



IATF 16949:2016 – Automotive Quality Management System

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APPROVED BY:	
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5 Leadership

5.1 Leadership and Commitment

Organization Name's Top Management ensures that performance of quality management system implementation and provides a commitment to developing an effective system to exhibit its leadership and commitment.

- The quality policy and the objectives of the quality management system should be established and matched to the direction of the company;
- To integrate quality management system requirements into business processes of the Organization Name;
- To check for resources accessibility for the QMS;
- The quality management audit should be made or conducted to achieve its future result by proper evaluation and maintenance;
- An effectiveness of quality management system is attained by direction and support to persons;
- Encouraging continual improvement;
- To establish leadership responsibility, support other relevant management roles in their areas.

5.2 Quality Policy

5.2.1 Establishing the Quality Policy

Top Management is committed to maintaining high-quality standards in delivering prompt and cost-effective services or solutions to customers by continual improvement of business processes amongst all employees, and recognizing the integrity, confidentiality, and availability of information assets to relevant stakeholders including customers.

- It should be suitable to purpose and quality management of the Organization Name;
- Offers a framework to review and set up objectives of the QMS;
- Organization Name provides quality awareness training to all employees with proper work instruction to maintain and improve the effectiveness of the quality management system;
- Directs communications between external and internal;
- Guarantee continual improvement of the QMS;
- Directs to ensure capabilities needed for quality management system.

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1 Purpose

This procedure describes the method for ensuring that all instruments used for inspection, measurement and control of parameters affecting product quality are properly selected, calibrated or verified to ensure the adequacy and precision of the equipment at hand.

2 Scope

The procedures are applicable for all inspection, measuring, and testing instruments used in Inspection and testing areas, production areas, and assembly lines to measure the process parameters and quality of the products.

3 Responsibility

- 3.1 It is the responsibility of the Head of QA to plan, select, procure, calibrate, verify, and maintain inspection, measuring, testing equipment and instruments which are appropriate, precise and accurate for the intended purpose. In addition, he keeps all records of calibration of equipment and instruments, and related instructions.
- 3.2 A Functional Head or Employee is responsible for ensuring only calibrated or verified equipment is employed for testing and measurements to verify that the product meets the specified requirements.
- 3.3 The Senior Management, the concerned Functional Heads and all employees are responsible for calibrating all inspection instruments and equipment before the calibration validity expires. The calibration status of the device must also be maintained by them.

4 Description of Activity

4.1 Equipment Selection / Specifications

- 4.1.1 At the various work places, the QA Head ensures that inspection, measuring, and testing instruments are used with the required precision, accuracy, range, etc. He procures the items lacking with approval of HOD / top management if anything is found lacking. Our process / inspection requirements determine the least count / accuracy of our instruments, which is then verified using our equipment.
- 4.1.2 It is necessary to calibrate the instruments used for inspection, testing, and process control. The Calibration Status of the Instruments (F-QMS-03) should record these calibrations.

4.2 Calibration Periodicity

- 4.2.1 In accordance with the Calibration Status of the Instruments (F-QMS-03), periodic calibration of the instruments / equipment used for demonstrating the product conformance with the company's specific requirements has already been established. Calibration Status of the Instruments (F-QMS-03) contains information about instruments that may influence product quality, such as calibration frequency and method.

4.3 System of Calibration of Instruments

Instruments used in process and QC are calibrated by Outside Calibration Labs where their validity is known because they are related to nationally / internationally recognized standards.

In order to establish and maintain a traceable calibration system, the following features need to be taken into consideration:

4.3.1 Calibration is done on all critical inspection instruments. No calibration is done on equipment that's used only for the indication (such as voltmeters). Validation may also be required for processes such as welding, sterilization, training, heat treatment, calls center service or emergency response.

4.3.2 After considering measurement requirements, test criteria, and the process or product, the Head of Q.C. identifies the critical instruments and equipment. It is necessary to calibrate only such instruments. Our system does not require calibration or verification of the instruments used for indicator or not relevant to our system; these are considered as indicators.

4.4 New / Repaired Instruments

If the instrument is not accompanied by a calibration certificate from the manufacturer, all new or repaired measuring instruments must undergo calibration before they can be used. Further, the Head of Production issues them an identification number in order to identify them and sends them to the concerned work area.

4.5 Identification of Calibration Status

It is necessary to identify the calibration status of the equipment by stickers, tags, or records to recall when calibration is due.

4.6 Withdrawal of Equipment

Whenever anyone finds a piece of equipment having a systematic error nearer to the acceptance criteria or a part of the instrument not working, it is marked with a correction factor or a limited use. An instrument is sent for repair or a withdrawal identification mark is applied if there is an unsystematic error or a major fault.

4.7 Calibration Recall Service

Head of Production operates a calibration recall service that advises users about the calibration validity of their instruments, at least one week before the validity expires, based on the status report of calibration status.

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1 Purpose

To create written procedures for establishing, validating and maintaining inspection and development records for demonstrating the conformance of product characteristics with the specified requirements of developed products.

2 Scope

Product design and development is covered in this procedure.

3 Reference

Quality Manual, Section 8.3

4 Responsibility

With assistance from the R&D Manager, the Q.C. Manager and Production Manager are responsible for creating product records.

5 Procedure

Product samples/drawings serve as inputs for the design and development of a new product. It contains details on the implementation, maintenance and development of a system. This plan also includes the subsequent quality assurance process.

5.1 Design and Development Planning

On the various products manufactured until date, past data about a similar development activity, technical specifications (given by the customer / applicable specification / samples) and feedback from production / users are available. The design team develops the execution plan, which includes activities, responsibilities, and schedules. Updates are made as and when necessary. Design planning for each D&D activity is evaluated internally and externally by way of critical design review, verification of the breadboard or engineering model, and validation of the prototype or final product. D&D activities are assigned to qualified personnel with adequate resources by the R&D manager. It is recorded what inputs are made to what outputs are produced. To achieve effective communication and clarity of responsibilities among members of different groups engaged in D&D and development, intergroup interaction is managed.

5.2 Design and Development Input

Product design and development are based on samples, drawings, customer requirements, and expected quality levels said in contract documents, as well as requirements raised by potential customers, or those received from the customer. The following inputs are defined and documented for the product requirements:

- a. Product's functionality and performance requirements;
- b. Data derived from previous similar development activities;
- c. Regulatory and legislative requirements applicable;

- d. Standards, specifications, codes or procedures applicable;

5.3 Design and Development Controls

The R&D Manager and all concerned Functional Heads review the design at various stages of development and / or design. Throughout the design process, meetings have been held to review and control the design development. During the design review meetings, all of the design and development documents and parameters are reviewed. Upon receiving suggestions, changes are made.

In the process of designing and developing we have implemented controls

- a. There is a clear set of goals to achieve;
- b. Design and development outcomes are evaluated by conducting reviews;
- c. During development, the inputs are verified against the output requirements;

5.4 Design and Development Verification and Validation Testing

Upon completion of the design process, the organization ensures the design meets all specified operational conditions through reports, calculations, test results, etc.

5.5 Manufacturing Process Design Input

During the process design of a new product, we consider the customer requirements, and the expected quality level given in the contract documents and/or during customer interactions. Specifications and inputs pertaining to manufacturing process requirements are defined and documented. These include:

- a. The data output from a product design, including Drawings, Design Calculations, and Bills of Materials (BOMs);
- b. Production goals, process capabilities, process timing, and cost objectives (including component, assembly, and overhead);
- c. Technologies that replace manufacturing;
- d. Customer requirements;

5.6 Design and Development Outputs

When the design and development is complete, a Designing Record, Bill of Materials, Product specification, Drawings, Process control plan, further technical specifications, and monitoring/measuring requirements are written along with the acceptance criteria. The Manager for Research & Development ensures that Design and Development output matches design specifications and references product acceptance criteria. In order for the products supplied to be used safely and properly, crucial performance characteristics must be identified.

Internal Audit Non-Conformity Report			
NC Report No:		Date:	
Department / Area:		Document Ref:	
Auditor:		IATF 16949 Clause No:	
Audit Criteria:		Control #:	
Description of Non-Conformity:			
Person Responsible:			
Date of Completion	Planned:		Actual:
Auditee:		Auditor:	
Signature		Signature	
Root Cause of Non-Conformity:			
Action Taken to Resolve the Non-Conformities:			
Corrective Action Taken:			
Review of Action Taken:		Status:	☐ Closed ☐ Open
		Signature:	
		Date:	
Planned Date for Reviewing Effectiveness:			
Review of Effectiveness of Action Taken (Next Audit):			
Effectiveness Checked On	Date:		Sign:

PREVENTIVE ACTION REPORT		
Sr. No:		Date:
Department:		
Ref. CAR No., If Any:		
Potential Areas of Improvement		
☐ Quality Management System Operations	Handling of Complaints	
☐ Quality Report	Management Review Meeting	
☐ Products or Services	Internal Audit	
☐ Risk Management	Others, Specify	
Description of Potential Cause of Non-Conformities		
Description of Cause of Potential Non-Conformities:		
Date:		Identified By:
Action Recommended:		Responsibility:
Action Taken:		
Date:		Taken By:
Summary of Document Change etc:		
Planned Date for Reviewing Effectiveness:		
Review Effectiveness of Corrective Action Taken:		
Date:		Reviewed & Approved By:
		QMS Coordinator

