



**EAGLE** Certification Group  
SERVICE • INTEGRITY • VALUE

# EAGLE IATF 16949:2016 Client Training

February 2017



## Tools Required for Successful Completion of This Training:

- *New Automotive QMS Standard or IATF 16949 Standard;*
- *Copy of ISO9001: 2015 Standard; and*
- *Old ISO/TS16949: 2009 Standard*

*New, and enhanced/revised sections from ISO/TS16949:2009 to New IATF16949:2016 Standard highlighted in Blue.*



**Automotive Industry's Intent with New IATF16949: 2016**  
**for all Stakeholders is Based on**  
**Seven Quality Management Principles:**

- 1. Customer Focus***
- 2. Leadership***
- 3. Engagement of People***
- 4. Process Approach***
- 5. Improvement***
- 6. Evidenced Based Decision***
- 7. Relationship Management***



## Why New IATF16949?

- *Strengthening of Requirements Based on Automotive Lessons Learned(e.g. Management/Leadership, Risk Analysis, Supplier Control);*
- *Adding of Common CSR Requirements(100+);*
- *Adding of New Requirements (e.g. Products with Embedded Software, NC Product Disposition, Warranty Management);  
And*
- *The Primary Goal is to Reduce Risk(s) in the Automotive Industry and Improve Performance Throughout the Supply Chain.*



## Section 4.3.2 (various different spots in ISO/TS 16949)

### 4.3.2 Customer-specific requirements(CSRs)

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

**Rationale: This requirement specifically addresses the need to have a process to gather, communicate/evaluate, and implement all applicable CSRs in the quality management system(QMS)**



## Section 4.4.1.2 Product Safety (New)

*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: Subclauses a)-m) e.g.*

- a) Identification by the organization of statutory and regulatory product-safety requirements; .....
- m) Lessons learned for new product introduction.

**Rationale: This is a new section with new / enhanced requirements that address current and emerging issues the automotive industry is facing related to product and process safety.**



## 5.1 Leadership and Commitment/Section 5.1.1.1 Corporate Responsibility (New enhancement to address industry interests)

*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-blower policy”).*

**Rationale: ISO 9001:2015 expanded the ISO 9001:2008 concept of Management Responsibility and Commitment into a set of Leadership behaviors to ensure an effective Quality Management System. The IATF supplemented the ISO requirements by adopting a Corporate Responsibility requirement to address increasing market and governmental expectations for improved integrity in social and environmental matters.**



### Section 5.1.1.3 Process Owners (New)

*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 these roles (see ISO9001, Sect. 7.2)*

**Rationale: ISO/TS 16949:2009 addressed management responsibility and authority, but it did not explicitly mention that management ensure process owners understand their role and are competent. The IATF adopted this requirement to ensure that management understands this expectation.**





## **Section 6.1 Actions to address risks and opportunities/ 6.1.2.1 Risk analysis (various sections in ISO/TS 16949)**

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

**Rationale: *The approach and requirements concerning the identification of risks is not new to current users of the ISO/TS 16949:2009. The need to identify, analyze and consider actual and potential risks was already covered in various areas of ISO/TS 16949:2009. The IATF adopted the above requirements recognizing the need to analyze and respond to risk, and to have organizations consider specific risks associated with the automotive industry.***



**Section 6.1.2.2 Contingency plans (Enhancements to formerly 6.3.2 in ISO/TS 16949).** *The organization shall: a-g*

- 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 satisfied;*
- b) define contingency plans according to risk and impact to the customer;*

**Rationale:** The IATF enhanced the requirement found in ISO/TS 16949:2009 by comprehending what's considered to be either best-practice or already state-of-the-art requirements in the automotive industry



## Cont.- Section 6.1.2.2 Contingency plans (formerly 6.3.2 in ISO/TS 16949)

The organization shall(a-g):

- d) include, as a supplement to the contingency plans, notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations;*
- e) periodically test the contingency plan 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 contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).*



**Section 7.1.5.2.1 Calibration/Verification Records(formerly 7.6.2 in ISO/TS)- Enhanced.**

*-The organization shall have a documented process for managing calibration/verification records.*

*-The organization shall ensure that calibration/verification activities and records shall incl. the following details: (New)*

*c) An assessment of the risk of the intended use of the product caused by the Out of Spec condition;*

*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, incl. the associated standard's last calibration date and the next due date on the calibration report; (New)*

*g) Verification that the software version used for product and process control is as specified; (New)*

*h) Records of the calibration and maintenance activities for all gauging(Incl. employee-owned equipment, customer owned equipment, or on-site supplier-owned equipment); (New)*

*i) Production-related software verification used for product & process control(Incl. software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).(New)*

**Rationale: Ensuring that customer requirements are met, enhanced calibration/ verification record retention requirements, including software installed on employee-owned or customer-owned equipment**



## **Section 7.2.3- Internal Auditor Competency (Enhancements to previous 8.2.2.5 in ISO/TS 16949)**

*The organization shall have a documented process(es) to verify that internal auditors are competent, taking into account any customer-specific requirements. QMS auditors, Mfg Process auditors, and product auditors shall be able to demonstrate the following min. competencies, a-g, e.g. a) understanding of the automotive process approach for auditing, incl. risk-based thinking.*

**Rationale: Improve internal auditor competency in order to effectively ensure meeting internal and external customer specific requirements(CSRs).**



## **Section 7.2.4- Second Party Auditor Competency (New Requirement)**

*The organization shall demonstrate the competence of the auditors undertaking second party audits to meet customer specific requirements(CSRs) for auditor qualification and demonstrate the min. following core competencies, incl.: (a-f)*

*e.g. a)Automotive Process Approach to Auditing, incl. risk based thinking, and b) applicable customer and organization specific requirements.....f)*

**Rationale: Improve overall performance of problem suppliers having repeat issues meeting customer specific requirements(CSRs).**



### **Section 7.5.1.1 QMS Documentation (formerly 4.2 in ISO/TS)**

The organization's QMS shall be documented and incl. a quality manual, which can be a series of documents. The quality manual shall incl. as a min., the following

- a) Scope of the QMS, incl. details of and justification for exclusions;
- b) Documented processes established for the QMS;
- c) The organization's processes and their sequence and interactions(inputs and outputs), incl. type and extent of control of any outsourced processes;
- d) A document(i.e. matrix indicating where within the organization's QMS their CSRs are addressed.

**Rationale: Retained the quality manual requirement; however, this can be one main document or a series of multiple documents. Also requires that the organization's processes and interactions are documented as part of their QMS.**



## **Section 8.1.1- Operational Planning and Control (formerly 7.1.1 of ISO/TS)**

*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 (refer to section 8.3.2)*
- e) acceptance criteria*

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

**Rationale: Ensures key processes are included and considered when planning for product realization**





### **Section 8.3.2.3 – Development of Products with Embedded Software (New Requirement)**

*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.*

**Rationale: Strengthening of requirements for design and development validation, adding embedded software.**

### **Section 8.3.3.1 – Product Design Input (Enhancements to previous 7.3.2.1 in ISO/TS 16949)**

*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-h):*

- a) product specifications including, but not limited to, special characteristics (see Section 8.3.2.1);*
- b) boundary and interface requirements(New)*
- c) Identification, traceability, and packaging;*
- d) consideration of design alternatives(New)*

**Rationale: Expanded the minimum set of product design input requirements, emphasizing regulatory and software requirements**



### Cont./Section 8.3.3.1 – Product Design Input (Enhancements to previous 7.3.2.1 in ISO/TS 16949)

*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-h):*

- e) assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis;(NEW)*
- f) targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, and environmental, development timing, and cost;*
- g) applicable statutory and regulatory requirements of the customer-identified country of destination, if provided(NEW)*
- h) embedded software requirements(NEW)*

**Rationale: Expanded the minimum set of product design input requirements, emphasizing regulatory and software requirements**



## **Section 8.3.4.2 -Design and development validation (formerly 7.3.6.1 in ISO/TS)**

*-Design and development validation shall be performed in accordance with customer requirements and applicable industry and regulatory standards.*

*-The timing of design and development validation shall be aligned 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.*

**Rationale: Strengthening of requirements for design and development validation, adding embedded software.**



## **Section 8.3.4.4 Product approval process (Enhancements to 7.3.6.3 of ISO /TS)**

- The organization shall establish, implement, and maintain a product and manufacturing process approval process conforming to requirements defined by the customer(s).*
- The organization shall ensure that all externally provided products and services have been approved per Section 8.4.3 prior to submission of their part approval to the customer.*
- Documented customer product approval is required prior to shipment. Records of such approval shall be retained.*

**Rationale: Clarified approval requirements, with emphasis on outsourced products and services, and record retention**

### **Section 8.3.5.1 Design and development outputs – supplemental (formerly 7.3.3.1 of ISO/TS)**

*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-j)**:*

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

**Rationale: Recognition of use of 3D models, inclusion of service parts and packaging**



### **Cont.- Section 8.3.5.1 Design and development outputs – supplemental (formerly 7.3.3.1 of ISO/TS)**

*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-j):*

- f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GT&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 trade-off process.*

**Rationale: Recognition of use of 3D models, inclusion of service parts and packaging**



## **Section 8.3.5.2 Manufacturing process design output (formerly 7.3.3.2 of ISO/TS)**

*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 includes, but is not limited to, the following(a-n):*

- 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;*
- e) manufacturing process flow charts/layout, including linkage of product, process, and tooling;*

**Rationale: Strengthened verification requirements, process input variables, capacity analysis, maintenance plans and correction of process nonconformities**



### Cont.- Section 8.3.5.2 Manufacturing process design output (formerly 7.3.3.2 of ISO/TS) .

*The manufacturing process design output includes, **but is not limited to**, the following(a-n):*

- 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 nonconformities.*

**Rationale: Strengthened verification requirements, process input variables, capacity analysis, maintenance plans and correction of process nonconformities**



### **Section 8.3.6.1 -Design and development changes - supplemental (formerly 7.3.7 Note of ISO/TS)**

- *The organization shall evaluate all design changes after initial product approval, incl. those proposed by the organization or its suppliers, for potential impact on fit, 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.*

**Rationale: Strengthened requirement for change validation and approval prior to implementation, reduced CSRs, added embedded software**



## Section 8.4.1.2 - Supplier selection process (New Content)

*The organization shall have a documented supplier selection process. The selection process shall incl:*

- 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 QMS;*
- d) multidisciplinary decision making; and*
- e) an assessment of software development capabilities, if applicable.*

*Rationale: Reduction of Customer Specific Requirements*



## Cont- Section 8.4.1.2 - Supplier selection process (New Content)

*Other supplier selection criteria that should be considered incl. 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*

*Rationale: Reduction of Customer Specific Requirements*



Section 8.4.1.3 - Customer-directed sources (also known as “Directed–Buy”) formerly 7.4.1.3 of ISO/TS)

- **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 Section 8.4.1.1) 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.

**Rationale: Clarification of organization’s responsibilities for customer directed sources**



## **Section 8.4.2.1 - Type and extent of control – supplemental (formerly 7.4.3.1 of ISO/TS)**

*-The organization shall have a documented process to select the types and extent of controls used to ensure conformity of externally provided products, processes, and services to internal 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.*

**Rationale: Strengthened requirement, including assessment of risks**



## Section 8.4.2.2 - Statutory and regulatory requirements (formerly 7.4.1.1 of ISO/TS)

*-The organization shall define actions and methodologies 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 of 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, incl. at suppliers.*

**Rationale:** *Strengthened requirements, clarified applicability of statutory and regulatory requirements (homologation)*

### **Section 8.4.2.3 -Supplier QMS development (Enhancement to Note in 7.4.1.2 of ISO/TS)**

-The organization shall require their suppliers of automotive products and services to develop, implement, and improve a QMS certified to ISO9001, 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 this requirement(a-e)::**

- a) compliance to ISO9001 through second-party audits;
- b) certification to ISO9001 through third party audits;
- c) Certification to ISO9001 with compliance to other customer defined QMS requirements(e.g. Min. Automotive QMS Requirements for Sub-Tier Suppliers( MAQMSR) or equivalent) thru second-party audits;
- d) Certification to ISO9001 with compliance to IATF 16949 thru second party audits.
- e) Certification to TS 16949 thru third party audits by valid certification bodies.

**Rationale: Providing a method to strengthen ISO9001 certification, alignment of customer specific requirements, clarification on acceptable third party certification bodies.**





### **Section 8.4.2.3.1 – Automotive product-related software or automotive products with embedded software (New)**

*-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.*

**Rationale: Added requirements for software developer capability assessments**



### **Section 8.4.3.1 Information for External Providers - Supplemental (New)**

*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.*

**Rationale: Require organizations to provide key information to their supply chain.**



### **Section 8.5.1.4 Verification after shutdown (New)**

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

**Rationale: Definition of requirement for verification after shutdown, based on industry lessons learned**



### **Section 8.5.1.5 Total Productive Maintenance (former 7.5.1.4)-Enhanced.**

The organization shall develop, implement, and maintain a documented total productive maintenance system. At a minimum, the system shall include the following (items a-j):

- e) Applicable Customer-Specific Requirements(New);
- f ) Documented maintenance objectives, e.g. 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 ISO9001, Section 9.3) (New);
- g) Regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved (New);
- j) Periodic overhaul(New);

**Rationale: Evidence of insufficient maintenance impacting the customers and Lessons Learned.**



### **Section 8.5.6.1.1 Temporary Change of Process Controls (New)**

*-The organization shall identify, document, and maintain a list of process controls, incl. 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 the alternate methods, based on risk analysis(such as FMEA), severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.*

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

**Rationale: Added to address issues experienced by the customers involving bypassed processes.**



## **Section 8.6.1 Release of products and services — supplemental (New)**

- 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 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 ISO9001, Section 8.5.6.*

**Rationale: Strengthening the standard to ensure process controls align with Control Plan**



## Section 8.6.5 Statutory and regulatory conformity (formerly 7.4.3)

*Prior to release of externally provided products into its production flow, the organization shall confirm and be 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.*

**Rationale: Strengthening standard to require evidence.**



## **Section 8.7.1.2 Control of nonconforming product – customer specified process (New)**

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

**Rationale: Ensures customer Controlled Shipping requirements are followed, reduces customer specific requirements.**





### **Section 8.7.1.3 Control of suspect product (formerly 8.3.1)**

*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.*

**Rationale: Strengthening requirements by ensuring containment training is implemented.**

### **Section 8.7.1.4 Control of Reworked Product (formerly 8.3.2)**

*-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. (New)*

*-Instructions for **disassembly or** rework, incl. 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 incl. quantity, disposition, disposition date, and applicable traceability information. (New)*

**Rationale: Strengthening requirements reworked products to ensure customer product specifications.**



## **Section 8.7.1.7 Non-Conforming Product Disposition (New)**

*-The organization shall have a documented process for disposition of non-conforming 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 non-conforming product to service or other use without prior customer approval.*

**Rationale: New automotive requirements to address modifications in ISO9001 requirements and address customer issues**

### 9.1.1.1 Monitoring and Measurement of Manufacturing Processes (8.2.3.1 & 8.2.4 in ISO/TS) Enhanced

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-e)*:

- a) Measurement Techniques; b) Sampling Plans; c) Acceptance Criteria(A.C.);*
- d) Records of Actual Measurement Value and/or Test Results for Variable data. (New)*
- e) Reaction plans and Escalation Process when A.C. are not met.*

**Rationale:** The organization must verify the process(es) adhere to their planned activities with records of actual measurement values and/or test results, and through reaction plans and escalation process(es) when A.C. are not met. Both the way to record/plot the measurements and the escalation process(es) should be within the control Plan.

### **9.2.2.1 Internal Audit Programme (formerly 8.2.2.4 in ISO/TS) Enhanced**

- The organization shall have a documented internal audit process. The process shall include the development and implementation of an internal audit programme that covers the entire QMS, incl. QMS audits, manufacturing process audits, and product audits.*
- The audit programme shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es). (New)*
- Where the organization is responsible for software development, the organization shall include software development capability assessments in their internal audit programme. (New)*
- The frequency of audits shall be reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external audit non-conformities, and/or customer complaints. The effectiveness of the audit programme shall be reviewed as a part of the management review.*

**Rationale: Need to drive a risk based approach to the development and deployment of an organization wide audit program**



### 9.2.2.2 Quality Management System Audit (formerly 8.2.2.1 in ISO/TS) Enhanced.

*-The organization shall audit all QMS processes over each three-year calendar period, according to an annual programme, using the process approach to verify compliance with this Automotive QMS Standard.*

*-Integrated with these audits, the organization shall sample customer-specific QMS requirements for effective implementation. (New)*

**Rationale: Experience has shown significant weakness “a lack” of process approach used , resulting in missed opportunity to drive process improvement.**



### **9.2.2.3 Manufacturing Process Audit (formerly 8.2.2.2 in ISO/TS)**

*-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. (New)*

*-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. (New)*

**Rationale: Need to drive formal approaches to ensure the benefits of effective manufacturing process audits are achieved by organizations. List of the approaches validated by IATF.**



### **9.3.1.1 Management Review-Supplemental (formerly 5.6.1.1 in ISO/TS)-Enhanced**

*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 QMS and performance-related issues.*

**Rationale: New minimum requirement of annual, and linked to risk/issues.**





### 9.3.2.1 Management review inputs - supplemental (Enhancements to 5.6.2.1 in ISO/TS)

**Input to management review shall include:**

- a) cost of poor quality (cost of internal and external nonconformance); (New)*
- b)-c) Measures of Process Effectiveness and Efficiency; (New)*
- e) Assessment of **manufacturing feasibility** made for changes to existing operations and for new facilities or new product feasibility (see Sect 7.1.3.1); (New)*
- g) Review of performance vs. maintenance objectives; (New)*
- h) Warranty Performance (where applicable); (New)*
- j) Identification of Potential Field Failures identified thru Risk Analysis (FMEA)*

**Rationale: Consolidation of requirements from OEM customer specific's.**



### **9.3.3.1 Management Review Outputs - supplemental (New)**

*Top management shall document and implement an action plan when customer requirements are not met.*

**Rationale: New requirement to ensure action(s) is/are taken where customer requirements are not achieved, support continual analysis of process performance and risk.**



## **Section 10.2.5 Warranty Management (New Requirement)**

*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 an NTF (no trouble found). When specified by the customer, the organization shall implement the required warranty management process.*

*Rationale: New requirement based on the increasing importance of warranty management and consolidates OEM customer specific requirements.*



## Key changes to Rules 5<sup>th</sup> edition

- Accessory Parts was added to the definition as eligible:  
Shall be understood as additional parts manufactured to OEM specifications that are procured or released by the OEM and are mechanically attached or electrically connected to the vehicle before or after delivery.
- 5.8 h A major NCR shall be issued if no action plan is in place to address the customer objectives/targets that are not achieved, if the plan is not implemented in a timely manner, and/or the completed actions are found to not be effectively implemented.



- 5.11 Client Responsibilities for Major and Minor NCRs
  - Includes timings for submittal of plan, evidence, verification actions,
  - Take note of 5.11.1 c which calls out that the response must include consideration of similar processes and products.
    - This is not new, but is not consistently applied by certified organizations.



**END OF PRESENTATION**

**Thank You.**