
TIA QuEST Forum

TL 9000 Quality Management System

Requirements Handbook

R6.2 Point Release

*The ICT Quality Management System
Performance Excellence through Global ICT Quality*

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visit <https://www.tiaonline.org/what-we-do/business-performance/>

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Throughout this document the term 'TL 9000' refers to *TL 9000 Quality Management System Requirements Handbook Point Release R6.2*, namely this volume, unless specifically stated otherwise. Also, the term 'ISO 9001' refers to ISO 9001:2015 [\[2\]](#), unless specifically stated otherwise.

Requirements Handbook Point Release R6.1 included changes to Sections 8.3 and 8.6 intended to clarify how these requirements apply regardless of the design and development methodology used by the organization.

Requirements Handbook Point Release R6.2 modifies two requirements (8.3.2.C.1 Project Planning and 8.3.3.C.2 Design and Development Requirements), rewords three others, and updates the terminology in one. It also rewords three notes, adds one new note, and renumbers a note.

All TL 9000 Certified organizations are required to transition to meet Requirements Handbook Point Release R6.2 even if not impacted by the changes in this release.

Approved and Adopted
by
TIA QuEST Forum
Effective

April 1, 2020

4. Context of the organization

4.1 Understanding the organization and its context

There are no additional requirements for this section of ISO 9001

4.2 Understanding the needs and expectations of interested parties

There are no additional requirements for this section of ISO 9001

4.3 Determining the scope of the quality management system

Additional requirements for TL 9000 are shown below

4.3.C.1 Declaration of Requirement and Measurement Applicability – The organization shall declare in its registration profile any requirements determined as not applicable, as well as any measurement exemptions claimed.

4.3.C.1-NOTE 1 It is not necessary for an organization to declare a TL 9000 requirement as not applicable if the requirement is outside the scope of the TL 9000 registration specialty option(s) the organization has selected. Also, it is not necessary for an organization to declare as not applicable any TL 9000 requirement where the requirement itself or an associated note states the requirement is not applicable to the organization's product or service category type.

4.3.C.1-NOTE 2 See Measurements Handbook [\[5\]](#) for definition of measurement exemptions.

4.3.C.2 TL 9000 Profile and Scope – An organization seeking certification shall determine, in coordination with its Certification Body (CB), the

- TL 9000 scope statement,
- ISO 9001 scope statement,
- requirements determined as not applicable,
- measurement exemptions,
- registration specialty options,
- NACE codes,
- product categories,
- locations or sites,
- ISO 9001 version,
- TL 9000 Requirements and Measurements release levels, and
- use of Advanced Surveillance and Reassessment Procedure (ASRP).

All the registration information shall be recorded and maintained on TL 9000's Registration Management System (RMS) in a registration profile. The TL 9000 Administrator shall provide relevant information to the IAF database of accredited certifications. The certificate issued by the CB shall reference the registration profile on the RMS by the TL ID number assigned to the registration by the TL 9000 Administrator when the profile is created.

The scope statement shall include

- a) an identification of the organization being registered, which may encompass the entire organization, an organizational unit, or a combination of units, and
- b) products/product lines covered by the registration. If not all products/product lines are included in the registration, then either the included or excluded products/product lines shall be listed.

The scope statement shall not include

- a) product category codes,
- b) locations or sites,
- c) ISO 9001, Requirements Handbook and Measurements Handbook release levels,
- d) registration specialty option, and
- e) other parameters identified as individual fields in the registration profile.

4.4 Quality management system and its processes

4.4.1

There are no additional requirements for this section of ISO 9001

4.4.2

There are no additional requirements for this section of ISO 9001

6.2 Quality objectives and planning to achieve them

6.2.1

Additional requirements for TL 9000 are shown below

6.2.1.C.1 TL 9000 Measurements Targets – Quality objectives shall include targets for the TL 9000 measurements defined in the Measurements Handbook [5].

6.2.2

Additional requirements for TL 9000 are shown below

6.2.2.C.1 Customer Input – The organization shall implement methods for collaboration with customers on quality planning activities. The organization should establish joint quality improvement programs with selected customers.

6.2.2.C.2 External Provider Input – The organization shall implement methods for collaboration with external providers on quality planning activities.

6.2.2.C.3 Long- and Short-Term Quality Planning – The organization's quality planning activities shall include plans to achieve long- and short-term quality objectives. Performance to these quality objectives shall be monitored and reported to top management. Top management shall demonstrate their active involvement in long- and short-term quality planning.

6.2.2.C.3-NOTE Factors that may be considered for planning are

- a) cycle time,
- b) customer service,
- c) training,
- d) cost,
- e) delivery commitments,
- f) product reliability,
- g) security and privacy, and
- h) sustainability.

7. Support

7.1 Resources

7.1.1 General

Additional requirements for TL 9000 are shown below

7.1.1.C.1 Business Continuity Planning – The organization shall establish and maintain documented plans for continuity of operations, disaster recovery, infrastructure, and security restoration to ensure the organization's ability to continue to support its products and services. Business continuity plans shall include, at a minimum, crisis management, disaster recovery, and information technology. Business continuity plans shall be periodically evaluated for effectiveness and reviewed with appropriate levels of management.

7.1.1.C.1-NOTE 1 Types of recovery capabilities should include a series of statements related to infrastructure, personnel, and data. Examples include who is notified, under what circumstances are they notified, who has the authority to act, and who will coordinate the steps outlined in the plan.

7.1.1.C.1-NOTE 2 Business continuity planning may consider recovery from security incidents such as cybersecurity, malware, and ransomware attacks.

7.1.2 People

There are no additional requirements for this section of ISO 9001

7.1.3 Infrastructure

Additional requirements for TL 9000 are shown below

7.1.3.C.1 Infrastructure Security – The organization shall determine, provide, and maintain security for the infrastructure.

7.1.6 Organizational knowledge

There are no additional requirements for this section of ISO 9001

7.2 Competence

Additional requirements for TL 9000 are shown below

7.2.C.1 Internal Course Development – Organizations that develop internal training courses shall establish and maintain methods to ensure consistency in course planning, development, and delivery.

7.2.C.2 Quality and Process Improvement Concepts – Personnel who have a direct impact on the quality of products and services, including top management, shall be trained in and apply the fundamental concepts of continual improvement, problem solving, and customer satisfaction.

7.2.C.3 Quality Training Opportunity Awareness – The organization shall implement methods to ensure personnel are aware of and able to participate in training that affects product or service quality. Methods should address

- a) communication of training opportunities, and
- b) availability of training.

7.2.C.4 Electrostatic Discharge (ESD) Training – All personnel with functions that involve handling, storage, packaging, preservation, or delivery of ESD-sensitive products shall receive training in ESD protection prior to performing their jobs. The type and frequency of ESD refresher training shall be defined by the organization.

7.2.C.5 Advanced Quality Training – The organization shall offer appropriate levels of advanced quality training.

7.2.C.5-NOTE Examples of advanced quality training include statistical techniques, process capability, statistical sampling, data collection and analysis, problem identification, problem analysis, root cause analysis, and enabling tools..

7.2.C.6 Hazardous Conditions Training Content – Where the potential for hazardous conditions exists, training content shall include

- a) methods for task execution,
- b) personal safety requirements and appropriate protective equipment,
- c) awareness of hazardous environment, and
- d) protection of the equipment.

7.2.HV.1 Operator Qualification and Requalification – The organization shall identify activities for which operator qualification and requalification are necessary. Qualification and requalification requirements shall be established for identified activities. At a minimum, these requirements shall address education, experience, training, and demonstrated skills. The organization shall communicate this information to all those affected.

7.2.HV.1-NOTE Examples of activities that require qualification and requalification include wire wrapping, fiber-optic fusion splicing, soldering, welding, fork lift operation, and tower climbing.

7.3 Awareness

There are no additional requirements for this section of ISO 9001

8.3.2 Design and development planning

Additional requirements for TL 9000 are shown below

8.3.2.C.1 Project Planning - The organization's project planning activities shall be based on the defined product and service life cycle model (see 8.1.C.1). Throughout the project life cycle, the planning activities should include

- a) project organizational structure,
- b) roles, responsibilities, and accountabilities of the project team,
- c) roles, responsibilities, and accountabilities of related teams or individuals, within and outside the organization, and interfaces between them and the project team,
- d) methods for scheduling, issue resolution, and management reporting,
- e) estimation of project factors,
- f) assumptions in the plan,
- g) budgets, staffing, and schedules associated with project activities,
- h) the various method(s), standards, documented information, and tools to be used,
- i) other related project dependencies (e.g., risk management, development, testing, configuration management, and quality),
- j) project-specific development or service delivery environment and physical resource considerations (e.g., resources to address development, user documentation, testing, operation, required development tools, secure computing environment, lab space, workstations, etc.),
- k) customer, user, and external provider involvement during the product and service life cycle (e.g., joint reviews, informal meetings, and approvals),
- l) management of project quality, including appropriate quality measures,
- m) design for X (DFx) as appropriate to the product and service life cycle,
- n) lessons learned from previous post-project analyses and retrospectives, including root cause analysis and corrective actions to be taken to preclude repetition in future projects,
- o) project-specific training requirements,
- p) required certifications (e.g., product and/or service certifications or employee technical certifications), and
- q) proprietary, usage, ownership, warranty, and licensing rights.

8.3.2.C.1-NOTE 1 Work instructions defining tasks and responsibilities common to all development projects need not be replicated per individual project.

8.3.2.C.1-NOTE 2 Estimation may consider project factors such as size, complexity, requirements changes, effort, staffing, schedules, cost, quality, reliability, velocity, and productivity. Data from the estimation process should be analyzed to compare original estimates to actuals.

8.3.2.C.1-NOTE 3 DFx examples include Manufacturability, Reliability, Regulatory, Serviceability, Safety, Sustainability, Security, Privacy, and Testability. See 'Design for X (DFx) Guidance Document' at tl9000.org/handbooks/rh_guidance.html for a list of examples and other information on DFx.

8.3.2.HS.1 Configuration Management Planning - The organization shall establish and maintain a method(s) to perform configuration management, which should include

- a) identification and scope of the configuration management activities,
- b) schedule for performing these activities,
- c) configuration management tools,
- d) configuration management methods and documented information,
- e) organizations and responsibilities assigned to them,
- f) level of required control for each configuration item, and
- g) point at which items are brought under configuration management.

8.3.2.HS.3-NOTE See the document 'Set Up and Operation of a Design Process Measurement System' referenced at I9000.org/links.html for guidelines to aid in selecting and establishing appropriate design and development process measurements for the project.

8.3.2.HS.4 Migration Planning - The organization shall develop and document a migration plan when a system, hardware or software product is planned to be migrated to a new operational environment. If the old environment will no longer be supported, users shall be given notification of migration plans and activities which shall include a description of the new environment with its date of availability and a description of other support options available, if any, once support for the old environment has been removed.

The migration plan should also include

- a) requirements analysis and definition of migration,
- h) development of migration tools,
- i) conversion of product and data,
- j) migration execution,
- k) migration verification, and
- l) support for the old environment in the future.

8.3.2.HS.4-NOTE 1 The operational environment is made up of hardware, software, or systems on which the product depends, including what the customer purchases and installs separately, from either the organization or other suppliers. Examples of changes to new software operational environments include upgrades to the operating system, database, or communications protocol stack. Examples of changes to new hardware operational environments include using existing circuit packs in new racks or with new controllers, or upgrading computer hardware. Both hardware and software platform migration could affect either hardware or software components or systems so migration plans need to cover all possibilities.

8.3.2.HS.4-NOTE 2 If the old environment will no longer be supported, consideration should be given to arrangements for access to data that was used by, or associated with, the old operational environment, for data protection and audit purposes, in accordance with regulatory and contractual requirements.

8.3.3 Design and development Inputs

Additional requirements for TL 9000 are shown below

8.3.3.C.1 Customer and External Supplier Input – The organization shall establish and maintain methods for collaboration with customers and external providers during the development of new or revised product/service requirements.

8.3.3.C.2 Design and Development Requirements – Design and development requirements shall be defined and documented, and should include

- a) quality and reliability requirements,
- b) functions and capabilities of the products and services,
- c) business, organizational, and user requirements,
- d) safety, environmental, sustainability, security, and privacy requirements,
- e) manufacturability, installability, usability, interoperability, and maintainability requirements,
- f) design constraints,
- g) testing requirements,
- h) product computing resources,
- i) lessons learned from previous projects and retrospectives, and
- j) hardware packaging requirements.

8.3.3.C.3 Requirements Allocation - The organization shall document the allocation of product and service requirements to their architecture.

8.4 Control of externally provided processes, products and services

8.4.1 General

Additional requirements for TL 9000 are shown below

8.4.1.C.1 Procurement Process – The organization shall maintain documented information on the procurement process to ensure

- a) product and service requirements are clearly defined,
- b) risks are understood and managed,
- c) qualification criteria are established,
- d) acceptance criteria are established,
- e) contracts are defined,
- f) proprietary, usage, ownership, warranty, and licensing rights are satisfied,
- g) future support for products and services is planned,
- h) ongoing supply-base management and monitoring is in place, and
- i) external provider selection criteria are defined.

8.4.1.C.2 External Provider Performance Management – The organization shall plan and perform external provider performance management and development activities so that

- b) external provider quality performance is tracked, and feedback is provided to external providers to drive continual improvement, and
- c) for identified key external providers, alignment toward conformity to TL 9000 requirements and measurements or other appropriate quality management systems for the external provider's products and services occurs, with a preference toward TL 9000.

8.4.1.C.2-NOTE 1 External provider performance management planning and activities should be in conjunction with the organization improvement processes of Section 10.

8.1.C.2-NOTE 2 It is recognized that it is not possible for an organization to provide the same level of interaction with all external providers. The level provided may depend on the amount of business with an external provider, the criticality of products or services, history of problems, organization expectations, significance of an external provider within the supply chain or other factors.

8.4.1.C.2-NOTE 3 Examples of alignment toward conformity to appropriate quality management systems may include

- a) surveys,
- b) external provider questionnaires,
- c) external provider education and training regarding conformance to standards,
- d) the use of TL 9000 requirements and measurements, in full or in part,
- e) second-party audits evaluating TL 9000 conformance or conformance to an appropriate quality management system, and
- f) Certification to TL 9000 or other quality standards accredited by a signatory of the IAF MLA (where this is available) or by the appropriate sector accreditation body. Examples include ISO 9001 [\[2\]](#), AS9100 [\[6\]](#), CMMI [\[7\]](#), IATF 16949 [\[8\]](#), etc.

8.4.2 Type and extent of control

There are no additional requirements for this section of ISO 9001

8.4.3 Information for external providers

There are no additional requirements for this section of ISO 9001

8.5.4.HV.1 Deterioration – Where the possibility of deterioration exists, the organization shall establish and maintain methods to determine when materials that may impact product and service quality have deteriorated or exceeded their expiration dates, and assess any required subsequent action.

8.5.4.S.1 Software Virus Protection – The organization shall establish and maintain methods for software virus prevention, detection, and removal from the deliverable product.

8.5.5 Post-delivery activities

Additional requirements for TL 9000 are shown below

8.5.5.H.1 Testing of Repair and Return Products – Repair and return products shall be subjected to the appropriate evaluation(s) and/or test(s) to ensure functionality to product specification(s).

8.5.5.HS.1 Emergency Service Provisioning – The organization shall ensure that services and resources are available to support recovery from emergency failures of product in the field throughout its expected life. The organization shall identify potential situations that may have an impact on its ability to provide the emergency service and shall have response plans to address these situations. These plans shall be based on risk and periodically assessed.

8.5.5.S.1 Software Patching Information – The organization shall maintain documented information for software patching that

- a) guides the decision to solve problems by patching,
- b) addresses patch development information, propagation (forward and backward), and resolution,
- c) is consistent with customer needs or contractual requirements for maintenance support,
- d) ensures that the organization provides the customer with a statement of impact on the customer's operation for each patch, and
- e) ensures that all documentation required to describe, test, install, and apply a patch has been verified and delivered with the patch.

8.5.6 Control of changes

There are no additional requirements for this section of ISO 9001

8.6 Release of products and services

Additional requirements for TL 9000 are shown below

8.6.HV.1 Inspection and Test Documentation – Each inspection or testing activity performed during production, operation, maintenance, and disposal of products or cessation of services shall have detailed documentation. Details should include, but are not limited to

- a) parameters to be checked with acceptable tolerances,
- b) the use of statistical techniques, control charts, etc.,
- c) sampling plan, including frequency, sample size, and acceptance criteria,
- d) handling of nonconformities,
- e) documented information to be retained (see 7.5.3),
- f) defect classification scheme,
- g) method for designating an inspection item or lot, and
- h) electrical, functional, and feature testing.