

MINIMUM AUTOMOTIVE QUALITY MANAGEMENT SYSTEM REQUIREMENTS FOR SUB-TIER SUPPLIERS

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1 CONTROL PLANS

1.1 Control plan

The organization shall

- develop control plans (see Annex) at the system, subsystem, component and/or material level for the product supplied, including those for processes producing bulk materials as well as parts, and
- have a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs.

The control plan shall

- list the controls used for the manufacturing process control,
- include methods for monitoring of control exercised over special characteristics defined by both the customer and the organization,
- include the customer-required information, if any, and
- initiate the specified reaction plan when the process becomes unstable or not statistically capable.

Control plans shall be reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources or FMEA.

NOTE Customer approval may be required after review or update of the control plan.

1.2 Work instructions

The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact conformity to product requirements. These instructions shall be accessible for use at the work station.

These instructions shall be derived from sources such as the quality plan, the control plan and the product realization process.

1.3 Verification of job set-ups

Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover or job change.

Work instructions shall be available for set-up personnel. The organization shall use statistical methods of verification, where applicable.

— NOTE Last-off-part comparisons are recommended.

The organization shall identify the person(s) responsible and having the authority for the activity, plans and execution of job set ups.

1.4 Preventive maintenance

The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system. As a minimum, this system shall include the following:

- planned maintenance activities;
- packaging and preservation of equipment, tooling and gauging;
- availability of replacement parts for key manufacturing equipment;
- documenting, evaluating and improving maintenance objectives.

NOTE: It is recommended that predictive maintenance methods should be considered in the implementation of the total preventive maintenance system.

1.5 Identification and Traceability

The organization shall identify the product by suitable means throughout the product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout the product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records.

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.

2 PROCESS APPROACH

2.1 Process application

The organization shall define its product realization system. Each process and sub-process shall be defined. Each defined process shall be implemented and controlled including the interactions and linkages between processes. The processes shall be monitored for effectiveness.

Note: From ISO 9001:2008

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and meeting requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

3 PERFORMANCE

3.1 Customer satisfaction

Customer satisfaction with the organization shall be monitored through continual evaluation of performance of the realization processes. Performance indicators shall be based on objective data and include, but not be limited to:

- delivered part quality performance,
- delivery schedule performance (including incidents of premium freight), and
- customer complaints, including field returns,

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

3.2 Incoming product conformity to requirements

The organization shall have a process to assure the quality of purchased product utilizing one or more of the following methods:

- receipt of, and evaluation of, statistical data by the organization;
- receiving inspection and/or testing, such as sampling based on performance;
- second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product conformity to requirements;
- part evaluation by a designated laboratory;
- another method agreed with the customer

3.3 Supplier monitoring

Supplier performance shall be monitored through the following indicators:

- delivered product conformity to requirements,
- delivery schedule performance (including incidents of premium freight), and
- customer complaints, including field returns

The organization shall promote supplier monitoring of the performance of their manufacturing processes including supplier self-assessment of its processes.

3.4 Problem solving and root cause analysis

The organization shall have a defined process for problem solving leading to root cause identification and elimination.

If a customer prescribed problem solving format exists, the organization shall use the prescribed format.

4 INTERNAL AUDITING

4.1 Quality management system audit

The organization shall audit its quality management system to verify compliance with the Automotive Quality Management System Requirements for Sub-tier Suppliers and any additional quality management system requirements.

4.2 Manufacturing process audit

The organization shall audit each manufacturing process to determine that they are fully compliant with the organization's control plan.

4.3 Product audit

The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labelling, at a defined frequency.

4.4 Internal audit plans

Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan.

When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased.

NOTE Specific checklists should be used for each audit.

4.5 Internal auditor qualification

The organization shall have internal auditors who are qualified to audit the requirements of ISO 9001:2008 and this Automotive Quality System Requirements Supplement for Sub-tier supply organizations.

NOTE: ISO 19011 auditor competency requirements should be utilized for internal auditor qualifications.

5 CONTROL of NON-CONFORMING PRODUCT

5.1 Control of nonconforming product

Product with unidentified or suspect status shall be classified as nonconforming product.

5.2 Control of reworked product

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

5.3 Customer information

Customers shall be informed promptly in the event that nonconforming product has been shipped.

5.4 Customer waiver

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 maintain a record of the expiration date or quantity authorized. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization 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.

6 PART APPROVAL

6.1 Product approval process

The organization shall conform to a product and manufacturing process approval procedure recognized by the customer.

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

This product and manufacturing process approval procedure shall also be applied to suppliers.

6.2 Engineering specifications

The organization shall have a process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule. Timely review should be as soon as possible, and shall not exceed two working weeks.

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

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

6.3 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. The results of process studies shall be documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions. These documents shall include objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria.

The organization shall maintain manufacturing process capability or performance as specified by the customer part approval process requirements. The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified

- measurement techniques,
- sampling plans,
- acceptance criteria, and
- reaction plans when acceptance criteria are not met.
- Significant process events, such as tool change or machine repair, shall be recorded.

The organization shall initiate a reaction plan from the control plan for characteristics that are either not statistically capable or are unstable. These reaction plans shall include containment of product and 100 % inspection, as appropriate. A corrective action plan shall then be completed by the organization, indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable. The plans shall be reviewed with and approved by the customer when so required.

The supplier organization shall apply manufacturing process capability studies to process or product changes.

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

6.4 Measurement system analysis

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

6.5 Calibration/verification records

Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to determined requirements, including employee- and customer-owned equipment, shall include

- equipment identification, including the measurement standard against which the equipment is calibrated,
- revisions following engineering changes,
- any out-of-specification readings as received for calibration/verification,
- an assessment of the impact of out-of-specification condition,
- statements of conformity to specification after calibration/verification, and notification to the customer if suspect product or material has been shipped.

6.6 Change Control

The organization shall have a process to control and react to changes that impact product realization. The effects of any change, including those changes caused by any supplier, shall be assessed, and verification and validation activities shall be defined, to ensure compliance with customer requirements. Changes shall be validated before implementation.

When required by the customer, additional validation/verification/identification requirements, such as those required for new product introduction, shall be met.

Note: Examples of changes include changes to process, design or site.

6.7 Change Control Notification

The customer shall be notified of any changes that impact product realization as described in 6.6 above during the life of the product.

Note: Notify the authorized customer representative of all changes.

7 MANAGEMENT RESPONSIBILITY

7.1 Process monitoring

Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency.

7.2 Quality objectives

Top management shall define quality objectives and measurements in the product realization process and to be to deploy the quality policy.

NOTE Action Plans are necessary to support implementation of the organization's quality objectives. In addition, quality objectives and action plans need to address customer expectations and be achievable within a defined time period.

7.3 Responsibility for quality

Managers with responsibility and authority for corrective action shall be promptly informed of products or processes which do not conform to requirements.

Personnel responsible for conformity to product requirements shall have the authority to stop production to correct quality problems.

Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

7.4 Customer representative

Top management shall designate personnel with responsibility and authority to ensure that customer requirements are addressed. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development.

7.5 Quality management system performance

Quality management system reviews shall include all requirements of the quality management system and its performance trends as an essential part of the continual improvement process.

Part of the management review shall be the monitoring of quality objectives, including the costs associated with non-conforming product.

These results shall be recorded to provide, as a minimum, evidence of the achievement of

— the quality objectives specified, and

— customer satisfaction with product supplied.

7.5.1 Review input

Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety or the environment.

7.5.2 Contingency Plans

The organization shall prepare contingency plans to satisfy customer requirements in the event of emergency such as utility interruptions, labour shortages, key equipment failure and field returns.

ANNEX (normative)

Control plan

Phases of the control plan

The control plan shall cover three distinct phases, as appropriate.

- a) Prototype: a description of the dimensional measurements, material and performance tests that will occur during building of the prototype. The organization shall have a prototype control plan, if required by the customer.
- b) Pre-launch: a description of the dimensional measurements, material and performance tests that occur after prototype and before full production. Pre-launch is defined as a production phase in the process of product realization which may be required after prototype build.
- c) Production: documentation of product/process characteristics, process controls, tests and measurement systems that occur during mass production.

Each part shall have a control plan but, in many cases, family control plans may cover a number of similar parts produced using a common process. Control plans are an output of the quality plan.

Elements of the control plan

The organization shall develop a control plan that includes, as a minimum, the following contents.

a) General data

- control plan number,
- issue date and revision date, if any,
- customer information (see customer requirements),
- organization's name/site designation,
- part number(s),
- part name/description,
- engineering change level,
- phase covered (prototype, pre-launch, production),
- key contact,
- part/process step number,
- process name/operation description.

b) Product control

- product-related special characteristics,
- other characteristics for control (number, product or process),
- specification/tolerance.

c) Process control

- process parameters,
- process-related special characteristics,
- machines, jigs, fixtures, tools for manufacturing.

d) Methods

- evaluation measurement technique,
- error-proofing,
- sample size and frequency,
- control method.

e) Reaction plan and corrective actions

- reaction plan (include or reference),
- corrective action.