

**Checklist—ISO/TS 16949**

Auditor:

Area/Dept. Audited:

Date:

4.2.3.1 Review, distribution and implementation of customer engineering standards & specifications

- Process for timely review
- Process for distribution
- Process for implementation
- Record of date of change
- Associated documents update

4.2.4.1 Retention of quality related documents and records

- Defined retention periods
- Complies with customer reqts
- Satisfies regulatory requirements
- Disposition includes disposal

5.1.1 Monitor and support processes to assure efficiency

- Process monitoring methods
- Process support examples

5.4.1.1 Objectives for achieving quality must be included in business plan

- Objectives included the business plan
- Measurements defined
- Address customer expectation

5.5.1.1 Responsibility for quality in management and production

- Do personnel have authority to stop production to correct quality problems?
- Quality responsibility designated across all shifts

5.5.2.1 Designated customer representatives Who are designated personnel for...

- Setting quality objectives
- Selecting special char.
- Training
- Corrective & Preventive Action

5.6.1.1 Reviews of quality management system performance

- Includes all elements
- Metrics on performance trends
- Monitoring of quality objectives
- Reporting cost of poor quality
- Evidence of achievement of objectives in business plan
- Evidence of customer satisfaction

5.6.2.1 Management review inputs  Does review include analysis of actual & potential field failure?  
 What action plans?

6.2.2.1 Product design skills  Are product design personnel qualified with design skills?  
 Applicable techniques used?

6.2.2.2 Procedure for identifying training needs.  
Personnel performing specific tasks must be qualified

- Documented procedure
- Training plan and records

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- Proof of job competence
  - Certified as applicable
  - Applies to all employees affecting quality at all levels
- 6.2.2.3 Training on the job  Is on the job training provided for new jobs? (records)
- Includes contract personnel?
  - Are personnel aware of job related quality requirements?
- 6.2.2.4 Process for employee motivation and empowerment
- Is formal program established?
  - Does environment promote innovation and quality?
  - Any incentives?
  - Includes continual improvement?
  - Do personnel have awareness of relevance of their job to quality objectives?
- 6.3.1 Multidisciplinary approach to plant, facility and equipment planning
- Who makes up this team?
  - Does layout optimize use of space and material flow
  - Methods to monitor effectiveness of operations
- 6.3.2 Contingency plans
- Are plans prepared, in event of utility outage, key equipment failure, labor shortage?
- 6.4.1 Policy to address personnel safety to minimize risks
- Is safety policy established?
  - Personnel training?
  - Applicable to design?
  - Applicable to manufacturing?
  - Hazard warnings?
- 6.4.2 Cleanliness of premises  Inspection for state of order
- State of repair
- 7.1.1 Inclusion of customer requirements and technical specs in quality planning
- Must be components of the quality plan
- 7.1.2 Acceptance criteria, especially for attribute data sampling
- Acceptance criteria defined?
  - Approved by customer, as reqd.
  - Zero-accept for attribute plans
- 7.1.3 Confidentiality of customer contracted products and projects under development
- What methods are used?
  - Non-disclosure agreements
  - Non-compete agreements
- 7.1.4 Process to control and react to changes that impact product realization
- What is the process for control of supplier initiated change?
  - Assessment of impact
  - Verification & validation method
  - Review w/ customer as reqd.
  - Applicable to manufacturing changes
- 7.2.1.1 Customer designated special characteristics
- Methods for designation, documentation and control
- 7.2.2.1 Manufacturing feasibility  Feasibility investigated during contract review
- Includes risk analysis
  - Documented feasibility
- 7.2.3.1 Communication of necessary information to customer
- Specified language ability
  - Specified format compatible
  - CAD data

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Electronic data exchange, EDI

## 7.3.1.1 Multidisciplinary approach in product realization

- Makeup of cross-functional team
- What is the quality planning process?
- Cross-functional review on:
  - Developing and finalizing special characteristics
  - FMEA develop & review
  - Control plan development/review

## 7.3.2.1 Review of product design inputs to include specified requirements, information and targets

- Documented
- Does review of inputs include...
  - Customer requirements
  - Special characteristics
  - Use of information gained from previous design
  - Targets for quality, reliability, durability, maintainability, cost
  - Design FMEA

## 7.3.2.2 Review of manufacturing process design inputs as specified

- Documented
- Does review of inputs include...
  - Product design output data
  - Targets for productivity and cost
  - Targets for process capability
  - Customer requirements, if any
  - Previous experience
  - Use of error-proofing methods

## 7.3.2.3 Identification of special characteristics

- Are all special characteristics included in control plan?
- Complies with customer symbol
- Identify process control documents (drawings, FMEA, operator instructions) with SC's

## 7.3.3.1 Design output expressed in terms that can be verified and validated

Verify that design output includes...

- Design FMEA, reliability
- Product special characteristics
- Error-proofing as appropriate
- Product definition (e.g. drawing)
- Design review results
- Diagnostic guidelines, as reqd.

## 7.3.3.2 Manufacturing process design output expressed in terms that can be verified and validated.

Verify that design output includes...

- Specifications & drawings
- Process flowchart
- Process FMEA
- Control plan
- Work instructions
- Process study basis and approval criteria
- Production process parameters
- Quality, reliability, maintainability
- Error-proofing, examples of
- Methods for rapid detection of process nonconformities

## 7.3.4.1 Stages of design and development shall be monitored with results to management

- Defined measurements/stages
- Evidence of analyses
- Status report to mgmt. (records)

## 7.3.6.1 Design and development validation in accordance with customer requirements

- Customer specified validation method
- Within program timing

## 7.3.6.2 As required, a prototype program and control plan

- Prototype example
- Control plan
- Use of same suppliers, tooling and manufacturing process
- Leadership over outsourced prototyping services

## 7.3.6.3 Conformance to customer specified procedure for product approval and process approval

- PPAP or equivalent customer specified method
- Includes product and process approvals
- Application to suppliers as well

## 7.4.1.1 All purchased materials satisfy applicable regulatory requirements

- Responsible party
- Awareness of applicable regulatory requirements

## 7.4.1.2 Supplier quality management systems and development

- Suppliers to organization must be 3<sup>rd</sup> party registered to ISO- 9001:2000 (by 15 Dec. 2003)
- Records in supplier files
- Prioritization plan for development of suppliers

## 7.4.1.3 Use of customer approved sources as specified in contract

- Use of specified sources
- Includes tool/gauge suppliers
- Responsibility for ensuring quality of purchased products

## 7.4.3.1 Process to assure the quality of purchased product

- Defined methods for incoming product test or verification, e.g.
- Receipt & evaluation of supplier statistical data
- Receiving inspect or test
- Assessments of supplier site
- Part evaluation by laboratory
- Other agreed method

## 7.4.3.2 Monitoring of supplier performance

- Method for performance monitor:
- Delivered part quality history
- Customer disruptions
- Delivery schedule performance
- Premium freight incidents
- Special status notifications

## 7.5.1.1 Development of control plans for product supplied, including customer required information and review/update

Are control plans developed for...

- System and sub-system level
- Component or material level
- Pre-launch and production
- Considering FMEA

Do control plans address...

- Manufacturing process controls
- Method for monitor of special changes
- Customer required information
- Reaction plan
- Evidence of update if significant product or process change

## 7.5.1.2 Work instructions for employees having process operations responsibility

- Documented
- Accessible at the work station
- Derived from sources such as control plan, quality plan

## 7.5.1.3 Verification of job set-ups, according to set-up work instructions

Check set-up verifications at...

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- Initial run of job
- Material changeover
- Job change
- Are work instructions available?
- Are statistical methods of verification used?

7.5.1.4 Preventive maintenance programs for key process equipment;  
Predictive maintenance programs to continually improve efficiency of production equipment

Includes maintenance objectives

- Identification of key process equipment
- Resources provided
- Preventive maintenance plan
- PM plan includes:
  - Planned activities
- Packaging and preservation of equipment, tooling, gauging
- Availability of replacement parts
- Documented maintenance objectives

7.5.1.5 Production tooling management, including monitor of any outsourced work

- Resources for tool and gauge design, fabrication, verification
- Tooling management program includes:
  - Maintenance and repair
  - Set-up, storage, recovery
  - Tool change, for perishable tools
  - Tool modification documentation
  - Tool identification & status

7.5.1.6 Production scheduling must meet customer requirements

- Defined customer requirements
- Just-in-time or Order-driven
- Real-time information system on production status at key stages

7.5.1.7 Process for feedback of information from service

- Established process
- Includes service concerns
- Includes manufacturing, engineering/design functions
- Personnel awareness of issues external to the organization

7.5.1.8 Verifying effectiveness of servicing agreement with customer

- How does organization verify effectiveness of...
- Service centres
- Special purpose tools/measure
- Training of servicing personnel

7.5.2.1 Requirements of 7.5.2 must apply to all processes for production & service provision

- Verify scope of application
- Verify actual examples from products offered/jobs running

7.5.3.1 Requirements for identification of product must apply through entire product realization

- Defined method
- Suitable means
- Traceability identification

7.5.4.1 Marking of customer-owned production tooling

Marking must be permanent and visible for following:

- Customer owned tools
- Manufacturing equipment/tooling
- Test or inspection equipment

7.5.5.1 System to control product in stock, storage and inventory

- What is inventory management system?
- How is stock rotation ensured?
- How is obsolete product controlled?
- Is condition of stock assessed at intervals?

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## 7.6.1 Requirement for statistical studies to analyze variation in measuring/test equipment.

- System must conform to those in customer reference manual (such as MSA, GR&R)
- Statistical basis and analysis
- Applicable to IMTE systems referenced on control plan

## 7.6.2 Specific requirements for records of calibration activity

- Must include gauges, measuring and test equipment including employee-owned and customer owned gauges

Records must include following:

- Equipment identification
- Revisions after engineering chg
- Out-of-spec readings as received
- Assessment of impact
- Statement of conformance to spec after calibration
- Notification to customer if suspect product shipped

## 7.6.3.1 Internal laboratory must have a defined scope, and meet listed technical requirements

- Laboratory scope defined
- Documented in quality system

Meet technical requirements for:

- Adequate procedures
- Qualification of lab personnel
- Testing of commodities
- Capability to perform tests
- Traceability to standard
- Quality records

## 7.6.3.2 External laboratory must have Use of external/commercial lab appropriate scope for capability to perform inspections, tests or calibrations facilities, e.g. calibration

- Records of lab scope
- Accreditation to ISO/IEC 17025
- Evidence of lab acceptable to the customer

## 8.1.1 Determination of appropriate statistical tools during advance quality planning

- Methods cited
- Included on control plan

## 8.1.2 Knowledge of basic statistical concepts

- Interview employees on basic concept/applications of:
  - Variation
  - Control/stability
  - Process capability
  - Over-adjustment
- Evaluate charts for interpretation

## 8.2.1.1 Performance indicators for customer satisfaction

- How is customer satisfaction monitored?
- Does objective data include:
  - Delivered part quality
  - Customer disruptions
  - Delivery schedule performance
  - Incidents of premium freight
- Customer notification on quality or delivery issues

## 8.2.2.1 Internal audits must cover entire quality system and verify compliance with all TS16949 and additional requirements

- Does the audit plan provide for audits of the entire quality management system to TS 16949, including any additional requirements, such as customer
  - Interview audit manager
  - Review audit reports
- Audit reports on specific customer requirements

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8.2.2.2 Manufacturing process audit  Does audit program include audits of each manufacturing process for effectiveness?

- Scope of audit plan
- Links to related objectives

8.2.2.3 Product audit  Does audit program include audits of products at appropriate stages of production and delivery, e.g.

- Product dimensions
- Functionality
- Packaging/labelling

8.2.2.4 Scope of internal audit plans  Verify internal audit plan covers...

- Quality management processes
- Quality activities
- All shifts
- Is there an annual plan?
- Is audit frequency adjusted if complaints/nonconformities?

8.2.2.5 Qualifications of internal auditors

- Auditor training records
- Appropriate content of training
- Interview auditors, for familiarity with ISO/TS 16949 criteria

8.2.3.1 Monitoring and measurement of manufacturing processes, to verify and maintain process capability and include objectives and acceptance criteria.

- How are process studies done?
- Does this include all new manufacturing processes
- Are process study results documented, with specs?
- Objectives for process capability, such as Cpk
- Objectives for reliability, maintainability
- Defined acceptance criteria
- Is process operated per control plan and process flow diagram?
- Notation of significant events on process control charts
- Reaction plans, established and initiated when needed
- Corrective action plans
- Records of effective date of process changes

8.2.4.1 Layout inspection and functional testing

- Performed on all products at sufficiently frequent intervals?
- Per control plan and customer performance standards
- Layout results documented

8.2.4.2 Appearance items  Appropriate resources, e.g. lighting evaluation

- Masters, for color, grain, gloss
- Control of appearance masters
- Qualified personnel

8.3.1 Supplemental controls over nonconforming product

- How is suspect product treated?
- How is unidentified product treated?

8.3.2 Controls over reworked product to include instructions for rework and re-inspection

- How are rework instructions provided?
- Verification of use of instructions

8.3.3 Customer information  Any examples of nonconforming product having been shipped?  
How was customer notified?

8.3.4 Customer waiver, whenever product or process is different from that approved

- Examples?
- Customer deviation permit
- Record of expiration date or qty
- Compliance to original spec afterwards
- Applies also to purchased product

**8.4.1 Analysis and use of data to lead to action toward objectives**

- What data is gathered on quality and operational performance?
- How is this trend-analyzed?
- Examples of actions generating priorities for prompt solutions to customer related problems
- Decision making regards key customer-related trends
- Information system for timely reporting
- Are data compared to benchmarks?

**8.5.1.1 Continual improvement**

- How is the process of company wide continual improvement implemented?

**8.5.1.2 Manufacturing process improvement must focus on control and reduction of variation**

- Examples of product characteristics, from control plan, with improvement
- Examples of process parameters related to above

**8.5.2.1 Problem solving**  Defined problem solving process, in customer prescribed format

- Examples of root-cause identification and elimination

**8.5.2.2 Use of error-proofing**  Examples of error-proofing applications

- Related to corrective actions

**8.5.2.3 Corrective action impact**  Examples of application of corrective action to other similar products/processes

- Method of control implemented

**8.5.2.4 Returned product test and analysis, with records and associated corrective action**

- Returned product log
- Records of analyses of returns
- Examples from rejected parts, dealerships
- Records of associated corrective action
- Minimization of cycle time