QuEST Forum

TL 9000
Quality Management System

Requirements Handbook

Point Release 6.1

The ICT Quality Management System
Performance Excellence through Global ICT Quality

8. Operation

8.3 Design and development of products and services

8.3.1 General

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) budgets, staffing, and schedules associated with project activities,
g) the various method(s), standards, documented information, and tools to be used,
h) other related project dependencies (e.g., risk management, development, testing, configuration management, and quality),
i) 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.),
j) customer, user, and external provider involvement during the product and service life cycle (e.g., joint reviews, informal meetings, and approvals),
k) management of project quality, including appropriate quality measures,
l) design for X (DFx) as appropriate to the product and service life cycle,
m) 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,
n) project-specific training requirements,
o) required certifications (e.g., product and/or service certifications or employee technical certifications), and
p) 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, 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.C.2 Project Risk Management – The organization shall identify, analyze, and control the risks to the project that can impact cost, schedule, quality, or performance of product and service.

8.3.2.C.2-NOTE Risk management should be performed during all phases of product and service development and may include, depending on the scope and complexity of the project,
a) the means to determine risk sources, categories, and priorities,
b) identification of significant or critical characteristics and failure modes, including customer experience,
c) a definition of risk parameters (e.g., probability of occurrence, severity of impact) to be used in determining risk priorities and any scoring mechanisms to be used (e.g., FMEA - Failure Mode Effects Analysis),
d) how risks will be managed (e.g., tools to be used, actions to reduce risk, mitigation strategies, monitoring and reporting requirements),
e) inputs from appropriate functional disciplines, and
f) a mechanism for capturing and applying lessons learned.

8.3.2.C.3 Requirements Traceability - The organization shall establish and maintain documented information to trace each documented requirement through design and test.

8.3.2.C.4 Test Planning - Test planning should include determining and documenting, as necessary, the
a) scope of testing (e.g., unit, feature, integration, system, acceptance, field, migration, and regression),
b) types of tests to be performed (e.g., functional, boundary, usability, performance, regression, interoperability, stress),
c) traceability to requirements,
d) test environment (e.g., relevancy to customer environment, operational use),
e) test coverage (degree to which a test verifies product and service requirements, sometimes expressed as a percent of requirements tested),
f) expected results,
g) data definition and database requirements,
h) set of tests and repeatable test cases (e.g., inputs, outputs, test criteria),
i) use of external testing,
j) method(s) of reporting and resolving defects,
k) customer test requirements, and
l) predefined exit criteria.

The results of testing and subsequent action taken shall be retained as documented information.

8.3.2.C.5 Integration Planning - The organization shall develop and execute a plan to integrate the hardware, software, and/or service components to ensure they interact as designed. The planning shall include
a) methods and documented information,
b) responsibilities,
c) schedule for integration, and
d) test requirements.

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.2 Product Computing Resources - The organization shall estimate and track critical performance parameters for any computing device utilized by the product.

8.3.2.HS.2-NOTE Examples of these critical performance parameters are memory utilization, storage capacity, availability, channel capacity, latency, throughput, real-time performance, scalability, power dissipation, and input/output channels.

8.3.2.HS.3 Development Process Quality Measurement – During the design and development activities, the organization shall identify the appropriate design and development process quality measures for the project. During these activities, the measurement system shall be implemented appropriately to the project. On request by the customer, communications shall include reporting and evaluation of a jointly agreed set of design and development process measurements.

8.3.2.HS.3-NOTE See the document 'Set Up and Operation of a Design Process Measurement System' referenced at tl9000.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,
b) development of migration tools,
c) conversion of product and data,
d) migration execution,
e) migration verification, and
f) 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 Provider Input– The organization shall establish and maintain methods for soliciting and considering customer and external provider input 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 and security 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
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.

8.3.3.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.

8.3.4 Design and development controls

Additional requirements for TL 9000 are shown below

8.3.4.C-NOTE Organizations may include customers or third parties during various validation stages.

8.3.4.C.1 Verification of User Documentation - The organization shall verify the customer and/or user documentation for products and services prior to delivery.

8.3.4.HS.1 Stress Testing – To confirm design margins, the organization shall test the product under stress conditions, including, but not limited to

a) out-of-boundary and invalid input conditions,
b) high-volume and peak load simulations, and
c) operational errors.

8.3.4.HS.2 Abnormal Conditions - The organization shall test the products to confirm expected product operation under abnormal conditions, which shall include, as appropriate
a) hardware failures,
b) software failures,
c) operations, administration, maintenance and provisioning (OAM&P) errors,
d) overload traffic,
e) invalid user input, and
f) system recovery from an outage.

8.3.4.HS.3 System Testing – The product release shall be subjected to system testing in accordance with test documentation (see 8.3.2.C.4).

8.3.4.HS.4 Release Management - The organization shall maintain documented information to ensure that the release and delivery of products and related documentation are carried out under controlled conditions. The documented information should provide for the delivery to the customer of
a) product information and release schedules,
b) detailed descriptions of product features delivered, including any changes incorporated in new and existing products or releases, and
c) advisories regarding current or planned changes to contractual terms (see 8.3.6.C.2).

8.3.5   Design and development outputs

Additional requirements for TL 9000 are shown below

8.3.5.HS.1 Product Design and Development Output – Product design and development outputs to support, maintain, and use the product should include, but are not limited to
a) system architecture,
b) system detailed design,
c) source code, and
d) user documentation.

8.3.5.HS.1-NOTE Product design and development output may also include items such as training materials and Application Program Interface (API) specifications.

8.3.5.V.1 Services Design and Development Output - The required output from the services design and development shall contain a complete and precise statement of the service to be provided. Design and development outputs should include, but are not limited to
a) documented service delivery information,
b) resource and skill requirements,
c) reliance on external providers,
d) service characteristics subject to customer evaluation, and
e) standards of acceptability for each service characteristic.

8.3.6   Design and development changes

Additional requirements for TL 9000 are shown below

8.3.6.C.1 Change Management Process - The organization shall maintain documented information to ensure that all requirements and design changes, which may arise at any time during the product and service life cycle, are managed and tracked in a systematic and timely manner. The organization shall ensure that 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
a) impact analysis, including impact on resources and schedule,
b) planning,
c) implementation,
d) testing,
e) documentation,
f) communication, and
g) review and approval.

8.3.6.C.1-NOTE A change management process is required throughout the life cycle. For example, during design and development the organization needs the ability to react to rapidly changing customer requirements and take advantage of emerging technologies with an encompassing, responsive change management process. After General Availability, the change management process scope considers how changes to the operation and maintenance of products and services and the installed base impact the community of interested parties. The consideration includes quality, reliability, and functional intent.

8.3.6.C.2 Informing Customers of Design Changes – The organization shall ensure that customers are informed when design changes affect contractual commitments.

8.3.6.C.3 Problem Resolution Configuration Management – The organization shall ensure that its configuration management system tracks fixes to problems and incorporates those fixes in future revisions.

8.3.6.H.1 Component Changes - The organization shall maintain documented information to ensure that material or component substitutions or changes do not adversely affect conformity to product/service requirements or performance. The documented information should include
a) functional testing,
b) qualification testing,
a) stress testing,
b) approved parts listing, and/or
c) critical parts listing.

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.

8.6.HV.2 Documentation Retained from Inspection and Test Activities - Documentation retained from inspection or test activities shall include
a)   product or service identification,
b)   quantity of product,
c)   documented procedure(s) followed,
d)   person(s) performing the test or inspection,
e)   calibrated equipment used (see 7.1.5),
f)   date performed,
g)   test and inspection results, and
h)   number, type, and as applicable, severity of defects found.

8.6.S.1 Test Documentation - Documented information retained from software testing shall include
 a)   test results,
 b)   analysis of test results,
 c)   conformity to expected results, and
 d)   problem reporting for nonconforming items.