

Summary of ISO 9001:2015 New and Changed Requirements

This is a summary of the new and changed ISO 9001:2015 requirements compared to ISO 9001:2008.

4. Context of the Organization

4.1 Changes – Understanding the Organization and its Context

- New requirement on context of organization
- Links quality system and business system
- See new NOTES for examples of external and internal issues
- Organization may already monitor and review external and internal issues
- Will need evidence of determination, monitoring, and reviews

4.2 Changes – Understanding the Needs and Expectations of Interested parties

- New requirement on interested parties
An interested party is “A person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.”
- Interested parties may be:
 - customers, owners, employees, providers, bankers
 - regulators, unions, partners, community, news media
 - competitors, law enforcement, emergency responders
- Relevant interested parties may change
- Relevant requirements of interested parties may change
- Will need evidence of determination, monitoring, and reviews

4.3 Changes – Determining the Scope of the Quality Management System

- Specification of quality management system scope is not new
- Now must explicitly consider issues, interested parties, and products and services
- Clause replaces old clause 1.2, Application
- “Exclusions” are no longer limited to old clause 7, Product Realization
- If performing functions addressed by ISO 9001, they must be included in scope statement
- See Annex A.5 for Applicability discussion

4.4 Changes – Quality Management System and its Processes

- Replaces old clause 4.1 on general process-based requirements
- Adds determining inputs and expected outputs
- Adds determining and addressing process-related risks and opportunities
- New focus on performance indicators for effective operation and control
- Discussion of outsourcing in old clause 4.1 was moved to new clauses 8.1 and 8.4

5. Leadership

5.1 Leadership and Commitment

5.1.1 Changes - General

- Replaces old 5.1 on Management Commitment
- Expands that management must demonstrate leadership and accountability
- Now requires that quality policy and objectives be compatible with strategic direction
- Includes new focus on process approach and risk-based thinking
(don't implement standard just to get certified, use it to better manage your business)
- QMS requirements must now be integrated into business processes
- More of a hands-on role for top management
- Notice number of “ensure” requirements; someone else can do it
(vs. take, promote, communicate, engage, support)
- More questions will be directed to top management by internal and external auditors

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5.1.2 Changes – Customer Focus

- Replaces old clause 5.2 on Customer Focus
- Includes determining legal requirements from old clause 7.2.1
- Primary clauses for customer requirements are in new 8.2.2 and 8.2.3
- Adds requirement to determine and address risks and opportunities that affect conformity
- Note that this clause can be met by effectively addressing all the other parts of the standard

5.2 Changes - Policy

Replaces old clause 5.3 on Quality Policy.

Quality Policy must now:

- Support the strategic direction
- Be available and maintained
- Be applied, not just communicated and understood
- Made available to relevant interested parties, as appropriate

5.3 Changes – Organizational Roles, Responsibilities, and Authorities

- Replaces old clause 5.5.1 on Responsibility and Authority
- Adds responsibilities to be assigned and understood
- Identifies specific responsibilities to be assigned
- May not have management representative for assignments
- Old duties could be spread among top management
- Registrars will still need a nominated point of contact
- Doesn't preclude a management representative being appointed

6. Planning

6.1 Changes – Actions to Address Risks and Opportunities

This is a new clause on risks and opportunities.

- Expands on old clause 5.4.2 on Planning
- Replaces old clause 8.5.3 on Preventive Action
- Need methodology to identify and address risks
- Could decide to accept risk and take no action
- ISO 9001:2008, clauses 4-8, does not mention "risk".
- ISO 9001:2015, clauses 4-10, mentions "risk" 16 times.
- Alternative: "Crisis" Management

6.2 Changes – Quality Objectives and Planning to Achieve Them

- Replaces old clause 5.4.1 on Quality Objectives
- Expands to establish quality objectives for relevant "processes"
- Adds quality objectives for service conformity and enhancement of customer satisfaction
- Quality objectives must also consider "applicable requirements"
- Adds planning approach (what, who, when, how) for achievement of quality objectives

6.3 Changes – Planning of Changes

- Replaces old clause 5.4.2.b in Quality Management System Planning
- Adds consideration of potential consequences, resources, and responsibilities

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7. Planning

7.1 Resources

7.1.1 Changes - General

- This clause updates old clause 6.1 on Resources
- Removes mention of customer satisfaction (still multiple other references, including 9.1.2)
- Adds consideration of internal resources and external providers

7.1.2 Changes - People

- This clause focuses on the people resource from old clause 6.1, Provision of Resources
- Adds for operation and control of processes

People are addressed in more actionable ways in:

- 7.1.6 Organizational knowledge
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication

7.1.3 Changes - Infrastructure

- Updates old clause 6.3 on Infrastructure
- Reworded infrastructure examples moved from requirements section to a NOTE

7.1.4 Changes – Environment for the Operation of Processes

- Updates old clause 6.4 on Work Environment.
- Clarifies that now covers operation of processes.

The NOTE:

- Adds social and psychological environments
- Adds physical factors of heat, airflow, hygiene

7.1.5 Changes – Monitoring and Measuring Resources

- Replaces old clause 7.6 on control of monitoring and measuring equipment
- Adds verification of conformity of “services”
- General clause 7.1.5.1 refers to “resources” instead of equipment
- Humans may carry out activity without equipment
- Resources must be “suitable” and maintained for “fitness for purpose”
- Software version control now in clause 7.5.2

7.1.6 Changes – Organizational Knowledge

- New requirement considers “tribal” knowledge
- Should be an input to 7.2 on Competence
- See Annex A.7 on Organizational Knowledge
- Safeguard from loss of knowledge, e.g.,
 - staff turnover
 - failure to capture and share information
- Encourage knowledge acquisition, e.g.,
 - learning from experience
 - mentoring; benchmarking

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7.2 Changes – Competence

- Replaces most of old clause 6.2 on Human Resources
- Old clause 6.2.2.d now in new clause 7.3 on Awareness
- Use of “under its control” includes contract, agency, and outsourcing
- See clause 8.4.3.c on competence of external providers
- Adds NOTE with examples of applicable actions

Competence is defined as *“the ability to apply knowledge and skills to achieve intended results.”*
Demonstrated competence is sometimes referred to as *“qualification”*.

7.3 Changes - Awareness

- Elevates old clause 6.2.2.d to a separate clause
- Expands personnel to persons doing work “under organization’s control”
- Awareness now includes quality policy and quality objectives
- Adds awareness of the “implications” of not conforming with QMS requirements

7.4 Changes – Communication

- Replaces old clause 5.5.3 on Internal Communication
- Explicit: What, When, to Whom, How, Who
- Expands to include “external” communication
- Note that “customer communication” moved from old clause 7.2.3 to new clause 8.2.1

7.5 Documented Information

7.5.1 Changes - General

- Replaces old clauses 4.2.1.c and 4.2.1.d on documentation requirements
- Changes from procedures and records to “documented information”
- NOTE on “extent” is from NOTE 2 in old 4.2.1
- Drops requirement for documented procedure
- Lack of “documented procedure” requirement ≠ book burning
- Undocumented processes are difficult to communicate, monitor, review, and revise

7.5.2 Changes – Creating and Updating

- Gathered from old clause 4.2.3.a, b, c, and e
- Adds description, format, and media examples
- Drops “re-approval” language, but “approval” applies to both creating and updating

7.5.3 Changes – Control of Documented Information

- Gathered from old clause 4.2.3 (c, d, e, f)
- Includes requirements from old clause 4.2.4
- Adds examples for protection (confidentiality, use, and integrity)
- Protection of evidence from unintended alteration
- No mention of obsolete documents or their retention; covered by version control
- No specific change identification language
- Adds NOTE on types of access
- See Annex A.6 on Documented Information

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8. Operation

8.1 Changes – Operational Planning and Control

- Replaces old clause 7.1, Planning of Product Realization
- Expands to control of processes; planned changes
- Reviews consequences of unintended changes
- Adds to act to mitigate adverse effects
- Includes “outsourced” processes from old 4.1
- Refers to 8.4 for control of “outsourced” processes
- Planning of quality objectives is covered in 6.2

8.2 Requirements for Products and Services

8.2.1 Changes – Customer Communication

- Replaces old clause 7.2.3 on customer communication
- Moves customer communication before step of determining requirements
- Adds communication of specific requirements for possible “contingency actions”
- Includes handling or controlling customer property
- See clause 9.1.2 regarding customer satisfaction
- See clause 8.5.3 for more on customer property

8.2.2 Changes – Determining the Requirements for Products and Services

- Replaces old clause 7.2.1 on Determination of Requirements Related to the Product
- Expands that must meet “claims” for products and services offered to customers
- Does this involve Marketing and Sales?

8.2.3 Changes – Review of Requirements for Products and Services

- Replaces old clause 7.2.2 on review of requirements related to product
- Clause 8.2.3.1 replaces old clause 7.2.2.c on ability to meet defined requirements
- Merges in requirements from old clause 7.2.1.a, b, and c

8.2.4 Changes – Changes to Requirements for Products and Services

- Includes requirement from old clause 7.2.2 on review of product requirements
- Given own sub-clause for focus on changes
- Same text except addition of term “services”

8.3 Design and Development of Products and Services

8.3.1 Changes – General

- New “General” design and development clause
- Adds that design and development process is to ensure subsequent provision of products and services

8.3.2 Changes – Design and Development Planning

Expands on old clause 7.3.1 with considerations for:

- nature, duration, and complexity of process activities
- internal and external resource needs
- involving customers and end users
- requirements for subsequent provision of products and services
- level of control by customers and other relevant interested parties
- documented information to demonstrate process requirements are met

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8.3.3 Changes – Design and Development Inputs

- Replaces old clause 7.3.2 - Design and Development Inputs
- Changes from must “include” to must “consider”
- Adds standards and codes of practice that organization is committed to implement
- Adds potential consequences of failure > risk

8.3.4 Changes – Design and Development Controls

- Adds new controls clause to group together Reviews, Verification, and Validation
- Merges old clauses 7.3.4, 7.3.5, and 7.3.6
- Includes old NOTE from 7.3.1 on Planning
- Drops validation completing prior to delivery or implementation of “product”, when practical (Validation of “services” is typically at delivery)

8.3.5 Changes – Design and Development Outputs

- Replaces old clause 7.3.3 on design outputs
- Output expanded to include or reference monitoring and measuring requirements
- Drops providing information for purchasing, production, and service provision
- Replaces with output being adequate for “subsequent processes”
- Changes from safe and proper “use” to safe and proper “provision” (providing or supplying)
- Adds to retain documented information on the design and development outputs

8.3.6 Changes – Design and Development Changes

- Replaces old clause 7.3.7 on control of design and development changes
- Verify and validate changes now covered by use of term “control” (also see 8.3.4)
- Drops mention of evaluating effect of change on constituent parts and delivered product (now addressed by avoiding adverse impact on conformity to requirements)
- Identifies the specific “records” to be retained

8.4 Control of Externally Provided Processes, Products, and Services

8.4.1 Changes – General

- Replaces most of old clause 7.4.1 on purchasing process
- Includes outsourcing and drop shipments
- External provider is outside scope of system:
 - purchasing from a supplier,
 - arrangement with an associate company,
 - outsourcing of processes.
- Adds monitoring of external provider performance
- See Annex A.8 on control of externally provided processes, products, and services

8.4.2 Changes – Type and Extent of Control

- Expands old clause 7.4.1 on type and extent of control
- Old clause 4.1 NOTE 3 on outsourcing controls now auditable as a requirement
- Apply controls on external providers and their outputs
- Considers effectiveness of external provider’s controls
- Considers “potential impact” of externally provided processes, products, and services
- Includes verification from old clause 7.4.3 on verification of purchased product

8.4.3 Changes – Information for External Providers

- Includes requirements from old clauses 7.4.2, 7.4.3
- Adds interactions with organization, e.g., Supplier Corrective Action Request
- Adds control and monitoring of external provider’s performance
- Adds “validation” activities

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8.5 Production and Service Provision

8.5.1 Changes – Control of Production and Service Provision

- Replaces old clause 7.5.1 on control of production and service provision
- Changes “work instructions” to “documented information”
- Clarifies that documented information defines activities to be performed and expected results
- Adds verification that control criteria and acceptance criteria have been met
- Adds actions to prevent “human error”
- Use of suitable equipment expanded to use of infrastructure and environment for operation (see 7.1.3 for more on infrastructure; see 7.1.4 for more on environment)
- Adds appointment of competent persons, including any required qualification
- Moves old clause 7.5.2 on “special processes” into clause 8.5.1.f and lessens its emphasis

8.5.2 Changes – Identification and Traceability

- Replaces old clause 7.5.3 on Identification and Traceability
- Changes from use of “product” to “outputs”
- Output = products, services, or process output

8.5.3 Changes – Property Belonging to Customers or External Providers

- Replaces old clause 7.5.4 on Customer Property
- Expands to include external provider’s property
- Could be a supplier’s consigned inventory (See 8.5.2 for more on property identification; see 8.4 for more on property control)
- Expands NOTE on examples of property to include materials, components, tools and equipment, and premises

8.5.4 Changes – Preservation

- Replaces old clause 7.5.5 on preservation of product
- Changes from “product” to “outputs”
- Moves types of preservation into new NOTE
- NOTE adds contamination control, plus transmission and transportation

8.5.5 Changes – Post-Delivery Activities

- New clause on post-delivery requirements
- Expands old clauses 7.2.1.a, 7.5.1.f on post-delivery
- Adds consideration of:
 - legal requirements; customer feedback
 - potential undesired consequences
 - nature, use, and lifetime of products and services
- Includes NOTE from old clause 7.2.1 for examples of post-delivery actions
- See clause 8.2 on product and service requirements

8.5.6 Changes – Control of Changes

- New clause on control of changes
- Refer to clause 6.3 on planning of changes
- Clause 6.3 is more proactive, strategic, system-wide
- Clause 8.5.6 is reactive, tactical, operations-related
- See clause 8.1 on operational planning and control

8.6 Changes – Release of Products and Services

- Replaces old clause 8.2.4 on monitoring and measurement of product
- Expands on old clause 7.5.1.f on product release
- More focus on “release”, but “verifying” products and services still a requirement

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8.7 Changes – Control of Nonconforming Outputs

- Replaces old clause 8.3 on control of nonconforming product
- Changes from “product” to “outputs”
- Clarifies it also applies to services
- Includes segregation, containment, return, or suspension as ways to deal with nonconformity
- Adds informing customer as possible action
- Drops requirement for a documented procedure

9. Performance Evaluation

9.1 Monitoring, Measurement, Analysis, and Evaluation

9.1.1 Changes – General

- Includes general requirements from old clause 8.1 (monitoring, measurement, analysis, improvement)
- Replaces “improvement” with “evaluation”
- Adds “what” and “when” for monitoring and measurement
- Adds “when” for analysis and evaluation
- Determine the methods to ensure “valid results”
- Retain appropriate documented information (records) as evidence of results
- Evaluate performance (not just conformity)
- See clause 9.1.3 for more on analysis and evaluation
- Moves mention of “statistical techniques” into NOTE under 9.1.3
- See clauses 10.1 and 10.3 for more on improvement

9.1.2 Changes – Customer Satisfaction

- Replaces old clause 8.2.1 on customer satisfaction
- Revises requirements to “needs and expectations”
- Changes methods to “obtain and use” to methods to “obtain, monitor, and review”
- Revises monitoring examples in NOTE
 - uses market-share analysis instead of lost business analysis
 - adds customer meetings
- What about social media ratings and reviews?
- See clause 9.3.2.c.1 on customer satisfaction being a topic for management review

9.1.3 Changes – Analysis and Evaluation

- Replaces old clause 8.4 on analysis of data
- Changes from suitability to performance of system
- Adds use of analysis and evaluation to evaluate if “planning” was implemented effectively
- Assess “performance” of external providers instead of provide information on suppliers
- Evaluate “degree” of customer satisfaction, not just provide information on customer satisfaction
- Drops reference to preventive action

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9.2 Changes – Internal Audit

- Replaces old clause 8.2.2 on internal audits
- Considers changes affecting organization
- Moves to more risk-based internal audit
- May result in more updates to audit schedule
- Clarifies audit frequency and audit methods are planned for “audit program”
- Clarifies audit criteria and audit scope are defined for “each audit”
- Drops reference to a follow-up audit
(see clause 10.2.1.d for review of effective corrective action)
- Drops need for documented procedure
- No mention of not auditing own work
(still requires impartial and objective audits)
- Adds need for documented information as evidence of audit program implementation

9.3 Changes – Management Review

- Replaces old clause 5.6 on management review
- Moves follow-up actions to top of review inputs
- Adds review of issues and strategic direction
- Adds focus on resources, performance, and trends
- Adds input on actions to address risks (see 6.1)
- Adds specific “input” topic for quality objectives
- Drops reference to preventive action
- Revises customer feedback to be customer satisfaction
- Adds feedback from relevant interested parties
- Evidence now “results of” not “records from” review

10. Improvement

10.1 Changes – General

- New clause 10.1 added to Annex SL clauses
- Expands old clause 8.5.1 on Continual Improvement
- Determine and select improvement opportunities
- Improve products and services, not just QMS
- Improve for “future” needs and expectations
- New focus on “undesired effects”
- Adds NOTE on examples of improvement

See clauses 5.3.c, 9.1.3.g, 9.3.2.f, 9.3.3.a, and 10.3 for more on opportunities for improvement.

10.2 Changes – Nonconformity and Corrective Action

- Replaces old clause 8.5.2 on corrective action
- Drops need for old clause 8.5.3 on preventive action
- Drops requirement for documented procedure
- Adds control, correct, deal with consequences
- See if similar nonconformities exist or could occur
- Adds to make changes to system if necessary
- Adds to update risks and opportunities identified during planning, if necessary

10.3 Changes – Continual Improvement

- Replaces old clause 8.5.1 on continual improvement
- Adds to consider needs or opportunities
- Drops references to policy, objectives, audit results, and corrective and preventive actions