

Summary of TL 9000 R4.0 Requirements Beyond ISO 9001:2000

This summary identifies the additional TL 9000 Release 4.0 requirements beyond those stated in ISO 9001:2000. See the TL 9000 R4.0 Handbook for the actual TL 9000 R4.0 requirements.

ISO 9001:2000 section numbers and titles are boxed to set them off from the TL 9000 R4.0 requirements. The ISO 9001:2000 requirements are not included in this summary.

Note TL 9000 identifies its extra requirements as being C = Common, or specific to Hardware (H), Software (S), Services (V), or unique to Hardware-Software (HS) or Hardware-Services (HV).

4. Quality Management System
4.1 General Requirements
4.2 Documentation Requirements
4.2.1 General
4.2.2 Quality Manual
4.2.3 Control of Documents

4.2.3.C.1 Control of Customer-Supplied Documents and Data

Establish and maintain a documented procedure to control all customer-supplied documents and data if these documents and data influence the realization and/or support of the product.

Examples of these documents and data include network architecture, topology, capacity, installation termination assignments, drawings, and database.

4.2.4 Control of Records

5. Management Responsibility
5.1 Management Commitment
5.2 Customer Focus

5.2.C.1 Customer Relationship Development

Top management must demonstrate active involvement in establishing and maintaining mutually beneficial relationships between the organization and its customers.

5.2.C.2 Customer Communication Procedures

Establish and maintain methods for communicating with selected customers to:

- Share expectations
- Solicit and consider customer input for quality planning activities
- Ensure product quality improvement.

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The outcome of customer communication should:

- generate actions to resolve identified issues
- provide opportunities for improving customer satisfaction

5.2.C.2 - Note

It is not possible to provide the same level of communication with all customers. The level provided depends on the amount of business, the history of problems, customer expectations, and other factors.

Refer to document, "Guidance for Communication with Customers", in the TL 9000 Registration Guidance section of <tl9000.org>.

5.3 Quality Policy 5.4 Planning 5.4.1 Quality Objectives
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5.4.1.C.1 Quality Objectives

Include quality targets for the measurements in the TL 9000 Measurements Handbook.

5.4.2 Quality Management System Planning
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5.4.2.C.1 Long and Short Term Quality Planning

Include long and short-term plans with goals for improving quality and customer satisfaction. Monitor and report performance to these goals.

These plans must address the business factors relevant to the organization and its customers, including performance objectives established jointly with selected customers.

5.4.2.C.1 - Note 1

Example factors that might be considered for planning are cycle time, customer service, training, cost, delivery commitments, and product reliability.

5.4.2.C.1 - Note 2

Top management should demonstrate their active involvement in the long and short-term quality planning.

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5.4.2.C.2 Customer Input

Implement methods for soliciting and considering customer input for quality planning activities. The organization should establish joint quality improvement programs with customers.

5.4.2.C.3 Supplier Input

Implement methods for soliciting and using supplier input for quality planning activities.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

5.5.2 Management Representative

5.5.3 Internal Communication

5.5.3.C.1 Organization Performance Feedback

Inform employees of your quality performance and level of customer satisfaction.

5.6 Management Review

5.6.1 General

5.6.2 Review Input

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

6.2.2.C – Note

Education and training needs may vary greatly depending on the nature of your activities, individual responsibilities, and the stage of organizational and personal development.

Methods of delivery may include:

- *On-the-job training*
- *Cross-training*
- *Job rotation*
- *Classroom experience*
- *Computer-based training*
- *Distance learning*

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6.2.2.C.1 Internal Course Development

Establish and maintain methods to ensure consistency in course planning, development, and delivery of any internally developed courses.

6.2.2.C.2 Quality and Process Improvement Concepts

Train employees having a direct impact on product quality, including top management, in the fundamental concepts of continual improvement, problem solving, and customer satisfaction. These trained employees must apply the concepts.

6.2.2.C.3 Product Quality Training Opportunity Awareness

Where training that affects product quality is required, implement methods to ensure employees are enabled to participate. Methods should address:

- Communication of training opportunities
- Availability of training

6.2.2.C.4 Electrostatic Discharge (ESD) Training

For employees that handle, store, package, preserve, or deliver ESD-sensitive products, train them on ESD protection prior to the performance of their jobs.

6.2.2.C.5 Advanced Quality Training

Offer the appropriate levels of advanced quality training. Examples include statistical techniques, process capability, statistical sampling, data collection and analysis, problem identification, problem analysis, and corrective and preventive action.

6.2.2.C.6 Hazardous Conditions Training Content

Include this training content when the potential for hazardous conditions exists: task execution, personal safety, appropriate protective equipment, awareness of hazardous environment, and equipment protection.

6.2.2.HV.1 Qualification of Personnel

Establish personnel qualification and re-qualification requirements for all applicable processes. Address qualification requirements for employee education, experience, training, and demonstrated skills.

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6.2.2.HV.1 - Note

Examples of processes which may require qualification and re-qualification include wire wrapping, soldering, welding, and fiber-optic fusion splicing.

6.3 Infrastructure

6.3.C.1 Infrastructure

Identify the critical areas of the infrastructure and provide the security needed to protect these areas. Develop and periodically assess your security restoration plans.

6.4 Work Environment

6.4.1.C.1 Work Areas

Keep areas used for handling, storage, and packaging of products clean, safe, and organized to ensure they do not adversely affect quality or personnel performance.

7. Product Realization

7.1 Planning of Product Realization

7.1.C.1 Life Cycle Model

Establish and maintain an integrated set of methods that cover the product life cycle. The methods must contain, as appropriate, the processes, activities, and tasks involved in the concept, definition, development, production, operation, maintenance, and (if required) product disposal, over the life of the product.

7.1.C.1 - Note

New product introduction methods should include programs such as quality and reliability prediction studies, pilot production, demand and capacity studies, sales and service personnel training, customer documentation and training, and new product post-introduction evaluations.

7.1.C.2 Disaster Recovery

Establish and maintain documented plans for disaster recovery to ensure your ability to recreate and service the product throughout its life cycle.

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7.1.C.2 - Note

Types of recovery capabilities should include a series of action statements related to disaster recovery. Examples include: who is notified, under what circumstances are they notified, who has authority to act, and who will coordinate the steps outlined in the plan.

7.1.C.3 End of Life Planning

Establish and maintain a documented procedure for the discontinuance of manufacturing and/or support of a product.

The procedure should include:

- Cessation of full or partial support after a certain period of time
- Archiving product documentation and software
- Responsibility for any future residual support issues
- Transition to the new product, if applicable
- Accessibility of archive copies of data

7.1.C.4 Tools Management

Ensure that internally developed software and/or tools used in the product life cycle are subject to the appropriate quality methods.

7.1.C.4 - Note

Tools to be considered include: design and development tools, testing tools, configuration management tools, documentation tools, and diagnostic tools (including scripts and customizations, as well as, software used to build and test the product).

7.1.HS.1 Configuration Management Plan

Establish and maintain a configuration management plan, which should include:

- Identification and scope of the configuration management activities
- Schedule for performing these activities
- Configuration management tools
- Configuration management methods and documented procedures
- Organizations and assigned responsibilities
- Level of required control for each configuration item
- Point at which items are brought under configuration management

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7.1.HS.1 - Note

Work instructions defining general configuration management tasks and responsibilities need not be replicated as part of a specific documented configuration management plan. The Configuration Management Plan does not need to be contained in a single document.

7.1.V.1 Service Delivery Plan

If you are responsible for the delivery or implementation of a service, but not responsible for its design and development, you must comply with the Project Plan requirements in 7.3.1.C.1.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

7.2.2 Review of Requirements Related to the Product

7.2.2.C - Note

The product acceptance plan should include, as appropriate, acceptance review process, acceptance criteria, documented test procedures, test environment, test cases, test data, test responsibilities, resources involved, methods for problem tracking and resolution, and required acceptance test reports.

7.2.2.C.1 Closure Tracking

Track all actions to closure that result from requirements reviews.

7.2.2.C.2 Contract Review

Establish and maintain a contract review process that should include:

- Product acceptance criteria and criteria review process
- Methods for handling problems detected after customer acceptance, including complaints
- Plans for removal and/or correction of nonconformities after applicable warranty period or during product maintenance contract period
- Identification of risks and possible contingencies
- Adequate protection of proprietary information
- Definition of responsibility for any outsourced work
- Customer activities, including their role in requirements, specifications, and acceptance
- Facilities, tools, and software items provided by the customer
- All referenced standards and procedures

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7.2.3 Customer Communication

7.2.3.C.1 Notification About Problems

Establish and maintain a documented procedure to notify all customers who may be affected by a reported problem.

7.2.3.C.2 Problem Severity

Assign severity levels to customer reported problems based on the impact to the customer (in accordance with the definitions of Critical, Major, and Minor problem reports as defined in the TL 9000 Requirements Handbook). Use the severity level to determine the timeliness of your response.

7.2.3.C.2 - Note

The customer and organization should jointly determine the priority for resolving customer-reported problems.

7.2.3.C.3 Problem Escalation

Establish and maintain a documented escalation procedure to resolve customer-reported problems.

7.2.3.C.4 Customer Feedback

Establish and maintain a documented procedure to provide the customer with feedback on their problem reports in a timely and systematic manner.

7.2.3.HS.1 Organization's Recall Process

Establish and maintain a documented procedure for identifying and recalling products that are unfit to remain in service.

7.2.3.HS.2 Design and Development Process Quality Measurements Data Reporting

On request by the customer, include in communications the reporting and evaluation of a jointly agreed to set of design and development process measurements.

7.3 Design and Development

7.3.1 Design and Development Planning

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7.3.1.C.1 Project Plan

Base your project planning activities on the defined product life cycle model (see 7.1.C.1). The project plan should include:

- Project organizational structure
- Roles, responsibilities, accountabilities of project team and related teams or individuals
- Interfaces for project team with internal and external organizations
- Means for scheduling, tracking, issue resolution, and management reporting
- Budgets, staffing, and schedules associated with project activities
- Methods, standards, documented procedures, and tools to be used
- References to related plans (e.g., development, testing, and quality)
- Project-specific or service delivery environment and physical resources considerations
- Customer, user, and supplier involvement (e.g., reviews, meetings, and approvals)
- Management of project quality
- Risk management and contingency plans (e.g., defects, rework risks, schedule variance)
- Project-specific training requirements
- Required certifications (e.g., product or employee)
- Proprietary, usage, ownership, warranty, and licensing rights
- Post-project analysis

7.3.1.C.1 - Note 1

The project plan and any related plans may be an independent document, a part of another document, or comprised of several documents.

7.3.1.C.1 - Note 2

Work instructions defining tasks and responsibilities common to all development projects need not be replicated as part of a project plan.

7.3.1.C.2 Requirements Traceability

Establish and maintain a method to trace documented requirements through design and test.

7.3.1.C.2 - Note

You should establish communication methods for dissemination of product requirements, and changes to requirements, to all impacted parties identified in the project plan.

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7.3.1.C.3 Test Planning

Document test plans, as well as, record test results and subsequent actions. Test plans should include:

- Scope of testing (e.g., unit, feature, integration, system, acceptance, field, regression)
- Types of test to be performed (e.g., functional, boundary, usability, performance, stress)
- Traceability to requirements
- Test environment (e.g., relevancy to customer environment, operational use)
- Test coverage (e.g., the degree a test verifies a product's functions)
- Expected results
- Data definition and database requirements
- Set of tests, test cases (inputs, outputs, test criteria), and documented test procedures
- Use of external testing
- Method of reporting and resolving defects
- Customer test requirements

7.3.1.HS.1 Migration Planning

Develop and document a migration plan when you plan to move a system or software product from an old to a new operational environment.

If the old environment will no longer be supported, notify users of migration plans and activities (include a description of the new environment with the date of its availability). Describe other available support options, if any, once support for the old environment has been removed.

The migration plan should also include:

- Requirements analysis and definition of migration
- Development of migration tools
- Conversion of products and data
- Migration execution and verification
- Support for the old environment in the future

7.3.1.HS.1 – Note 1

The operational environment consists of hardware, software, or systems on which the product depends (parts of environment could be purchased by customer and installed separately).

Software examples include upgrades to operating system and database. Hardware examples include using existing circuit packs in new racks or with new controllers.

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7.3.1.HS.1 – Note 2

If the old environment will no longer be supported, consider arrangements (per regulatory and contract requirements) for access to, and protection of, old data, and access for audit purposes.

7.3.1.HS.2 Design and Development Process Quality Measurement Planning and Implementation

Establish and maintain methods for selecting and reporting appropriate design and development process quality measures for the project. As recommended during this phase, implement this measurement system appropriately for the project.

7.3.1.HS.2 – Note

See the document, “Set Up and Operation of a Design Process Measurement System”, in the TL 9000 Registration Guidance section of <tl9000.org> for guidelines to help select and establish the appropriate design and development process measurements for the project.

7.3.1.S.1 Integration Planning

Develop and document a plan to integrate the software components into the product to ensure they interact as designed. The plan must include methods and documented procedures, responsibilities, integration schedule, and test requirements.

7.3.1.S.2 Estimation

Establish and maintain a method for estimating and tracking project factors during project planning, execution, and change management.

7.3.1.S.2 - Note

Project factors should include product size, complexity, requirements changes, effort, staffing, schedules, cost, quality, reliability, and productivity.

7.3.1.S.3 Computer Resources

Establish and maintain methods for estimating and tracking critical computer resources for the target computer (on which the software is intended to operate).

7.3.1.S.3 - Note

Computer resource examples are memory utilization, throughput, real-time performance, and I/O channels.

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7.3.1.S.4 Regression Test Planning

If regression testing is to be performed, specify in the test plans which tests are regression and what features and functions are covered by these regression tests.

7.3.2 Design and Development Inputs

7.3.2.C.1 Customer and Supplier Input

Establish and maintain methods for soliciting and using customer and supplier input during the development of new or revised product requirements.

7.3.2.C.2 Design and Development Requirements

Define and document the design and development requirements. These requirements should include:

- Quality and reliability requirements
- Product functions and capabilities
- Business, organizational, and user requirements
- Safety, environmental, and security requirements
- Installability, usability, and maintainability requirements
- Design constraints and testing requirements
- Computer resources for the target computer

7.3.2.C.3 Requirements Allocation

Document the allocation of the product requirements to the product architecture.

7.3.2.C.3 - Note

Examples of requirements which should be allocated are response time for software, heat dissipation for hardware, and service response time for services.

7.3.2.H.1 Content of Requirements

Include product requirements for, but do not limit to, nominal values and tolerances, maintainability needs, and end-item packaging requirements.

7.3.2.S.1 Identification of Software Requirements

Determine, analyze, and document the software component requirements of the system.

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7.3.3 Design and Development Outputs

7.3.3.HS.1 Design and Development Output

Include design and development outputs for, but do not limit to, system architecture, system detailed design, source code, and user documentation.

7.3.3.V.1 Services Design and Development Output

Include in the services design and development output a complete and precise statement of the service to be provided. Also include, but do not limit the output to:

- Service delivery procedures
- Resource and skill requirements
- Reliance on suppliers
- Service characteristics subject to customer evaluation
- Standards of acceptability for each service characteristic

7.3.4 Design and Development Review

7.3.5 Design and Development Verification

7.3.5.C.1 Verification of Documentation

Verify the customer and/or user documentation prior to product delivery.

7.3.5.HS.1 Stress Testing

Test the product under stress conditions, including, but not limited to, out-of-boundary and invalid input conditions, high volume and peak load simulations, and operational errors.

7.3.5.HS.2 Abnormal Conditions

Test the product under abnormal conditions, including as appropriate:

- Hardware and software errors
- Operations, administration, maintenance, and provisioning errors
- Overload traffic
- Invalid user input
- System recovery from an outage

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7.3.5.S.1 System Testing

Subject each software release to a system test in accordance with a documented system test plan.

7.3.6 Design and Development Validation

7.3.6.C - Note

You should include customers or a third party during various validation stages, as appropriate.

7.3.6.S.1 Release Management

Establish and maintain methods to ensure the release and delivery of software products and related documentation are carried out under controlled conditions. The methods should provide delivery to the customer of:

- Release planning information in advance of the release
- Product introduction and release schedules
- Descriptions of product features and changes in new software products or releases
- Advisories regarding current or planned changes to contractual terms

7.3.7 Control of Design and Development Changes

7.3.7.C.1 Change Management Process

Establish and maintain documented procedures to ensure all requirements and design changes, which may arise at any time during the product life cycle, are managed and tracked in a systematic and timely manner appropriate to the life cycle stage.

Ensure changes which adversely affect mutually agreed conditions for quality, reliability, and functional intent are reviewed with the customer prior to approval.

Management of changes should include impact analysis, planning, implementation, testing, documentation, communication, and review and approval.

7.3.7.C.1 - Note

While a change management process is required throughout the life cycle, the controls may depend on the life cycle stage. For example, during design: you should be able to react to rapidly changing customer requirements and take advantage of emerging technologies, so you need a responsive change management process.

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After general availability, the change management process scope should consider how the change on the operation and maintenance of the product and its installed base impacts the customers and stakeholders. Consider quality, reliability, and functional intent.

7.3.7.C.2 Informing Customers

Establish and maintain a documented procedure to ensure customers are informed when design changes affect contractual commitments.

7.3.7.C.3 Problem Resolution Configuration Management

Ensure that the configuration management system tracks fixes to problems and incorporates those fixes in future revisions.

7.3.7.H.1 Component Changes

Have a procedure in place to ensure that material or component substitutions or changes do not adversely affect product quality or performance.

The documented procedure should include functional, qualification, and stress testing, as well as, approved parts listing and/or critical parts listing.

7.4 Purchasing

7.4.1 Purchasing Process

7.4.1.C.1 Purchasing Procedure

Establish and maintain a documented purchasing procedure to ensure:

- Clearly defined product requirements
- Understood and managed risks
- Established qualification and acceptance criteria
- Defined contracts
- Proprietary, usage, ownership, warranty, and licensing rights are satisfied
- Planned future support for the product
- Ongoing supply-base management and monitoring is in place
- Defined supplier selection criteria
- Re-evaluation of suppliers on defined criteria
- Feedback provided to key suppliers based on data analysis of supplier performance

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7.4.1.C.1 - Note

The documented procedure should be applicable to off-the-shelf product. This typically includes original equipment manufacturer (OEM) products used in manufacturing and commercial off-the-shelf (COTS) products used in software systems.

7.4.2 Purchasing Information 7.4.3 Verification of Purchased Product

7.5 Production and Service Provision 7.5.1 Control of Production and Service Provision

7.5.1.C.1 Service Resources

Provide customer contact employees with the appropriate tools, training, and resources necessary to provide effective and timely customer service.

7.5.1.C.2 Product Delivery

Establish and maintain methods to minimize interference with the customer's normal site operation and service during product delivery and installation.

7.5.1.HS.1 Emergency Service

Ensure that services and resources are available to support recovery from emergency failures of product in the field throughout its expected life. Identify potential situations that may have an impact on its ability to provide the emergency service and have response plans to address these situations. Base these plans on risk and periodically assess them.

7.5.1.HS.2 Installation Plan

Establish and maintain a documented installation plan. Identify the resources, required information, sequence of events, and necessary records in the plan.

7.5.1.HV.1 Operational Changes

Each time a significant change is made in the established operation (e.g., new operator, machine, or technique), critically exam the first unit(s)/service(s) processed after the change.

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7.5.1.S.1 Patching Procedure

Establish and maintain a documented patching procedure that:

- Guides the decision to solve problems by patching
- Addresses patch development procedures, propagation (forward and backward), and resolution
- Is consistent with customer needs or contractual requirements for maintenance support
- Ensures the customer is provided with a statement of impact on the customer's operation for each patch

7.5.1.S.2 Patch Documentation

Establish and maintain methods to ensure that all documentation required to describe, test, install, and apply a patch has been verified and delivered with the patch.

7.5.1.S.3 Replication

Establish and maintain a documented procedure for replication, which should include:

- Identification of master copy
- Identification of replicate copies for delivery
- Quantities of replicates to deliver
- Type of media
- Labeling
- Identification of required documentation, such as, user guides
- Packaging of documentation
- Control of environment to ensure repeatable replication

7.5.1.V.1 Software Used in Service Delivery

Establish and maintain a documented procedure for the maintenance and control of software used in service delivery to ensure continued process capability and integrity.

7.5.1.V.2 Tool Changes

Establish and maintain a documented procedure to ensure that substitutions or changes to tools used in performing the service do not adversely affect the quality of the service.

7.5.2 Validation of Processes for Production and Service Provision

7.5.3 Identification and Traceability

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7.5.3.H.1 Traceability for Recall

Be able to trace Field Replaceable Units (FRU) throughout the product life cycle in a way that helps organizations and their customers identify products being recalled, needing to be replaced, or modified.

7.5.3.H.2 Traceability of Design Changes

Define and implement the methods necessary to provide traceability of design changes to identifiable manufacturing dates, lots, or serial numbers.

7.5.3.HS.1 Product Identification

Establish and maintain a process for the identification of each product and the level of required control. For each product and its version, identify (where they exist):

- Product documentation
- Development of production tools essential to repeat product creation
- Interfaces to other products
- Software and hardware environment

7.5.3.HS.1 - Note

Examples of product identification include barcode, tag, label, electronic ID, etc., containing information such as production lot numbers and dates, and serial numbers. New technologies for data retrieving, such as RFID, may also be considered.

7.5.4 Customer Property

7.5.5 Preservation of Product

7.5.5.C.1 Electrostatic Discharge Sensitive (ESDS) Protection

Employ, where applicable, anti-static protection for components and products susceptible to electrostatic discharge (ESD) damage.

7.5.5.C.1 – Note 1

Types of components and products which should be protected include electronic parts, integrated circuits, printed wiring board assemblies, magnetic tapes and disks, and other media used for software or data storage.

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7.5.5.C.1 – Note 2

Certification to ANSI/ESD S20.20 should be taken as indication that the certified facilities meet TL 9000 requirements for 6.2.2.C.4 and 7.5.5.C.1 concerning ESD protection.

7.5.5.HS.1 Packaging and Labeling Verification

Establish and maintain methods to ensure the packaging and labeling of products and components conform to specified requirements.

7.5.5.HS.1 - Note

Packaging and labeling verification is normally performed on products ready to ship and may include, for example, marking, labeling, kiting, documentation, customer-specific marks, and verification of quantities to be shipped.

7.5.5.H.1 Deterioration

Where the possibility of deterioration exists, establish and maintain methods to determine when materials that may impact product quality have deteriorated or exceeded their expiration dates. Assess any required subsequent action.

7.5.5.S.1 Software Virus Protection

Establish and maintain methods for software virus prevention, detection, and removal from the deliverable product.

7.6 Control of Monitoring and Measuring Devices

7.6.C.1 Equipment Identification

Visibly identify, and do not use, any monitoring and measuring devices that are either inactive or unsuitable for use. Identify all monitoring and measuring devices that do not require calibration.

8. Measurement, Analysis, and Improvement

8.1 General

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

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8.2.1.C.1 Customer Satisfaction Data

Establish and maintain a method to collect data directly from customers concerning their satisfaction with provided products. Collect customer data on how well you have met commitments and your responsiveness to customer feedback and needs. Analyze and trend this data.

8.2.2 Internal Audit

8.2.3 Monitoring and Measurement of Processes

8.2.3.C.1 Process Measurement

Identify, document, and monitor process measurements at appropriate points to ensure continued suitability and to promote increased process effectiveness. Include establishing design process measurements. You should have specific performance targets or control limits established for the key process measurements that impact product quality.

8.2.4 Monitoring and Measurement of Product

8.2.4.H.1 Periodic Retesting

Establish and maintain a documented procedure that ensures products are periodically retested to assess the product's ability to continue to meet design requirements. Consider the conditions in 8.2.4.H.3 when determining the depth of the retest.

8.2.4.H.2 Content of Testing

Ensure the initial test and periodic retest are more extensive than the routine quality tests. Include in the initial test those contained in the product specifications and/or contract. Document the results of these tests.

8.2.4.H.2 - Note

Product specifications may include environmental, vibration, flammability, operational stress type testing, and intrusion/penetration testing.

8.2.4.H.3 Frequency of Testing

Establish and document the frequency for test and periodic retest. When determining the test frequency, include:

- Product complexity and service criticality
- Number of design, engineering and/or manufacturing changes made to the product (and whether the changes affect form, fit, and/or function)

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- Changes to the manufacturing process
- Manufacturing variations, e.g., tooling wear
- Material and/or component substitutions and failure rates
- Field performance record of the product

8.2.4.H.4 Testing of Repair and Return Products

Subject the repaired and returned products to the appropriate evaluations and/or tests to ensure functionality to the product specification.

8.2.4.HV.1 Inspection and Test Documentation

Prepare detailed documentation for each inspection or testing activity. Details should include, but are not limited to:

- Parameters to be checked with acceptable tolerances
- The use of statistical techniques, control charts, etc.
- Sampling plan, including frequency, sample size, and acceptance criteria
- Handling of nonconformities
- Data to be recorded (see 4.2.4)
- Defect classification scheme
- Methods for designating an inspection item or lot
- Electrical, functional, and feature testing

8.2.4.HV.2 Inspection and Test Records

Include the following information in inspection and test records:

- Product identification
- Quantity of product
- Documented procedures followed
- Person performing the test or inspection
- Calibrated equipment used (see 7.6)
- Date performed
- Number, type, and severity of defects found

8.2.4.S.1 Test Documentation

Conduct software tests to the test plan according to a documented procedure. Include test results, analysis of test results, conformity to expected results, and problem reporting for nonconforming items in the test records.

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8.3 Control of Nonconforming Product

8.4 Analysis of Data

8.4.C.1 Trend Analysis of Nonconforming Product

Perform trend analysis of discrepancies found in the nonconforming product on a defined, regular basis and use the results as input for corrective and preventive action.

8.4.H.1 Field Performance Data

Collect and analyze field performance data which can be used to help identify the cause and frequency of equipment failure. In addition, maintain No Trouble Found (NTF) data. Provide this information to the appropriate organizations to foster continual improvement.

8.4.V.1 Service Performance Data

Collect and analyze service performance data which can be used to help identify the cause and frequency of service failure. Provide this information to the appropriate organizations to foster continual improvement of the service.

8.5 Improvement

8.5.1 Continual Improvement

8.5.1.C.1 Quality Improvement Program

Establish and maintain a continual improvement program to improve customer satisfaction, product quality and reliability, and other processes, products, and services used within the organization.

8.5.1.C - Note

Inputs to the continual improvement process may include lessons learned from past experience, lessons learned from previous projects, analysis of measurements and post-project reviews, and comparisons with industry best practices.

8.5.1.2 Employee Participation

Implement methods for encouraging employee participation in the continual improvement process.

Summary of TL 9000 R4.0 Requirements Beyond ISO 9001:2000

8.5.2 Corrective Action

8.5.2.C - Note 1

Review of corrective action is intended to ensure the action taken was effective. Review activities may include ensuring the root cause was properly identified and addressed, appropriate containment action was taken, and corrective actions have not introduced additional problems.

8.5.2.C - Note 2

Consideration should be given to include training as part of implementing corrective and preventive actions.

8.5.2.S.1 Problem Resolution

Establish and maintain a documented procedure to initiate corrective action once a reported trouble is diagnosed as a problem. Provide guidelines in the procedure for distinguishing among potential solutions, such as:

- Patching
- Immediate source code corrections
- Deferring solutions to a planned release
- Providing documented "work-around" operational procedures and resolution within a designated timeframe based on the severity of the issue

8.5.3 Preventive Action