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
- 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.
  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
Summary of ISO 9001:2015 New and Changed Requirements

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
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