

Summary of Unique ISO/TS 16949:2009 Requirements

This document summarizes the additional ISO/TS 16949:2009 requirements, beyond those included from ISO 9001:2008.

ISO 9001:2008 clauses and titles are boxed to set them off from the ISO/TS 16949:2009 requirements. The ISO 9001:2008 requirements are not included in this summary.

4. Quality Management System 4.1 General Requirements
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4.1.1 General Requirements – Supplemental

Ensure the control over outsourced processes does not absolve the organization of its responsibility to conform to all customer requirements. *Note: See also 7.4.1 and 7.4.1.3.*

4.2 Documentation Requirements 4.2.1 General 4.2.2 Quality Manual 4.2.3 Control of Documents

4.2.3.1 Engineering Specifications

The organization must have a process to assure the timely review, distribution, and implementation of all customer standards, specifications, and changes based on the customer-required schedule. A “timely review” is as soon as possible and must not exceed two work weeks.

The organization must keep a record of the date on which each change was implemented in production. Implementation must include updated documents.

Note: A change requires an updated record of customer production part approval when the specifications are referenced in the design record, or if they affect PPAP documents.

4.2.4 Control of Records

Note 1: The disposition of records includes their disposal.

Note 2: Records to be controlled include customer-specified records.

4.2.4.1 Records Retention

Control of records must satisfy statutory, regulatory, and customer requirements.

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5. Management Responsibility
5.1 Management Commitment

5.1.1 Process Efficiency

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

5.2 Customer Focus
5.3 Quality Policy
5.4 Planning
5.4.1 Quality Objectives

5.4.1.1 Quality Objectives – Supplemental

Top management must define the quality objectives and measurements to be included in the business plan and used to deploy the quality policy.

Note: Quality objectives should address customer expectations and be achievable within a defined timeframe.

5.4.2 Quality Management System Planning

5.5 Responsibility, Authority, and Communication
5.5.1 Responsibility and Authority

5.5.1.1 Responsibility for Quality

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

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

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

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5.5.2 Management Representative

5.5.2.1 Customer Representative

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

5.5.3 Internal Communication

5.6 Management Review

5.6.1 General

5.6.1.1 Quality Management System Performance

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

Part of the management review must be the monitoring of quality objectives, and the regular reporting and evaluation of the cost of poor quality (see 8.4.1 and 8.5.1).

These results must be recorded to provide, at a minimum, evidence of achievement of the quality objectives in the business plan and customer satisfaction with supplied products.

5.6.2 Review Input

5.6.2.1 Review Input – Supplemental

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

5.6.3 Review Output

6. Resource Management

6.1 Provision of Resources

6.2 Human Resources

6.2.1 General

6.2.2 Competence, Awareness, and Training

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6.2.2.1 Product Design Skills

The organization must ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in the applicable tools and methods. The organization must identify the applicable tools and methods.

6.2.2.2 Training

The organization must establish and maintain documented procedures for identifying training needs and achieving competence for all personnel performing activities that affect conformity to product requirements. Personnel performing specific assigned tasks must be qualified, as required, with particular attention to the satisfaction of customer requirements.

Note 1: This requirement applies to all employees having an effect on quality at all levels of the organization.

Note 2: An example of a customer specific requirement is the application of digitized mathematically based data.

6.2.2.3 Training on the Job

The organization must provide on-the-job-training to all personnel in any new or modified job affecting conformity to product requirements, including contract or agency personnel. Personnel whose work can affect quality must be told about the consequences to the customer of any nonconformity to quality requirements.

6.2.2.4 Employee Motivation and Empowerment

The organization must have a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process must include the promotion of quality and technological awareness throughout the whole organization.

The organization must have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives (see 6.2.2.d).

6.3 Infrastructure

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6.3.1 Plant, Facility, and Equipment Planning

The organization must use a multi-disciplinary approach (see 7.3.1.1) for developing plant, facility, and equipment plans. Plant layouts must optimize material travel, handling, and value-added use of floor space, and facilitate asynchronous material flow.

Methods must be developed and implemented to monitor and evaluate the effectiveness of existing operations.

Note: These requirements should focus on lean manufacturing principles and the link to the effectiveness of the quality management system.

6.3.2 Contingency Plans

The organization must prepare contingency plans to satisfy customer requirements in the event of an emergency such as utility interruptions, labor shortages, key equipment failures, and field returns.

6.4 Work Environment

6.4.1 Personnel Safety to Achieve Conformity to Product Requirements

Product safety, and the means to minimize potential risks to employees, must be addressed by the organization, especially in the design and development process and in manufacturing process activities.

6.4.2 Cleanliness of Premises

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

7. Product Realization

7.1 Planning of Product Realization

Note: Some customers refer to project management or advanced product quality planning as a means to achieve product realization. Advanced product quality planning embodies the concepts of error prevention and continual improvement, as contrasted with error detection, and is based on a multidisciplinary approach.

7.1.1 Planning of Product Realization – Supplemental

Customer requirements and references to its technical specifications must be included in the planning of product realization as a component of the quality plan.

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7.1.2 Acceptance Criteria

Acceptance criteria must be defined by the organization and, where required, approved by the customer. For attribute data sampling, the acceptance level must be zero defects (see 8.2.3.1).

7.1.3 Confidentiality

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

7.1.4 Change Control

The organization must 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, must be assessed, and verification and validation activities must be defined, to ensure compliance with customer requirements. Changes must be validated before implementation.

For proprietary designs, impact on form, fit, and function (including performance and durability) must be reviewed with the customer so all effects can be properly evaluated.

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

Note 1: Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.

Note 2: The above requirement applies to product and manufacturing process changes.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Note 1: Post-delivery activities include any after-sales product service provided as part of the customer contract or purchase order.

Note 2: This requirement includes recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes (see 7.3.2.3).

Note 3: Compliance to item 7.2.1.c includes all applicable government, safety, and environmental regulations, applied to acquisition, storage, handling, recycling, elimination, or disposal of materials.

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7.2.1.1 Customer-Designated Special Characteristics

The organization must demonstrate conformity to customer requirements for designation, documentation, and control of special characteristics.

7.2.2 Review of Requirements Related to the Product

7.2.2.1 Review of Requirements Related to the Product – Supplemental

Waiving the requirement stated in 7.2.2 for a formal review (see the note in 7.2.2) requires customer authorization.

7.2.2.2 Organization Manufacturing Feasibility

The organization must investigate, confirm, and document the manufacturing feasibility of the proposed products in the contract review process, including risk analysis.

7.2.3 Customer Communication

Customer Communication – Supplemental

The organization must have the ability to communicate necessary information, including data, in a customer-specified language and format, for example, computer-aided design data and electronic data exchange.

7.3 Design and Development

Note: The requirements of 7.3 include product and manufacturing process design and development, and focus on error prevention rather than detection.

7.3.1 Design and Development Planning

7.3.1.1 Multidisciplinary Approach

The organization must use a multidisciplinary approach to prepare for product realization, including:

- Development, finalization, and monitoring of special characteristics
- Development and review of FMEAs, including actions to reduce potential risks
- Development and review of control plans

Note: A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, and other appropriate personnel.

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7.3.2 Design and Development Inputs

Note: Special characteristics (see 7.2.1.1) are included in this requirement.

7.3.2.1 Product Design Input

The organization must identify, document, and review the product design input requirements, including:

- Customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, traceability, and packaging
- Use of information: the organization must have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature
- Targets for product requirements, life, reliability, durability, maintainability, timing, and cost

7.3.2.2 Manufacturing Process Design Input

The organization must identify, document, and review the manufacturing process design input requirements, including:

- Product design output data
- Targets for productivity, process capability, and cost
- Customer requirements, if any
- Experience from previous developments

Note: The manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.

7.3.2.3 Special Characteristics

The organization must identify special characteristics (7.3.3.d) and

- Include all special characteristics in the control plan
- Comply with customer-specified definitions and symbols

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- Identify process control documents (including drawings, FMEAs, control plans, and operator instructions) with the customer's special characteristic symbol or the organization's equivalent symbol or notation to include those process steps that affect special characteristics.

Note: Special characteristics can include product characteristics and process parameters.

7.3.3 Design and Development Outputs

7.3.3.1 Product Design Outputs – Supplemental

The product design output must be expressed in terms that can be verified and validated against product design and requirements. The product design output must include:

- Design FMEA and reliability results
- Product special characteristics and specifications
- Product error-proofing, as appropriate
- Product definition, including drawings or mathematically based data
- Product design review results
- Diagnostic guidelines, where applicable

7.3.3.2 Manufacturing Process Design Output

The manufacturing process design output must be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output must include:

- Specifications and drawings
- Manufacturing process flow charts/layouts
- Manufacturing process FMEAs
- Control plan (see 7.5.1.1)
- Work instructions
- Process approval acceptance criteria
- Data for quality, reliability, maintainability, and measurability
- Results of error-proofing activities, as appropriate
- Methods of rapid detection and feedback of product/manufacturing nonconformities

7.3.4 Design and Development Review

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Note: These reviews are normally coordinated with the design phases and include manufacturing process design and development.

7.3.4.1 Monitoring

Measurements at specified stages of design and development must be defined, analyzed, and reported with summary results as an input to management review.

Note: These measurements include quality risks, costs, lead times, critical paths, and others, as appropriate.

7.3.5 Design and Development Verification

7.3.6 Design and Development Validation

Note 1: The validation process normally includes an analysis of field reports for similar products.

Note 2: The requirements of 7.3.5 and 7.3.6 apply to both product and manufacturing processes.

7.3.6.1 Design and Development Validation – Supplemental

Design and development validation must be performed in accordance with customer requirements, including program timing.

7.3.6.2 Prototype Program

When required by the customer, the organization must have a prototype program and control plan. The organization must use, wherever possible, the same suppliers, tooling, and manufacturing processes as will be used in production.

All performance testing activities must be monitored for timely completion and conformance to requirements.

While services may be outsourced, the organization must be responsible for the outsourced services, including technical leadership.

7.3.6.3 Product Approval Process

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

Note: Product approval should be after verification of the manufacturing process.

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The product and manufacturing process approval procedure must also be applied to suppliers.

7.3.7 Control of Design and Development Changes

Note: Design and development changes include all changes during the product program life (see 7.1.4).

7.4 Purchasing

7.4.1 Purchasing Process

Note 1: Purchased products include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services.

Note 2: When there are mergers, acquisitions, or affiliations associated with suppliers, the organization should verify the continuity of the supplier's quality management system and its effectiveness.

7.4.1.1 Statutory and Regulatory Conformity

All purchased products or materials used in a product must conform to applicable statutory and regulatory requirements.

7.4.1.2 Supplier Quality Management System Development

The organization must perform supplier quality management system development with the goal of supplier conformity with this Technical Specification. Conformity to ISO 9001 is the first step in achieving this goal.

Note: The prioritization of suppliers for development depends on, for example, the supplier's quality performance and the importance of the supplied product.

Unless otherwise specified by the customer, suppliers to the organization must be third party registered to ISO 9001 by an accredited third party certification body.

7.4.1.3 Customer-Approved Sources

Where specified by the contract (for example, customer engineering drawing or specification), the organization must purchase products, materials, and services from approved sources.

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The use of customer-designated sources, including tool and gauge suppliers, does not relieve the organization of the responsibility for ensuring the quality of the purchased products.

7.4.2 Purchasing Information

7.4.3 Verification of Purchased Product

7.4.3.1 Incoming Product Conformity to Requirements

The organization must have a process to assure the quality of purchased products (see 7.4.3) using 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 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

7.4.3.2 Supplier Monitoring

Supplier performance must be monitored through the following indicators:

- Delivered product conformity to requirements
- Customer disruptions, including field returns
- Delivery schedule performance, including incidents of premium freight
- Special status customer notifications related to quality or delivery issues

The organization must promote supplier monitoring of the performance of the manufacturing processes.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

7.5.1.1 Control Plan

The organization must:

- Develop control plans at the system, subsystem, component, and/or material level for the product supplied, including processes producing bulk materials, as well as, parts
- Have a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs

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The control plan must:

- List the controls used for manufacturing process control
- Include methods for monitoring of control exercised over special characteristics (see 7.3.2.3) defined by both the customer and the organization
- Include the customer-required information, if any
- Initiate the specified reaction plan (see 8.2.3.1) when the process becomes unstable or not statistically capable

Control plans must be reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, or FMEA (see 7.1.4).

Note: Customer approval may be required after review or update of the control plan

7.5.1.2 Work Instructions

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

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

7.5.1.3 Verification of Job Setups

Job setups must be verified whenever performed, such as and initial run of a job, material changeover, or job change. Work instructions must be available for setup personnel. The organization must use statistical methods of verification, where applicable.

Note: Last-off part comparisons are recommended.

7.5.1.4 Preventive and Predictive Maintenance

The organization must identify key process equipment and provide resources for its maintenance and develop an effective total preventive maintenance system. At a minimum, this system must include:

- 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

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The organization must use predictive maintenance methods to continually improve the effectiveness and efficiency of production equipment.

7.5.1.5 Management of Production Tooling

The organization must provide resources for tool and gauge design, fabrication, and verification activities.

The organization must establish and implement a system for production tooling management, including:

- Maintenance and repair facilities and personnel
- Storage and recovery
- Setup
- Tool changing programs for perishable tools
- Tool design modification documentation, including engineering change level
- Tool identification, defining the status, such as production, repair, or disposal

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

Note: This requirement also applies to the availability of tools for vehicle service parts.

7.5.1.6 Production Scheduling

Production must be scheduled to meet customer requirements, such as just-in-time supported by an information system that permits access to production information at key stages of the process and is order driven.

7.5.1.7 Feedback of Information from Services

A process for communication of information on service concerns to manufacturing, engineering, and design activities must be established and maintained.

Note: The intent of the addition of "service concerns" to this sub-clause is to ensure that the organization is aware of nonconformities outside of its organization.

7.5.1.8 Service Agreement with Customer

When there is a service agreement with the customer, the organization must verify the effectiveness of:

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- Any organization service centers
- Any special-purpose tools or measurement equipment
- The training of service personnel

7.5.2 Validation of Processes for Production and Service Provision

7.5.2.1 Validation of Processes for Production and Service Provision – Supplemental

The requirements of 7.5.2 apply to all processes for production and service provision

7.5.3 Identification and Traceability

Note: Inspection and test status is not indicated by the location of products 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.

7.5.3.1 Identification and Traceability – Supplemental

The words “Where appropriate” in 7.5.3 do not apply for this Technical Specification.

7.5.4 Customer Property

Note: Customer-owned returnable packaging is included in this clause.

7.5.4.1 Customer-Owned Production Tooling

Customer-owned tools, manufacturing, test, inspection tooling, and equipment must be permanently marked so that the ownership of each item is visible and can be determined.

7.5.5 Preservation of Product

7.5.5.1 Storage and Inventory

In order to detect deterioration, the condition of product in stock must be assessed at appropriate planned intervals.

The organization must use an inventory management system to optimize inventory turns over time and assure stock rotation, such as “first-in-first-out”. Obsolete product must be controlled in a similar manner to nonconforming product.

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7.6 Control of Monitoring and Measuring Equipment

Note: A number or other identifier traceable to the device calibration record meets the intent of the requirement in 7.6.c.

7.6.1 Measurement Systems Analysis

Statistical studies must be conducted to analyze the variation present in the results of each type of measuring and test equipment system. This requirement applies to measurement systems referenced in the control plan. The analytical methods and acceptance criteria used must 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.

7.6.2 Calibration/Verification Records

Records of the calibration/verification activity for all gauges, measuring, and test equipment needed to provide evidence of product conformity to determined requirements, including employee and customer-owned equipment, must 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 an out-of-specification condition
- Statements of conformance to specification after calibration/verification
- Notification to the customer if suspect product or material has been shipped

7.6.3 Laboratory Requirements

7.6.3.1 Internal Laboratory

An organization's own internal laboratory facility must have a defined scope that includes its capability to perform the required inspection, test, or calibration services. This scope must be included in the quality management system documentation. The laboratory must specify and implement, at a minimum, technical requirements for:

- Adequacy of the laboratory procedures
- Competence of the laboratory personnel
- Testing of the product
- Capability to perform these services correctly, traceable to the relevant process standard, such as ASTM, EN, etc.
- Review of the related records

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Note: Accreditation to ISO 17025 may be used to demonstrate supplier in-house laboratory conformity to the requirement, but is not mandatory.

7.6.3.2 External Laboratory

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

- There must be evidence that the external laboratory is acceptable to the customer, or
- The laboratory must be accredited to ISO 17025 or the national equivalent

Note 1: Such evidence may be demonstrated by customer assessment, for example, or a customer-approved second party assessment that the laboratory meets the intent of ISO 17025 or national equivalent.

Note 2: When a qualified laboratory is not available for a given piece of equipment, the equipment manufacturer may perform the calibration services. In such cases, the organization should ensure that the requirements in 7.6.3.1 have been met.

8. Measurement, Analysis, and Improvement 8.1 General
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8.1.1 Identification of Statistical Tools

Appropriate statistical tools for each process must be determined during advance quality planning and included in the control plan.

8.1.2 Knowledge of Basic Statistical Concepts

Basic statistical concepts, such as variation, control (stability), process capability, and over adjustment must be understood and used throughout the organization.

8.2 Monitoring and Measurement 8.2.1 Customer Satisfaction

Note: Consideration should be given to both internal and external customers.

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8.2.1.1 Customer Satisfaction – Supplemental

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

- Delivered part quality performance
- Customer disruptions, including field returns
- Delivery schedule performance, including incidents of premium freight
- Customer notifications related to quality or delivery issues

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

8.2.2 Internal Audit

8.2.2.1 Quality Management System Audit

The organization must audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements.

8.2.2.2 Manufacturing Process Audit

The organization must audit each manufacturing process to determine its effectiveness.

8.2.2.3 Product Audit

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

8.2.2.4 Internal Audit Plans

Internal audits must cover all quality management related processes, activities, and shifts, and must be scheduled according to an annual plan. When internal or external nonconformities or customer complaints occur, the audit frequency must be appropriately increased.

Note: Specific checklists should be used for each audit.

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8.2.2.5 Internal Auditor Qualification

The organization must have internal auditors who are qualified to audit the requirements of this Technical Specification (see 6.2.2.2).

8.2.3 Monitoring and Measurement of Processes

8.2.3.1 Monitoring and Measurement of Manufacturing Processes

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

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

- Measurement techniques
- Sampling plans
- Acceptance criteria
- Reaction plans when acceptance criteria are not met

Significant process events, such as tool change or machine repair, must be recorded.

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

The organization must maintain records of the effective dates of process changes.

8.2.4 Monitoring and Measurement of Product

Note: When selecting product parameters to monitor compliance to internal and external requirements, the organization determines the types of product characteristics, leading to:

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- *The types of measurement*
- *Suitable measurement means*
- *The required capability and skills*

8.2.4.1 Layout Inspection and Functional Testing

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

Note: Layout inspection is the complete measurement of all product dimensions shown on the design record.

8.2.4.2 Appearance Items

For organizations manufacturing parts designated by the customer as “appearance items”, the organization must provide:

- Appropriate resources, including lighting for evaluation
- Masters for color, grain, gloss, metallic brilliance, texture, distinctness of image, as appropriate
- Maintenance and control of appearance masters and evaluation equipment
- Verification that personnel making appearance evaluations are competent and qualified to do so

8.3 Control of Nonconforming Product

8.3.1 Control of Nonconforming Product – Supplemental

Product with unidentified or suspect status must be classified as nonconforming product (see 7.5.3).

8.3.2 Control of Reworked Product

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

8.3.3 Customer Information

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

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8.3.4 Customer Waiver

The organization must 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 must maintain a record of the expiration date or quantity authorized. The organization must also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization must be properly identified in each shipping container.

This applies equally to purchased product. The organization must agree with any requests from suppliers before submission to the customer.

8.4 Analysis of Data

8.4.1 Analysis and Use of Data

Trends in quality and operational performance must be compared with progress toward objectives and lead to action to support:

- Development of priorities for prompt solutions to customer-related problems
- Determination of key customer-related trends and correlation for status review, decision making, and longer term planning
- An information system for the timely reporting of product information arising from usage

Note: Data should be compared with those of competitors and/or appropriate benchmarks.

8.5 Improvement

8.5.1 Continual Improvement

8.5.1.1 Continual Improvement of the Organization

The organization must define a process for continual improvement .

8.5.1.2 Manufacturing Process Improvement

Manufacturing process improvement must continually focus on control and reduction of variation in product characteristics and manufacturing process parameters.

Note 1: Controlled characteristics are documented in the control plan.

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Note 2: Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.

8.5.2 Corrective Action

8.5.2.1 Problem Solving

The organization must have a defined process for problem-solving leading to root cause identification and elimination. If a customer-prescribed problem-solving format exists, the organization must use the prescribed format.

8.5.2.2 Error-Proofing

The organization must use error-proofing methods in their corrective action process.

8.5.2.3 Corrective Action Impact

The organization must apply the corrective action and implemented controls to other similar processes and products to eliminate the cause of the nonconformity.

8.5.2.4 Rejected Product Test/Analysis

The organization must analyze parts rejected by the customer's manufacturing plants, engineering facilities, and dealerships. The organization must minimize the cycle time of this process. Records of these analyses must be kept and made available upon request. The organization must perform analysis and initiate corrective action to prevent recurrence.

Note: Cycle time related to rejected product analysis should be consistent with the determination of root cause, corrective action, and monitoring the effectiveness of implementation.

8.5.3 Preventive Action

(End of ISO/TS 9001:2009 requirements summary document)