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 rqrts
- 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

 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 rqrd.
 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

 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 rqrd.

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 3rd 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…

- 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?

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

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