall be available and be maintained as documented information.

The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

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4.3.1 Determining the scope of the quality management system - supplemental

Supporting functions, whether on-site or remote (such as design centers, corporate headquarters, and distribution centers), shall be included in the scope of the Quality Management System (QMS).

The only permitted exclusion for this Automotive QMS Standard relates to the product design and development requirements within ISO 9001, Section 8.3. The exclusion shall be justified and maintained as documented information (see ISO 9001, Section 7.5).

Permitted exclusions do not include manufacturing process design.

IATF 16949:2016 QMS Requirements



4.3.2 Customer-specific requirements

Customer-specific requirements shall be evaluated and included in the scope of the organization's quality management system.

IATF 16949:2016 QMS Requirements



4.4 Quality management system and its processes

4.4.1

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

- a) Determine the inputs required and the outputs expected from these processes;
- b) Determine the sequence and interaction of these processes;
- c) Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

IATF 16949:2016 QMS Requirements



4.4 Quality management system and its processes

4.4.1

- d) Determine the resources needed for these processes and ensure their availability;
- e) Assign the responsibilities and authorities for these processes;
- f) Address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) Improve the processes and the quality management system.

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4.4.1.1 Conformance of products and processes

The organization shall ensure conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory, and regulatory requirements (see Section 8.4.2.2).

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4.4.1.2 Product safety

The organization shall have documented processes for the management of product-safety related products and manufacturing processes, which shall include but not be limited to the following, where applicable:

- a) Identification by the organization of statutory and regulatory product safety requirements;
- b) Customer notification of requirements in item a);
- c) Special approvals for design FMEA;
- d) Identification of product safety-related characteristics;

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4.4.1.2 Product safety

- e) Identification and controls of safety-related characteristics of product and at the point of manufacture;
- f) Special approval of control plans and process FMEAS;
- g) Reaction plans (see section 9.1 .1 .1);
- h) Defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;
- i) Training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;

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4.4.1.2 Product safety

- j) Changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, section 8.3.6);
- k) Transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see section 9.4.3. 1);
- l) Product traceability by manufactured lot (at a minimum) throughout the supply chain (see section 8.5.2.1);
- m) Lessons learned for new product introduction.

Note: Special approval is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.

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4.4.2

To the extent necessary, the organization shall:

- a) Maintain documented information to support the operation of its processes;
- b) Retain documented information to have confidence that the processes are being carried out as planned.



Any Questions?



IATF 16949:2016 QMS

Requirements Clause 5 Leadership

IATF 16949:2016 QMS Requirements



5 Leadership

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

- a) Taking accountability for the effectiveness of the quality management system;
- b) Ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
- c) Ensuring the integration of the quality management system requirements into the organization's business processes;

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5.1 Leadership and commitment

5.1.1 General

- d) Promoting the use of the process approach and risk-based thinking;
- e) Ensuring that the resources needed for the quality management system are available;
- f) Communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) Ensuring that the quality management system achieves its intended results;
- h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

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5.1 Leadership and commitment

5.1.1 General

- i) Promoting improvement;
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to “business” in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence, whether the organization is public, private, for profit or not for profit.

IATF 16949:2016 QMS Requirements



5.1.1.1 Corporate responsibility

The organization shall define and implement corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy (“whistle-blowing policy”).

5.1.1.2 Process effectiveness and efficiency

Top management shall review the product realization processes and support processes to evaluate and improve their effectiveness and efficiency. The results of the process review activities shall be included as input to the management review (see Section 9.3.2.1.)

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5.1.1.3 Process owners

Top management shall identify process owners who are responsible for managing the organization's processes and related outputs. Process owners shall understand their roles and be competent to perform those roles (see ISO 9001, Section 7.2).

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) The focus on enhancing customer satisfaction is maintained.

IATF 16949:2016 QMS Requirements



5.2 Policy

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

- a) Is appropriate to the purpose and context of the organization and supports its strategic direction;
- b) Provides a framework for setting quality objectives;
- c) Includes a commitment to satisfy applicable requirements;
- d) Includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy

The quality policy shall:

- a) Be available and be maintained as documented information;
- b) Be communicated, understood and applied within the organization;
- c) Be available to relevant interested parties, as appropriate.

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5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

- a) Ensuring that the quality management system conforms to the requirements of this international standard;
- b) Ensuring that the processes are delivering their intended outputs;
- c) Reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
- d) Ensuring the promotion of customer focus throughout the organization;
- e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

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5.3.1 Organizational roles, responsibilities, and authorities - supplemental

Top management shall assign personnel with the responsibility and authority to ensure that customer requirements are met. These assignments shall be documented. This includes but is not limited to the selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals.

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5.3.2 Responsibility and authority for product requirements and corrective actions

Top management shall ensure that:

- a) Personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems;

NOTE Due to the process design in some industries, it might not always be possible to stop production immediately. In this case, the affected batch must be contained and shipment to the customer prevented.

- b) Personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform to requirements to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained;
- c) Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

Any Questions?





IATF 16949:2016 QMS

Requirements Clause 6 Planning

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 79

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IATF 16949:2016 QMS Requirements



6 Planning

6.1 Actions to address risks and opportunities

6.1.1

When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- a) Give assurance that the quality management system can achieve its intended result(s);
- b) Enhance desirable effects;
- c) Prevent, or reduce, undesired effects;
- d) Achieve improvement.

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 80

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6.1.2

The organization shall plan:

- a) Actions to address these risks and opportunities;
- b) How to:
 - 1) Integrate and implement the actions into its quality management system processes (see 4.4);
 - 2) Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

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6.1.2

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

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6.1.2.1 Risk analysis

The organization shall include in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework.

The organization shall retain documented information as evidence of the results of risk analysis.

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6.1.2.2 Preventive action

The organization shall determine and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the severity of the potential issues.

The organization shall establish a process to lessen the impact of negative effects of risk including the following:

- a) Determining potential nonconformities and their causes;
- b) Evaluating the need for action to prevent occurrence of nonconformities;
- c) Determining and implementing action needed;
- d) Documented information of action taken;
- e) Reviewing the effectiveness of the preventive action taken; utilizing lessons learned to prevent recurrence in similar processes (see ISO 9001, section 7.1.6).

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6.1.2.3 Contingency plans

The organization shall:

- a) Identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met;
- b) Define contingency plans according to risk and impact to the customer;
- c) Prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures (also see section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; labor shortages; or infrastructure disruptions;
- d) Include, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations;

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6.1.2.3 Contingency plans

- e) Periodically test the contingency plans for effectiveness (e.g., Simulations, as appropriate);
- f) Conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and update as required;
- g) Document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).

The contingency plans shall include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

IATF 16949:2016 QMS Requirements



6.2 Quality objectives and planning to achieve them

6.2.1

The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

- a) Be consistent with the quality policy;
- b) Be measurable;
- c) Take into account applicable requirements;
- d) Be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) Be monitored;
- f) Be communicated;
- g) Be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

IATF 16949:2016 QMS Requirements



6.2.2

When planning how to achieve its quality objectives, the organization shall determine:

- a) What will be done;
- b) What resources will be required;
- c) Who will be responsible;
- d) When it will be completed;
- e) How the results will be evaluated.

IATF 16949:2016 QMS Requirements



6.2.2.1 Quality objectives and planning to achieve them - supplemental

Top management shall ensure that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.

The results of the organization's review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

IATF 16949:2016 QMS Requirements



6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization shall consider:

- a) The purpose of the changes and their potential consequences;
- b) The integrity of the quality management system;
- c) The availability of resources;
- d) The allocation or reallocation of responsibilities and authorities.



Any Questions?



IATF 16949:2016 QMS

Requirements
Clause 7
Support

IATF 16949:2016 QMS Requirements



7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

- a) The capabilities of, and constraints on, existing internal resources;
- b) What needs to be obtained from external providers.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 93

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IATF 16949:2016 QMS Requirements



7.1.3 infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Infrastructure can include:

- a) Buildings and associated utilities;
- b) Equipment, including hardware and software;
- c) Transportation resources;
- d) Information and communication technology.

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 94

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7.1.3.1 Plant, facility, and equipment planning

The organization shall use a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans. In designing plant layouts, the organization shall:

- a) Optimize material flow, material handling, and value-added use of floor space including control of nonconforming product, and
- b) Facilitate synchronous material flow, as applicable.

Methods shall be developed and implemented to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments shall include capacity planning. These methods shall also be applicable for evaluating proposed changes to existing operations.

IATF 16949:2016 QMS Requirements



7.1.3.1 Plant, facility, and equipment planning

The organization shall maintain process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance (see Section 8.5.1.1), and verification on job set-ups (see Section 8.0.1.3).

Assessments of manufacturing feasibility and evaluation of capacity planning shall be inputs to management reviews (see ISO 9001, Section 9.3).

NOTE 1 These requirements should include the application of lean manufacturing principles.

NOTE 2 These requirements should apply to on-site supplier activities, as applicable.

IATF 16949:2016 QMS Requirements



7.1 .4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:

- a) Social (e.g. Non-discriminatory, calm, non-confrontational);
- b) Psychological (e.g. Stress-reducing, burnout prevention, emotionally protective);
- c) Physical (e.g. Temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

NOTE Where third-party certification to ISO 45001 (or equivalent) is recognized, it may be used to demonstrate the organization's conformity to the personnel safety aspects of this requirement.

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7.1.4.1 Environment for the operation of processes - supplemental

The organization shall maintain its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.

IATF 16949:2016 QMS Requirements



7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

- a) Are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) Are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

IATF 16949:2016 QMS Requirements



7.1.5.1.1 Measurement systems analysis

Statistical studies shall be conducted to analyze the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria used shall conform to those in reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

Records of customer acceptance of alternative methods shall be retained along with results from alternative measurement systems analysis (see Section 9. 1 .1.1).

NOTE Prioritization of MSA studies should focus on critical or special product or process characteristics.

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7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- a) Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) Identified in order to determine their status;
- c) Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

IATF 16949:2016 QMS Requirements



7.1.5.2 Measurement traceability

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

NOTE A number or another identifier traceable to the device calibration record meets the intent of the requirements in ISO 9001:2015.

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7.1.5.2.1 Calibration / verification records

The organization shall have a documented process for managing calibration / verification records. Record of the calibration/verification activity for all gauges and measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements shall be retained.

The organization shall ensure that calibration/verification activities and records shall include the following details:

- a) Revisions following engineering changes that impact measurement systems;
- b) Any out-of-specification readings as received for calibration/verification;
- c) An assessment of the risk of the intended use of the product caused by the out of-specification condition;

IATF 16949:2016 QMS Requirements



7.1.5.2.1 Calibration / verification records

- d) When a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use, documented information on the validity of previous measurement results obtained with this piece of inspection measurement and test equipment shall be retained, including the associated standard's last calibration date and the next due date on the calibration report;
- e) Notification to the customer if suspect product or material has been shipped;
- f) Statements of conformity to specification after calibration/verification;

IATF 16949:2016 QMS Requirements



7.1.5.2.1 Calibration / verification records

- g) Verification that the software version used for product and process control is as specified;
- h) Records of the calibration and maintenance activities for all gauging (including employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment);
- i) Production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).

IATF 16949:2016 QMS Requirements



7.1.5.3 Laboratory requirements

7.1.5.3.1 Internal laboratory

An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test, or calibration services.

This laboratory scope shall be included in the quality management system documentation.

The laboratory shall specify and implement, as a minimum, requirements for:

- a) Adequacy of the laboratory technical procedures;
- b) Competency of the laboratory personnel;
- c) Testing of the product;

IATF 16949:2016 QMS Requirements



7.1.5.3 Laboratory requirements

7.1.5.3.1 Internal laboratory

- d) Capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.); When no national or international standard(s) is available, the organization shall define and implement a methodology to verify measurement system capability;
- e) Customer requirements, if any;
- f) Review of the related records.

NOTE Third-party accreditation to ISO/IEC 17025 (or equivalent) may be used to demonstrate the organization's in-house laboratory conformity to this requirement.

IATF 16949:2016 QMS Requirements



7.1.5.3.2 External laboratory

External / commercial / independent laboratory facilities used for inspection, test, or calibration services by that includes the capability to perform the required inspection, test, or calibration, and either:

- § The laboratory shall be accredited to ISO / IEC 17025 or national equivalent and include the relevant inspection, test, calibration service in the scope of the accreditation (certificate); the certificate of calibration shall include the mark of a national accreditation body; or
- § There shall be evidence that the external laboratory is acceptable to the customer

NOTE such evidence may be demonstrated by customer assessment, for example, or by customer approved second-party assessment that the laboratory meets the intent of ISO / IEC 17025 or national equivalent. The second-party assessment may be performed by the organization assessing the Laboratory using a customer-approved method of assessment.

IATF 16949:2016 QMS Requirements



7.1.5.3.2 External laboratory

Calibration services may be performed by the equipment manufacturer when a qualified laboratory is not available for a given piece of equipment. In such cases, the organization shall ensure that the requirements listed in Section 7.1.5.3.1 have been met.

Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to government regulatory confirmation, if required.

IATF 16949:2016 QMS Requirements



7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

IATF 16949:2016 QMS Requirements



7.1.6 Organizational knowledge

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

- a) Internal sources (e.g. Intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
- b) External sources (e.g. Standards; academia; conferences; gathering knowledge from customers or external providers).

IATF 16949:2016 QMS Requirements



7.2 Competence

The organization shall:

- a) Determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b) Ensure that these persons are competent on the basis of appropriate education, training, or experience;
- c) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) Retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

IATF 16949:2016 QMS Requirements



7.2.1 Competence - supplemental

The organization shall establish and maintain a documented process(es) for identifying training needs. (see Section achieving competence of all personnel performing activities affecting conformity to product and Personnel performing specific assigned tasks required, with particular attention to the satisfaction of customer requirements.)

IATF 16949:2016 QMS Requirements



7.2.2 Competence – on the job training

The organization shall provide on-the-job training (which shall include customer requirements training) for personnel in any new or modified responsibilities affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements, this shall include contract or agency personnel.

The level of detail required for on the job training shall be commensurate with the level of education the personnel possess and the complexity of the task(s) they are required to perform for their daily work.

Persons whose work can affect quality shall be informed about the consequences of nonconformity to customer requirements.

IATF 16949:2016 QMS Requirements



7.2.3 Internal auditor competency

The organization shall have a documented process(es) to verify that internal auditors are competent, taking into account any customer-specific requirements. For additional guidance on auditor competencies, refer to ISO 19011. The organization shall maintain a list of qualified internal auditors.

Quality management system auditors, manufacturing process auditors, and product auditors shall all be able to demonstrate the following minimum competencies:

- a) Understanding of the automotive process approach for auditing, including risk-based thinking;
- b) Understanding of applicable customer-specific requirements;
- c) Understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
- d) Understanding of applicable core tool requirements related to the scope of the audit;
- e) Understanding how to plan, conduct, report, and close out audit findings.

IATF 16949:2016 QMS Requirements



7.2.3 Internal auditor competency

Additionally, manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan.

Product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.

Where training is provided to achieve competency, documented information shall be retained to demonstrate the trainer's competency with the above requirements.

IATF 16949:2016 QMS Requirements



7.2.3 Internal auditor competency

Maintenance of and improvement in internal auditor competence shall be demonstrated through:

- f) Executing a minimum number of audits per year, as defined by the organization; and
- g) Maintaining knowledge of relevant requirements based on internal changes (e.g., Process technology, product technology) and external changes (e.g., ISO 9001, IATF 16949, core tools, and customer specific requirements).

IATF 16949:2016 QMS Requirements



7.2.4 Second-party auditor competency

The organization shall demonstrate the competence of the auditors undertaking the second-party audits. second-party auditors shall meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of:

- a) The automotive process approach to auditing, including risk based thinking;
- b) Applicable customer and organization specific requirements;
- c) Applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
- d) Applicable manufacturing process(es) to be audited, including PFMEA and control plan;
- e) Applicable core tool requirements related to the scope of the audit;
- f) How to plan, conduct, prepare audit reports, and close out audit findings.

IATF 16949:2016 QMS Requirements



7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

- a) The quality policy;
- b) Relevant quality objectives;
- c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) The implications of not conforming with the quality management system requirements.

IATF 16949:2016 QMS Requirements



7.3.1 Awareness - supplemental

The organization shall maintain documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with nonconforming product.

IATF 16949:2016 QMS Requirements



7.3.2 Employee motivation and empowerment

The organization shall maintain a documented process(es) to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.

IATF 16949:2016 QMS Requirements



7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

- a) On what it will communicate;
- b) When to communicate;
- c) With whom to communicate;
- d) How to communicate;
- e) Who communicates.

IATF 16949:2016 QMS Requirements



7.5 Documented information

7.5.1 General

The organization's quality management system shall include:

- a) Documented information required by this international standard;
- b) Documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

- § The size of organization and its type of activities, processes, products and services;
- § The complexity of processes and their interactions;
- § The competence of persons.

IATF 16949:2016 QMS Requirements



7.5.1.1 Quality management system documentation

The organization's quality management system shall be documented and include a quality manual, which can be a series of documents (electronic or hard copy).

The format and structure of the quality manual is at the discretion of the organization and will depend on the organization's size, culture, and complexity.

If a series of documents is used, then a list shall be retained of the documents that comprise the quality manual for the organization.

IATF 16949:2016 QMS Requirements



7.5.1.1 Quality management system documentation

The quality manual shall include, at a minimum, the following:

- a) The scope of the quality management system, including details of and justification for any exclusions;
- b) Documented processes established for the quality management system, or reference to them;
- c) The organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes;
- d) A document (i.e., Matrix) indicating where within the organization's quality management system their customer-specific requirements are addressed.

NOTE A matrix of how the requirements of this Automotive QMS standard are addressed by the organization's processes may be used to assist with linkages of the organization's processes and this Automotive QMS.

IATF 16949:2016 QMS Requirements



7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

- a) Identification and description (e.g. A title, date, author, or reference number);
- b) Format (e.g. Language, software version, graphics) and media (e.g. Paper, electronic);
- c) Review and approval for suitability and adequacy.

IATF 16949:2016 QMS Requirements



7.5.3 Control of documented information

7.5.3.1

Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

- a) It is available and suitable for use, where and when it is needed;
- b) It is adequately protected (e.g. From loss of confidentiality, improper use, or loss of integrity).

IATF 16949:2016 QMS Requirements



7.5.3.2

For the control of documented information, the organization shall address the following activities, as applicable:

- a) Distribution, access, retrieval and use;
- b) Storage and preservation, including preservation of legibility;
- c) Control of changes (e.g. Version control);
- d) Retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

IATF 16949:2016 QMS Requirements



7.5.3.2.1 Record retention

The organization shall define, document, and implement a record retention policy. The control of records shall satisfy statutory, regulatory, organizational, and customer requirements.

Production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or contracts and amendments shall be retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency.

NOTE Production part approval documented information may include approved product, applicable test equipment records, or approved test data.

IATF 16949:2016 QMS Requirements



7.5.3.2.2 Engineering specifications

The organization shall have a documented process describing the review, distribution, and implementation of all customer engineering standards/specifications and related revisions based on customer schedules, as required.

When an engineering standard/specification change results in a product design change, refer to the requirements in ISO 9001, Section 8.3.6. When an engineering standard/specification change results in a product realization process change, refer to the requirements in Section 8.5.6.1.

The organization shall retain a record of the date on which each change is implemented in production. implementation shall include updated documents.

IATF 16949:2016 QMS Requirements



7.5.3.2.2 Engineering specifications

Review should be completed within 10 working days of receipt of notification of engineering standards/specifications changes.

NOTE A change in these standards/specifications may require an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of the production part approval process, such as control plan, risk analysis (such as FMEAs), etc.

Any Questions?





IATF 16949:2016 QMS

Requirements Clause 8 Operation

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 133

TÜV®

IATF 16949:2016 QMS Requirements



8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- a) Determining the requirements for the products and services;
- b) Establishing criteria for:
 - 1) The processes;
 - 2) The acceptance of products and services;
- c) Determining the resources needed to achieve conformity to the product and service requirements;
- d) Implementing control of the processes in accordance with the criteria;

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 134

TÜV®

IATF 16949:2016 QMS Requirements



8 Operation

8.1 Operational planning and control

- e) Determining, maintaining and retaining documented information to the extent necessary:
 - 1) To have confidence that the processes have been carried out as planned;
 - 2) To demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the organization's operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

IATF 16949:2016 QMS Requirements



8.1.1 Operational planning and control - supplemental

When planning for product realization, the following topics shall be included:

- a) Customer product requirements and technical specifications;
- b) Logistics requirements;
- c) Manufacturing feasibility;
- d) Project planning refers to ISO 9001, section 8.3.2);
- e) Acceptance criteria.

The resources identified in ISO 9001, Section 8.1 c), refer to the required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance.

8.1.2 Confidentiality

The organization shall ensure the confidentiality of customer-contracted products and projects under development, including related product information.

IATF 16949:2016 QMS Requirements



8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

- a) Providing information relating to products and services;
- b) Handling enquiries, contracts or orders, including changes;
- c) Obtaining customer feedback relating to products and services, including customer complaints;
- d) Handling or controlling customer property;
- e) Establishing specific requirements for contingency actions, when relevant.

8.2.1.1 Customer communication - supplemental

Written or verbal communication shall be in the language agreed with the customer.

The organization shall have the ability to communicate necessary information, including data in customer-specified computer language and format (e.g. Computer-aided design data, electronic data interchange)

IATF 16949:2016 QMS Requirements



8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

- a) The requirements for the products and services are defined, including:
 - 1) Any applicable statutory and regulatory requirements;
 - 2) Those considered necessary by the organization;
- b) The organization can meet the claims for the products and services it offers.

8.2.2.1 Determining the requirements for products and services - supplemental

These requirements shall include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes. Compliance to ISO 9001, Section 8.2.2 item a) i), shall include but not be limited to the following: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

IATF 16949:2016 QMS Requirements



8.2.3 Review of the requirements for products and services

8.2.3.1

The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

- a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) Requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) Requirements specified by the organization;
- d) Statutory and regulatory requirements applicable to the products and services;
- e) Contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

IATF 16949:2016 QMS Requirements



8.2.3 Review of the requirements for products and services

8.2.3.1

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE in some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

8.2.3.1.1 Review of the requirements for products and services - supplemental

The organization shall retain documented evidence of a customer-authorized waiver for the requirements stated in ISO 9001, Section 8.2.3.1, for a formal review.

8.2.3.1.2 Customer-designated special characteristics

The organization shall conform to customer requirements for designation, approval documentation, and control of special characteristics.

IATF 16949:2016 QMS Requirements



8.2.3.1.3 Organization manufacturing feasibility

The organization shall utilize a multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization's manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer.

The organization shall conduct this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design. Additionally, the organization should validate through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate.

8.2.3.2

The organization shall retain documented information, as applicable:

- a) On the results of the review;
- b) On any new requirements for the products and services.

IATF 16949:2016 QMS Requirements



8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

IATF 16949:2016 QMS Requirements



8.3 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.1.1 Design and development of products and services - supplemental

The requirements of ISO 9001, section 8.3.1, shall apply to product and manufacturing process design and development and shall focus on error prevention rather than detection. The organization shall document the design and development process

IATF 16949:2016 QMS Requirements



8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

- a) The nature, duration and complexity of the design and development activities;
- b) The required process stages, including applicable design and development reviews;
- c) The required design and development verification and validation activities;
- d) The responsibilities and authorities involved in the design and development process;
- e) The internal and external resource needs for the design and development of products and services;

IATF 16949:2016 QMS Requirements



8.3.2 Design and development planning

- f) The need to control interfaces between persons involved in the design and development process;
- g) The need for involvement of customers and users in the design and development process;
- h) The requirements for subsequent provision of products and services;
- i) The level of control expected for the design and development process by customers and other relevant interested parties;
- j) The documented information needed to demonstrate that design and development requirements have been met.

IATF 16949:2016 QMS Requirements



8.3.2.1 Design and development planning - supplemental

The organization shall ensure that design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a multidisciplinary approach include but are not limited to the following:

- a) Project management (for example, APQP or VDA-RGA);
- b) Product and manufacturing process design activities (for example, DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes;
- c) Development and review of product design risk analysis (fmeas), including actions to reduce potential risks;
- d) Development and review of manufacturing process risk analysis (for example, FMEAS, process flows, control plans, and standard work instructions).

NOTE A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.

IATF 16949:2016 QMS Requirements



8.3.2.2 Product design skills

The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques. Applicable tools and techniques shall be identified by the organization.

NOTE an example of product design skills is the application of digitized mathematically based data.

IATF 16949:2016 QMS Requirements



8.3.2.3 Development of products with embedded software

The organization shall use a process for quality assurance for their products with internally developed embedded software. A software development assessment methodology shall be utilized to assess the organization's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall retain documented information of a software development capability self-assessment.

The organization shall include software development within the scope of their internal audit program (see Section 9.2.2.1).

IATF 16949:2016 QMS Requirements



8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

- a) Functional and performance requirements;
- b) Information derived from previous similar design and development activities;
- c) Statutory and regulatory requirements;
- d) Standards or codes of practice that the organization has committed to implement;
- e) Potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

IATF 16949:2016 QMS Requirements



8.3.3.1 Product design input

The organization shall identify, document, and review product design input requirements as a result of contract review. Product design input requirements include but are not limited to the following:

- a) Product specifications including but not limited to special characteristics (see section 8.3.3.3);
- b) Boundary and interface requirements;
- c) Identification, traceability, and packaging;
- d) Consideration of design alternatives;
- e) Assessment of risks with the input requirements and the organization's ability to mitigate / manage the risks, including from the feasibility analysis;

IATF 16949:2016 QMS Requirements



8.3.3.1 Product design input

- f) Targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;
- g) Applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;
- h) Embedded software requirements.

The organization shall have a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.

NOTE one approach for considering design alternatives is the use of trade-off curves

IATF 16949:2016 QMS Requirements



8.3.3.2 Manufacturing process design input

The organization shall identify, document, and review manufacturing process design input requirements including but not limited to the following:

- a) Product design output data including special characteristics;
- b) Targets for productivity, process capability, timing, and cost;
- c) Manufacturing technology alternatives;
- d) Customer requirements, if any;
- e) Experience from previous developments;
- f) New materials;
- g) Product handling and ergonomic requirements; and
- h) Design for manufacturing and design for assembly.

The manufacturing process design shall include the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered

IATF 16949:2016 QMS Requirements



8.3.3.3 Special Characteristics

The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

- a) Documentation of all special characteristics in the drawings (as required), risk analysis (such as FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are cascaded through each of these documents;
- b) Development of control and monitoring strategies for special characteristics of products and production processes;
- c) Customer-specified approvals, when required;
- d) Compliance with customer specified definitions and symbols or the organization's equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table shall be submitted to the customer, if required.

IATF 16949:2016 QMS Requirements



8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

- a) The results to be achieved are defined;
- b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements;
- d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
- e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) Documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

IATF 16949:2016 QMS Requirements



8.3.4.1 Monitoring

Measurements at specified stages during the design and development of products and processes shall be defined, analyzed, and reported with summary results as an input to management review (see Section 9.3.2.1).

When required by the customer, measurements of the product and process development activity shall be reported to the customer all stages specified, or agreed to, by the customer.

NOTE When appropriate, these measurements may include quality risks, costs, lead times, critical paths, and other measurements.

IATF 16949:2016 QMS Requirements



8.3.4.2 Design and development validation

Design and development validation shall be performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation shall be planned in alignment with customer-specified timing, as applicable.

Where contractually agreed with the customer, this shall include evaluation of the interaction of the organization's product, including embedded software, within the system of the final customer's product.

IATF 16949:2016 QMS Requirements



8.3.4.3 Prototype program

When required by the customer, the organization shall have a prototype program and control plan.

The organization shall use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production.

All performance testing activities shall be monitored for timely completion and conformity to requirements.

When services are outsourced, the organization shall include the type and extent of control in the scope of its quality management system to ensure that outsourced services conform to requirements (see ISO 9001, Section 8.4).

IATF 16949:2016 QMS Requirements



8.3.4.4 Product approval process

The organization shall establish, implement, and maintain a product and manufacturing approval process conforming to requirements defined by the customer(s).

The organization shall approve externally provided products and services per ISO 9001, section 8.4.3, prior to submission of their part approval to the customer.

The organization shall obtain documented product approval prior to shipment, if required by the customer.

Records of such approval shall be retained.

NOTE Product approval should be subsequent to the verification of the manufacturing process.

IATF 16949:2016 QMS Requirements



8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

- a) Meet the input requirements;
- b) Are adequate for the subsequent processes for the provision of products and services;
- c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) Specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

IATF 16949:2016 QMS Requirements



8.3.5.1 Design and development outputs - supplemental

The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include but is not limited to the following, as applicable:

- a) Design risk analysis (FMEA);
- b) Reliability study results;
- c) Product special characteristics;
- d) Results of product design error-proofing, such as DFSS, DFN4A, and FTA;
- e) Product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning and tolerancing (GD&T);

IATF 16949:2016 QMS Requirements



8.3.5.1 Design and development outputs - supplemental

- f) 2D drawings, product manufacturing information, and geometric dimensioning and tolerancing (GD&T);
- g) Product design review results;
- h) Service diagnostic guidelines and repair and serviceability instructions;
- i) Service part requirements;
- j) Packaging and labeling requirements for shipping.

NOTE interim design outputs should include any engineering problems being resolved through a tradeoff process.

IATF 16949:2016 QMS Requirements



8.3.5.2 Manufacturing process design output

The organization shall document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. The organization shall verify the outputs against manufacturing process design input requirements.

The manufacturing process design output shall include but is not limited to the following:

- a) Specifications and drawings;
- b) Special characteristics for product and manufacturing process;
- c) Identification of process input variables that impact characteristics;
- d) Tooling and equipment for production and control, including capability studies of equipment and process(es);
- e) Manufacturing process flow charts/layout, including linkage of product, process, and tooling;

IATF 16949:2016 QMS Requirements



8.3.5.2 Manufacturing process design output

- f) Capacity analysis;
- g) Manufacturing process FMEA;
- h) Maintenance plans and instructions;
- i) Control plan (see annex A);
- j) Standard work and work instructions;
- k) Process approval acceptance criteria;
- l) Data for quality, reliability, maintainability, and measurability;
- m) Results of error-proofing identification and verification, as appropriate;
- n) Methods of rapid detection, feedback, and correction of product manufacturing process non-conformities.

IATF 16949:2016 QMS Requirements



8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

- a) Design and development changes;
- b) The results of reviews;
- c) The authorization of the changes;
- d) The actions taken to prevent adverse impacts.

IATF 16949:2016 QMS Requirements



8.3.6.1 Design and development changes - supplemental

The organization shall evaluate all design changes after initial product approval, including those proposed by the organization or its suppliers, for potential impact on its, form, function, performance, and/or durability. These changes shall be validated against customer requirements and approved internally, prior to production implementation.

If required by the customer, the organization shall obtain documented approval, or a documented waiver, from the customer prior to production implementation.

For products with embedded software, the organization shall document the revision level of software and hardware as part of the change record.

IATF 16949:2016 QMS Requirements



8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

- a) Products and services from external providers are intended for incorporation into the organization's own products and services;
- b) Products and services are provided directly to the customer(s) by external providers on behalf of the organization;
- c) A process, or part of a process, is provided by an external provider as a result of a decision by the organization.

IATF 16949:2016 QMS Requirements



8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.

The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

IATF 16949:2016 QMS Requirements



8.4.1.1 General - supplemental

The organization shall include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.

IATF 16949:2016 QMS Requirements



8.4.1.2 Supplier selection process

The organization shall have a documented supplier selection process. The selection process shall include:

- a) An assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;
- b) Relevant quality and delivery performance;
- c) An evaluation of the supplier's quality management system;
- d) Multidisciplinary decision making; and
- e) An assessment of software development capabilities, if applicable.

IATF 16949:2016 QMS Requirements



8.4.1.2 Supplier selection process

Other supplier selection criteria that should be considered include the following:

- § Volume of automotive business (absolute and as a percentage of total business);
- § Financial stability;
- § Purchased product, material, or service complexity;
- § Required technology (product or process);
- § Adequacy of available resources (e.g., people, infrastructure);
- § Design and development capabilities (including project management);
- § Manufacturing capability;
- § Change management process;
- § Business continuity planning (e.g., disaster preparedness, contingency planning);
- § Logistics process;
- § Customer service.

IATF 16949:2016 QMS Requirements



8.4.1.3 Customer-directed sources (also known as "Directed-Buy")

When specified by the customer, the organization shall purchase products, materials, or services from customer-directed sources. All requirements of Section 8.4 (except the requirements in IATF 16949, Section 8.4.1.2) are applicable to the organization's control of customer-directed sources unless specific agreements are otherwise defined by the contract between the organization and the customer.

IATF 16949:2016 QMS Requirements



8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

- a) Ensure that externally provided processes remain within the control of its quality management system;
- b) Define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

IATF 16949:2016 QMS Requirements



8.4.2 Type and extent of control

- c) Take into consideration:
 - 1) The potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) The effectiveness of the controls applied by the external provider;
- d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

IATF 16949:2016 QMS Requirements



8.4.2.1 Type and extent of control - supplemental

The organization shall have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements.

The process shall include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks.

IATF 16949:2016 QMS Requirements



8.4.2.2 Statutory and regulatory requirements

The organization shall document their process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided.

If the customer defines special controls for certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including at suppliers.

IATF 16949:2016 QMS Requirements



8.4.2.3 Supplier quality management system development

The organization shall require their suppliers of automotive products and services to develop, implement, and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer, with the ultimate objective of becoming certified to this Automotive QMS Standard. Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:

- a) Compliance to ISO 9001 through second-party audits;
- b) Certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO 9001 by maintaining a third party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (international accreditation forum multilateral recognition arrangement) member and where the accreditation body's main scope includes management system certification to ISO / IEC17021

IATF 16949:2016 QMS Requirements



8.4.2.3 Supplier quality management system development

- c) Certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAOMSRI or equivalent] through second-party audits;
- d) Certification to ISO9001 with compliance to IATF 16949 through second-party audits;
- e) Certification to 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).

IATF 16949:2016 QMS Requirements



8.4.2.3.1 Automotive product-related software or automotive products with embedded software

The organization shall require their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

A software development assessment methodology shall be utilized to assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall require the supplier to retain documented information of a software development capability self-assessment.

IATF 16949:2016 QMS Requirements



8.4.2.4 Supplier monitoring

The organization shall have a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements.

At a minimum, the following supplier performance indicators shall be monitored:

- a) Delivered product conformity to requirements;
- b) Customer disruptions at the receiving plant, including yard holds and stop ships;
- c) Delivery schedule performance;
- d) Number of occurrences of premium freight.

If provided by the customer, the organization shall also include the following, as appropriate, in their supplier performance monitoring:

- e) Special status customer notifications related to quality or delivery issues;
- f) Dealer returns, warranty, field actions, and recalls.

IATF 16949:2016 QMS Requirements



8.4.2.4.1 Second- party audits

The organization shall include a second-party audit process in their supplier management approach. Second-party audits may be used for the following:

- a) Supplier risk assessment;
- b) Supplier monitoring;
- c) Supplier QN4S development;
- d) Product audits;
- e) Process audits.

IATF 16949:2016 QMS Requirements



8.4.2.4.1 Second-party audits

Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum, the organization shall document the criteria for determining the need, type, frequency, and scope of second-party audits.

The organization shall retain records of the second-party audit reports.

If the scope of the second-party audit is to assess the supplier's quality management system, then the approach shall be consistent with the automotive process approach.

NOTE Guidance may be found in the IATF Auditor Guide and ISO 19011, AIAG, ANFIA, FIEV, SMMT, VDA

IATF 16949:2016 QMS Requirements



8.4.2.5 Supplier development

The organization shall determine the priority, type, extent, and timing of required supplier development actions for its active suppliers.

Determination inputs shall include but not limited to are following,

- a) Performance issues identified through supplier monitoring (see section 8.4.2.4);
- b) Second-party audit findings (see section 8.4.2.4.1);
- c) Third-party quality management system certification status;
- d) Risk analysis.

The organization shall implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

IATF 16949:2016 QMS Requirements



8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

- a) The processes, products and services to be provided;
- b) The approval of:
 - 1) Products and services;
 - 2) Methods, processes and equipment;
 - 3) The release of products and services;
- c) Competence, including any required qualification of persons;
- d) The external providers' interactions with the organization;
- e) Control and monitoring of the external providers' performance to be applied by the organization;
- f) Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

IATF 16949:2016 QMS Requirements



8.4.3.1 information for external providers - supplemental

The organization shall pass down all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

IATF 16949:2016 QMS Requirements



8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

- a) The availability of documented information that defines:
 - 1) The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - 2) The results to be achieved;
- b) The availability and use of suitable monitoring and measuring resources;
- c) The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
- d) The use of suitable infrastructure and environment for the operation of processes;

IATF 16949:2016 QMS Requirements



8.5 Production and service provision

8.5.1 Control of production and service provision

- e) The appointment of competent persons, including any required qualification;
- f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) The implementation of actions to prevent human error;
- h) The implementation of release, delivery and post-delivery activities.

NOTE suitable infrastructure includes appropriate manufacturing equipment required to ensure product compliance. Monitoring and measuring resources includes appropriate monitoring and measuring equipment required to ensure effective control of manufacturing processes.

IATF 16949:2016 QMS Requirements



8.5.1.1 Control plan

The organization shall develop control plans (in accordance with Annex A) at the system, subsystem, component and/or material level for the relevant manufacturing site and all product supplied, including those for processes producing bulk materials as well as parts. Family control plans are acceptable for bulk material and similar parts using a common manufacturing process.

The organization shall, have a control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis (if provided by the customer), process flow diagram, and manufacturing process risk analysis outputs (such as FMEA)

The organization shall, if required by the customer, provide measurement and conformity data collected during execution of either the pre-launch or production control plans.

IATF 16949:2016 QMS Requirements



8.5.1.1 Control plan

The organization shall include in the control plan:

- a) Controls used for the manufacturing process control, including verification of job set ups;
- b) First off/last-off part validation, as applicable;
- c) Methods for monitoring of control exercised over special characteristics (see annex A) defined by both the customer and the organization;
- d) The customer-required information, if any;
- e) Specified reaction plan (see annex A); when nonconforming product is detected, the process becomes statistically unstable or not statistically capable. The organization shall review control plans, and update as required, for any of the following:
- f) The organization determines it has shipped nonconforming product to the customer;

IATF 16949:2016 QMS Requirements



8.5.1.1 Control plan

- g) When any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FNIEA) (see annex A);
- h) After a customer complaint and implementation of the associated corrective action, when applicable;
- i) At a set frequency based on a risk analysis.

If required by the customer, the organization shall obtain customer approval after review or revision of the control plan.

IATF 16949:2016 QMS Requirements



8.5.1.2 Standardized work - operator instructions and visual standards

The organization shall ensure that standardized work documents are:

- a) Communicated to and understood by the employees who are responsible for performing the work;
- b) Legible;
- c) Presented in the language(s) understood by the personnel responsible to follow them;
- d) Accessible for use at the designated work area(s).

The standardized work documents shall also include rules for operator safety.

IATF 16949:2016 QMS Requirements



8.5.1.3 Verification of job set-ups

The organization shall:

- § Verify job set-ups when performed, such as an initial run of a job, material changeover or job change that requires a new set-up;
- § Maintain documented information for set-up personnel;
- § Use statistical methods of verification, where applicable;
- § Perform first-off / last-off part validation, as applicable; where appropriate, first-off parts should be retained for comparison with the last-off parts; where appropriate, last-off-parts should be retained for comparison with first-off parts in subsequent runs;
- § Retain records of process and product approval following set-up and first-off/last-off part validations.

8.5.1.4 Verification after shutdown

The organization shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period

IATF 16949:2016 QMS Requirements



8.5.1.5 Total productive maintenance

The organization shall develop, implement and maintain a documented total productive maintenance system.

At a minimum, the system shall include the following:

- a) Identification of process equipment necessary to produce conforming product at the required volume;
- b) Availability of replacement parts for the equipment identified in item;
- c) Provision of resource for machine, equipment, and facility maintenance;
- d) Packaging and preservation of equipment, tooling, and gauging;
- e) Applicable customer-specific requirements;

IATF 16949:2016 QMS Requirements



8.5.1.5 Total productive maintenance

- f) Documented maintenance objectives, for example: OEE (overall equipment effectiveness)', MTBF (mean time between failure), and MTTR (mean time to repair)' and preventive maintenance compliance metrics. Performance to the maintenance objectives shall form an input into management review (see ISO 9001, section 9 3);
- g) Regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;
- h) Use of preventive maintenance methods;
- i) Use of predictive maintenance methods, as applicable;
- j) Periodic overhaul.

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8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment

The organization shall provide resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable.

The organization shall establish and implement a system for production tooling management, whether owned by the organization or the customer, including:

- a) Maintenance and repair facilities and personnel;
- b) Storage and recovery;
- c) Setup;
- d) Tool-change programs for perishable tools;

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8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment

- e) Tool design modification documentation, including engineering change level of the product;
- f) Tool modification and revision to documentation;
- g) Tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location.

The organization shall verify that customer-owned tools, manufacturing equipment, and test inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

The organization shall implement a system to monitor these activities if any work is outsourced.

IATF 16949:2016 QMS Requirements



8.5.1.7 Production scheduling

The organization shall ensure that production is scheduled in order to meet customer orders / demands such as Just-in-Time (JIT) and is supported by an information system that permits access to production information at key stages of the process and is order driven.

The organization shall include relevant planning information during production scheduling, e.g., customer orders, supplier on-time delivery performance, capacity, shared loading (multi-part station), lead time, inventory level, preventive maintenance, and calibration.

IATF 16949:2016 QMS Requirements



8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

NOTE inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted if the status is clearly identified, documented, and achieves the designated purpose.

IATF 16949:2016 QMS Requirements



8.5.2.1 Identification and traceability - supplemental

The purpose of traceability is to support identification of clear start and stop points for product received by the customer or in the field that may contain quality and/or safety-related nonconformities. Therefore, the organization shall implement identification and traceability processes as described below.

The organization shall conduct an analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers.

IATF 16949:2016 QMS Requirements



8.5.2.1 Identification and traceability - supplemental

These plans shall define the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

- a) Enable the organization to identify nonconforming and/or suspect product;
- b) Enable the organization to segregate nonconforming and/or suspect product;
- c) Ensure the ability to meet the customer and/or regulatory response time requirements;
- d) Ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements;
- e) Ensure serialized identification of individual products, if specified by the customer or regulatory standards;
- f) Ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics.

IATF 16949:2016 QMS Requirements



8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

IATF 16949:2016 QMS Requirements



8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

IATF 16949:2016 QMS Requirements



8.5.4.1 Preservation - supplemental

Preservation shall include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation shall apply to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery acceptance by the customer

In order to detect deterioration, the organization shall assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment.

IATF 16949:2016 QMS Requirements



8.5.4.1 Preservation - supplemental

The organization shall use an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "first-in-first-out" (FIFO).

The organization shall ensure that obsolete product is controlled in a manner similar to that of nonconforming product.

Organizations shall comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.

IATF 16949:2016 QMS Requirements



8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

- a) Statutory and regulatory requirements;
- b) The potential undesired consequences associated with its products and services;
- c) The nature, use and intended lifetime of its products and services;
- d) Customer requirements;
- e) Customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

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8.5.5.1 Feedback of information from service

The organization shall ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

NOTE 1 The intent of the addition of "service concerns" to this sub-clause is to ensure that the organization is aware of nonconforming product(s) and material(s) that may be identified at the customer location or in the field.

NOTE 2 "Service concerns" should include the results of field failure test analysis (see Section 10.2.6) where applicable.

IATF 16949:2016 QMS Requirements



8.5.5.2 Service agreement with customer

When there is a service agreement with the customer, the organization shall:

- § Verify that the relevant service centers comply with applicable requirements;
- § Verify the effectiveness of any special purpose tools or measurement equipment;
- § Ensure that all service personnel are trained in applicable requirements.

IATF 16949:2016 QMS Requirements



8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

IATF 16949:2016 QMS Requirements



8.5.6.1 Control of changes - supplemental

The organization shall have a documented process to control and react to changes that impact product realization.

The effects of any change including those changes caused by the organization, the customer, or any supplier, shall be assessed.

The organization shall:

- a) Define verification and validation activities to ensure compliance with customer requirements;
- b) Validate changes before implementation;
- c) Document the evidence of related risk analysis;

IATF 16949:2016 QMS Requirements



8.5.6.1 Control of changes - supplemental

- d) Retain records of verification and validation. Changes, including those made at suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process.

When required by the customer, the organization shall:

- e) Notify the customer of any planned product realization changes after the most recent product approval;
- f) Obtain documented approval, prior to implementation of the change;
- g) Complete additional verification or identification requirements, such as production trial run and new product validation.

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8.5.6.1.1 Temporary change of process controls

The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices, that includes the primary process control and the approved back-up or alternate methods.

The organization shall document the process that manages the use of alternate control methods.

The organization shall include in this process, based on risk analysis (such as FMEA), severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.

IATF 16949:2016 QMS Requirements



8.5.6.1.1 Temporary change of process controls

Before shipping product that was inspected or tested using the alternate method, if required, the organization shall obtain approval from the customer(s).

The organization shall maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan.

Standard work instructions shall be available for each alternate process control method.

IATF 16949:2016 QMS Requirements



8.5.6.1.1 Temporary change of process controls

The organization shall review the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible. Example methods include but are not limited to the following:

- a) Daily quality focused audits (e.g., layered process audits, as applicable);
- b) Daily leadership meetings.

Restart verification is documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.

The organization shall implement traceability of all product produced while any alternate process control devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).

IATF 16949:2016 QMS Requirements



8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization shall retain documented information on the release of products and services.

The documented information shall include:

- a) Evidence of conformity with the acceptance criteria;
- b) Traceability to the person(s) authorizing the release.

IATF 16949:2016 QMS Requirements



8.6.1 Release of products and services - supplemental

The organization shall ensure that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan (see Annex A).

The organization shall ensure that the planned arrangements for initial release of products and services encompass product or service approval.

The organization shall ensure that product or service approval is accomplished after changes following initial release, according to ISO 9001, Section 8.5.6.

IATF 16949:2016 QMS Requirements



8.6.2 Layout inspection and functional testing

A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans.

Results shall be available for customer review.

NOTE 1 Layout inspection is the complete measurement of all product dimensions shown on the design record(s).

NOTE 2 The frequency of layout inspection is determined by the customer

IATF 16949:2016 QMS Requirements



8.6.3 Appearance items

For organizations manufacturing parts designated by the customer as "appearance items" the organization shall provide the following:

- a) Appropriate resources, including lighting, for evaluation;
- b) Masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI) and haptic technology, as appropriate;
- c) Maintenance and control of appearance masters and evaluation equipment;
- d) Verification that personnel making appearance evaluations are competent and qualified to do so.

IATF 16949:2016 QMS Requirements



8.6.4 Verification and acceptance of conformity of externally provided products and services

The organization shall have a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following methods:

- a) Receipt and evaluation of statistical data provided by the supplier to the organization;
- b) Receiving inspection and/or testing, such as sampling based on performance;
- c) Second-party or third party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements;
- d) Part evaluation by a designated laboratory;
- e) Another method agreed with the customer.

IATF 16949:2016 QMS Requirements



8.6.5 Statutory and regulatory conformity

Prior to release of externally provided products into its production flow, the organization shall confirm and able to provide evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, and other requirements in the countries where they are manufactured and in the customer-identified countries of destination, if provided.

IATF 16949:2016 QMS Requirements



8.6.6 Acceptance criteria

Acceptance criteria shall be defined by the organization and, where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects (see section 9.1 .1 .1).

IATF 16949:2016 QMS Requirements



8.7 Control of nonconforming outputs

8.7.1

The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

IATF 16949:2016 QMS Requirements



8.7 Control of nonconforming outputs

8.7.1

The organization shall deal with nonconforming outputs in one or more of the following ways:

- a) Correction;
- b) Segregation, containment, return or suspension of provision of products and services;
- c) Informing the customer;
- d) Obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

IATF 16949:2016 QMS Requirements



8.7.1.1 Customer authorization for concession

The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved.

The organization shall obtain customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit.

IATF 16949:2016 QMS Requirements



8.7.1.1 Customer authorization for concession

The organization shall maintain a record of the expiration date or quantity authorized under concession.

The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased product).

The organization shall approve any requests from suppliers before submission to the customer.

IATF 16949:2016 QMS Requirements



8.7.1.2 Control of nonconforming product - customer-specified process

The organization shall comply with applicable customer-specified controls for nonconforming product(s).

8.7.1.3 Control of suspect product

The organization shall ensure that product with unidentified or suspect status is classified and controlled as nonconforming product. The organization shall ensure that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

IATF 16949:2016 QMS Requirements



8.7.1.4 Control of reworked product

The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, the organization shall obtain approval from the customer prior to commencing rework of the product.

The organization shall have a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance to original specifications.

Instructions for disassembly or rework, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel.

The organization shall retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

IATF 16949:2016 QMS Requirements



8.7.1.5 Control of repaired product

The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product. The organization shall obtain approval from the customer before commencing repair of the product.

The organization shall have a documented process for repair confirmation in accordance with the control plan or other relevant documented information.

Instructions for disassembly or repair, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel.

The organization shall obtain a documented customer authorization for concession for the product to be repaired.

The organization shall retain documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

IATF 16949:2016 QMS Requirements



8.7.1.6 Customer notification

The organization shall immediately notify the customer(s) in the event that nonconforming product has been shipped. initial communication shall be followed with detailed documentation of the event.

8.7.1.7 Nonconforming product disposition

The organization shall have a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, the organization shall verify that the product to be scrapped is rendered unusable prior to disposal.

The organization shall not divert nonconforming product to service or other use without prior customer approval.

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 227

TÜV®

IATF 16949:2016 QMS Requirements



8.7.2

The organization shall retain documented information that:

- a) Describes the nonconformity;
- b) Describes the actions taken;
- c) Describes any concessions obtained;
- d) Identifies the authority deciding the action in respect of the nonconformity.

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 228

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Any Questions?



IATF 16949:2016 QMS

Requirements Clause 9 Performance Evaluation

IATF 16949:2016 QMS Requirements



9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

- a) What needs to be monitored and measured;
- b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) When the monitoring and measuring shall be performed;
- d) When the results from monitoring and measurement shall be analyzed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.

IATF 16949:2016 QMS Requirements



9.1.1.1 Monitoring and measurement of manufacturing processes

The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics.

NOTE for some manufacturing processes, it may not be possible to demonstrate product compliance through process capability. For those processes, alternate methods such as batch conformance to specification may be used.

IATF 16949:2016 QMS Requirements



9.1.1.1 Monitoring and measurement of manufacturing processes

The organization shall maintain manufacturing process capability or performance results as specified by the customer's part approval process requirements. The organization shall verify that the process flow diagram, PFMEA, and control plan are implemented, including adherence to the following:

- a) Measurement techniques;
- b) Sampling plans;
- c) Acceptance criteria;
- d) Records of actual measurement values and/or test results for variable data;
- e) Reaction plans and escalation process when acceptance criteria are not met.

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9.1.1.1 Monitoring and measurement of manufacturing processes

Significant process events, such as tool change or machine repair, shall be recorded and retained as documented information.

The organization shall initiate a reaction plan indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable.

IATF 16949:2016 QMS Requirements



9.1.1.1 Monitoring and measurement of manufacturing processes

These reaction plans shall include containment of product and 100 percent inspection, as appropriate. A corrective action plan shall be developed and implemented by the organization indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable.

The plans shall be reviewed with and approved by the customer, when required.

The organization shall maintain records of effective dates of process changes.

IATF 16949:2016 QMS Requirements



9.1.1.2 identification of statistical tools

The organization shall determine the appropriate use of statistical tools. The organization shall verify that appropriate statistical tools are included as part of the advanced product quality planning (or equivalent) process and included in the design risk analysis (such as DFMEA) (where applicable), the process risk analysis (such as PFMEA), and the control plan.

9.1.1.3 Application of statistical concepts

Statistical concepts, such as variation, control (stability), process capability, and the consequences of over-adjustment, shall be understood and used by employees involved in the collection, analysis, and management of statistical data.

IATF 16949:2016 QMS Requirements



9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled.

The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

IATF 16949:2016 QMS Requirements



9.1.2.1 Customer satisfaction - supplemental

Customer satisfaction with the organization shall be monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements.

Performance indicators shall be based on objective evidence and include but not be limited to the following:

- a) Delivered part quality performance;
- b) Customer disruptions;
- c) Field returns, recalls, and warranty (where applicable);
- d) Delivery schedule performance (including incidents of premium freight);
- e) Customer notifications related to quality or delivery issues, including special status.

IATF 16949:2016 QMS Requirements



9.1.2.1 Customer satisfaction - supplemental

The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency.

The monitoring shall include the review of customer performance data including online customer portals and customer scorecards, where provided.

IATF 16949:2016 QMS Requirements



9.1.3 Analysis and evaluation

The organization shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

- a) Conformity of products and services;
- b) The degree of customer satisfaction;
- c) The performance and effectiveness of the quality management system;
- d) If planning has been implemented effectively;
- e) The effectiveness of actions taken to address risks and opportunities;
- f) The performance of external providers;
- g) The need for improvements to the quality management system.

NOTE Methods to analyze data can include statistical techniques.

IATF 16949:2016 QMS Requirements



9.1.3.1 Prioritization

Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

IATF 16949:2016 QMS Requirements



9.2 internal audit

9.2.1

The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

- a) Conforms to:
 - 1) The organization's own requirements for its quality management system;
 - 2) The requirements of this International Standard;
- b) Is effectively implemented and maintained.

IATF 16949:2016 QMS Requirements



9.2.2

The organization shall:

- a) Plan, establish, implement and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- b) Define the audit criteria and scope for each audit;
- c) Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) Ensure that the results of the audits are reported to relevant management;
- e) Take appropriate correction and corrective actions without undue delay;
- f) Retain documented information as evidence of the implementation of the audit program and the audit results.

NOTE See ISO 19011 for guidance.

IATF 16949:2016 QMS Requirements



9.2.2.1 internal audit program

The organization shall have a documented internal audit process. The process shall include the development and implementation of an internal audit program that covers the entire quality management system including quality management system audits, manufacturing process audits, and product audits.

The audit program shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es).

IATF 16949:2016 QMS Requirements



9.2.2.1 internal audit program

Where the organization is responsible for software development, the organization shall include software development capability assessments in their internal audit program.

The frequency of audits shall be reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints.

The effectiveness of the audit program shall be reviewed as a part of management review.

IATF 16949:2016 QMS Requirements



9.2.2.2 Quality management system audit

The organization shall audit all quality management system processes over each three-year calendar period, according to an annual program, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.

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9.2.2.3 Manufacturing process audit

The organization shall audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits.

Where not defined by the customer, the organization shall determine the approach to be used.

Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover.

The manufacturing process audit shall include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.

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9.2.2.4 Product audit

The organization shall audit products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements.

Where not defined by the customer, the organization shall define the approach to be used.

IATF 16949:2016 QMS Requirements



9.3 Management review

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

9.3.1.1 Management review - supplemental

Management review shall be conducted at least annually. The frequency of management review(s) shall be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance-related issues.

IATF 16949:2016 QMS Requirements



9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

- a) The status of actions from previous management reviews;
- b) Changes in external and internal issues that are relevant to the quality management system;
- c) Information on the performance and effectiveness of the quality management system, including trends in:
 - 1) Customer satisfaction and feedback from relevant interested parties;
 - 2) The extent to which quality objectives have been met;
 - 3) Process performance and conformity of products and services;
 - 4) Nonconformities and corrective actions;
 - 5) Monitoring and measurement results;
 - 6) Audit results;
 - 7) The performance of external providers;

IATF 16949:2016 QMS Requirements



9.3.2 Management review inputs

- d) The adequacy of resources;
- e) The effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) Opportunities for improvement.

IATF 16949:2016 QMS Requirements



9.3.2.1 Management review inputs - supplemental

Input to management review shall include:

- a) Cost of poor quality (cost of internal and external nonconformance);
- b) Measures of process effectiveness;
- c) Measures of process efficiency;
- d) Product conformance;
- e) Assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see section 7.1.3);
- f) Customer satisfaction (see ISO 9001, section 9.1.2);
- g) Review of performance against maintenance objectives;
- h) Warranty performance (where applicable);
- i) Review of customer scorecards (where applicable);
- j) Identification of potential field failures identified through risk analysis (such as FMEA);
- k) Actual field failures and their impact on safety or the environment.

IATF 16949:2016 QMS Requirements



9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

- a) Opportunities for improvement;
- b) Any need for changes to the quality management system;
- c) Resource needs.

The organization shall retain documented information as evidence of the results of management reviews

9.3.3.1 Management review outputs - supplemental

Top management shall document and implement an action plan when customer performance targets are not met.

Any Questions?





IATF 16949:2016 QMS

Requirements Clause 10 Improvement

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 255

TÜV®

IATF 16949:2016 QMS Requirements



10 Improvement

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

- a) Improving products and services to meet requirements as well as to address future needs and expectations;
- b) Correcting, preventing or reducing undesired effects;
- c) Improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

TÜV SÜD South Asia

02-Dec-16

IATF 16949:2016 IA Ed 2016 Rev 0

Slide 256

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IATF 16949:2016 QMS Requirements



10.2 Nonconformity and corrective action

10.2.1

When a nonconformity occurs, including any arising from complaints, the organization shall:

- a) React to the nonconformity and, as applicable:
 - 1) Take action to control and correct it;
 - 2) Deal with the consequences;
- b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - 1) Reviewing and analyzing the nonconformity;
 - 2) Determining the causes of the nonconformity;
 - 3) Determining if similar nonconformities exist, or could potentially occur;

IATF 16949:2016 QMS Requirements



10.2 Nonconformity and corrective action

10.2.1

When a nonconformity occurs, including any arising from complaints, the organization shall:

- c) Implement any action needed;
- d) Review the effectiveness of any corrective action taken;
- e) Update risks and opportunities determined during planning, if necessary;
- f) Make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

IATF 16949:2016 QMS Requirements



10.2.2

The organization shall retain documented information as evidence of:

- a) The nature of the nonconformities and any subsequent actions taken;
- b) The results of any corrective action.

IATF 16949:2016 QMS Requirements



10.2.3 Problem solving

The organization shall have a documented process(es) for problem solving including:

- a) Defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
- b) Containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001, Section 8.7);
- c) Root cause analysis, methodology used, analysis, and results;
- d) Implementation of systemic corrective actions, including consideration of the impact on similar processes and products;

IATF 16949:2016 QMS Requirements



10.2.3 Problem solving

- e) Verification of the effectiveness of implemented corrective actions;
- f) Reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan).

Where the customer has specific prescribed processes, tools, or systems for problem solving, the organization shall use those processes, tools, or systems unless otherwise approved by the customer.

IATF 16949:2016 QMS Requirements



10.2.4 Error-proofing

The organization shall have a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used shall be documented in the process risk analysis such as PFMEA) and test frequencies shall be documented in the control plan.

The process shall include the testing of error-proofing devices for failure or simulated failure. Records shall be maintained. Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.

IATF 16949:2016 QMS Requirements



10.2.5 Warranty management systems

When the organization is required to provide warranty for their product(s), the organization shall implement a warranty management process. The organization shall include in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, the organization shall implement the required warranty management process.

IATF 16949:2016 QMS Requirements



10.2.6 Customer complaints and field failure test analysis

The organization shall perform analysis on customer complaints and field failures, including any returned parts, and shall initiate problem solving and corrective action to prevent recurrence.

Where requested by the customer, this shall include analysis of the interaction of embedded software of the organization's product within the system of the final customer's product.

The organization shall communicate the results of testing/analysis to the customer and also within the organization.

IATF 16949:2016 QMS Requirements



10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

IATF 16949:2016 QMS Requirements



10.3.1 Continual improvement - supplemental

The organization shall have a documented process for continual improvement. The organization shall include in this process the following:

- a) Identification of the methodology used, objectives, measurement, effectiveness, and documented information;
- b) A manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
- c) Risk analysis (such as FNIEA).

NOTE Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics are predictable and meet customer requirements.



Any Questions?



IATF 16949:2016 QMS INTERNAL AUDIT

Internal Audit



Audit

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

Auditor

A person with the competence to conduct an audit.

Audit Team

One or more auditors conducting an audit, supported if needed by technical expert.

Technical Expert

Person who provides specific knowledge or expertise to the audit team.

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Slide 269

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Internal Audit



Audit Client

Organization or person requesting an audit

Auditee

An organization/function being audited.

Audit Plan

Description of the activities and arrangements for an audit

Audit Program

Set of one or more audits planned for a specific time frame and directed towards a specific purpose.

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Slide 270

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Internal Audit



Audit Evidence

Records, statements of fact or other information which are relevant to the audit criteria and verifiable. (Audit Notes)

Audit Findings

Results of the evaluation of the collected audit evidence against audit criteria. (Positive Finding, Conformity Finding, Nonconformity finding, Area for improvement)

Audit Conclusion

Outcome of the audit, provided by the audit team, after consideration of the audit objectives and all audit findings.

Nonconformity

The non-fulfillment of specified requirements.

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Internal Audit



Types of Audits

First Party Audit

Internal Audit conducted by Employees of the Organization

Second Party Audit

Audit conducted by interested parties / Customer

Third Party Audit

Audit conducted by independent Agency / Certification Body

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Internal Audit



Types of Audits,

Adequacy Audit

An Exercise to determine the extent to which the documented Quality System represented by the quality manual and the associated procedures ,adequately addresses and meet the requirements of the applicable standard.

Compliance Audit

An audit to establish the extent to which the documented system is implemented.

Combined Audit

Quality and environmental management systems are audited together

Integrated Audit

Audit of integrated systems (QMS and EMS)

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Internal Audit



Types of Audits.

QMS Internal Audit

Audit of Organization's processes considering QMS requirements

Manufacturing Process Audit

Audit of Manufacturing process considering process approach

Product Audit

Audit of Product considering Control Plan requirement

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Internal Audit



Principles for Audit and Auditor.

Ethical Conduct

Foundation of Professionalism - Trust, Integrity, Confidentiality

Fair Presentation

The obligation to report truthfully and accurately

Due Professional care

Auditors exercise care in accordance with the importance of the task they perform and the confidence placed in them by audit clients and other interested parties

Continued...

Internal Audit



Principles for Audit and Auditor ...continued

Independence

Auditors are independent of the activity being audited and are free from bias and conflict of interest, and to ensure that the audit findings and conclusions will be based only on the audit evidence.

Evidence based audit

The rational method for reaching reliable and reproducible audit conclusions in a systematic audit process

Internal Audit



Audit Objective – Purpose of Audit

To verify establishment, awareness, implementation, maintenance and effectiveness of QMS. To check Compliance to Audit Criteria. Value addition to the Organization

Audit Criteria – Set of policies, procedures and requirements

QMS Standard Requirements. Organizations' own QMS. Customer Specific Requirements. Statutory and Regulatory requirements related to Product

Audit Scope – Extent and boundaries of an audit

Site to be audited. Business Processes to be audited. Product Group and Manufacturing Processes to be audited

Internal Audit



Conformity WRT Requirements

Effectiveness WRT Objectives

Opportunity WRT Improvements

Compliance WRT Regulatory requirements

Certification WRT Standards

Internal Audit



Features of an Audit

- § Audit Planning and Preparation
- § Opening Meeting
- § Audit Conduct
- § Audit Method
- § Audit Reporting
- § Closing Meeting
- § Follow up for Corrective Action Verification

Internal Audit



Audit Planning and Preparation

- § Audit Objective
- § Audit Criteria and Audit Scope
- § Audit Man days
- § Audit Team
- § Audit Plan / Schedule and Audit Documentation
- § Communication and Confirmation from Auditee
- § Logistics Planning

Internal Audit



Opening Meeting

- § Greet Management and Auditees
- § Introduction of Audit Team and Auditees
- § Type of Audit, Audit Objective, Criteria and Scope
- § Audit Plan and Duration of Audit
- § Sampling Audit, Confidentiality
- § Language of Audit
- § Audit Reporting
- § Closing Meeting Schedule

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Slide 281

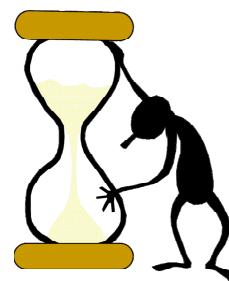
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Internal Audit



Audit Conduct

- § Time Management
- § Audit Objective
- § Audit Criteria
- § Audit Scope



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Slide 282

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Internal Audit



Audit Method

- § Select sufficient samples
- § Review documentation
- § Witness processes
- § Interview auditee
- § Check effectiveness of QMS
- § Follow audit trail
- § Ask open ended questions
- § Verify non-achievement and corrective actions
- § Look for Improvement Projects



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IATF 16949:2016 IA Ed 2016 Rev 0

Slide 283

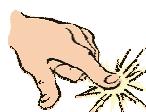
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Internal Audit



Audit Method

- § Check Establishment
- § Check Documentation
- § Check Communication
- § Check Awareness
- § Check Planning (PDCA)
- § Check Implementation
- § Check Performance
- § Check Problem solving (CAPA)
- § Check Improvements (CIP)



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Slide 284

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Internal Audit



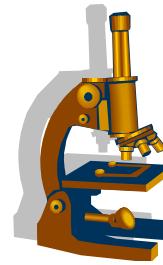
Process Approach based audit

Process Inputs

Man, Machine, Material, Method, Measurement, Management and Environment

Process Outputs

Productivity, Quality, Cost, Delivery, Compliance, Safety and Motivation



QMS Stages

Establishment (Documentation)
Awareness (Communication)
Implementation (PDCA)
Maintenance (CAPA)
Effectiveness (Improvement)

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Internal Audit



Internal Auditor Competency Requirement,

- § Educational Qualification
- § Industry Experience
- § QMS Experience
- § Auditing Experience
- § Knowledge of Manufacturing Process and Product Application
- § Knowledge of QMS, Core Tools and CSR
- § Knowledge of Auditing Guidelines
- § Knowledge of statutory and regulatory requirements related to the product
- § Professional Skills and Qualities

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Internal Audit



Internal Auditor Skills Requirement

- § Professional
- § Systematic
- § Time Management
- § Punctuality
- § Planning and Reporting skill
- § Communication (Language Fluency, phone etiquettes, mail etiquettes)
- § Explaining ability and convincing power
- § Questioning technique
- § Reading and Writing ability

Internal Audit



Internal Auditor Skills Requirement

- § Observing and listening ability
- § Ethical and un-biased
- § Fair
- § Trustworthy
- § Authoritative
- § Firm
- § Polite and Respectful
- § Talkative and Expressive
- § Mentoring skills
- § Friendly and helping nature

Internal Audit



Audit Reporting

- § Positive Findings (Appreciate Auditee)
- § Conformity Points
- § Improvement Points (Value Addition)
- § Minor NCs and Major NCs
- § Audit Result



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Internal Audit



Minor NC

- § Single deviation
 - In a process
 - In a particular clause

A single observed lapse in one item of QMS

A failure in some part of QMS

No evidence of Customer Dissatisfaction or Major Business Loss due to deviation

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Internal Audit



Major NC,

Number of deviations

- § In one process against different clause requirements
- § In different processes against requirement of one particular clause
- § In compliance to customer specific requirements
- § In compliance to statutory and regulatory requirements

Deviation which has resulted in to customer dissatisfaction or major business loss

Deviation which leads to probability of shipment of NC product to customer

Absence or complete failure of QMS

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Internal Audit



Closing Meeting

- § Greet Management and Auditees
- § Type of Audit, Audit Objective, Criteria and Scope
- § Audit Findings – SWOT
- § NC Report - Target Date and Responsibility to Close NCs
- § Follow Up to verify Closure of NC

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Any Questions?



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