

From ISO 9001:2008 to ISO 9001:2015

A close-up profile photograph of a woman with long, dark hair, looking towards the right. The image is partially obscured by a vertical green bar on the left edge of the slide.

No Doubt.

Let's create a level playing field >>

a guidance to conversion

From ISO 9001:2008 to ISO 9001:2015

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ISO 9001:2008

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ISO 9001:2015

4.1 Understanding the organization and its context

New chapter:

Setting the framework; defining and monitoring the way it interacts with internal and external aspects.

New: Note 1: Issues can be positive or negative factors.

4.2 Needs of interested parties

New chapter:

Determining and assessing the relevant interested parties and their requirements, i.e. the needs and expectations of the interested parties.

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ISO 9001:2008

1.2 Scope of application

Definition scope.

Exclusions (only chapter 7) must be substantiated.

4.1 General requirements

Identifying processes.

Controlling processes.

Ensuring CIP in processes.

Identify outsourced processes and monitor their results.

ISO 9001:2015

4.3 Scope of application

Definition of scope. NEW: A possible "non-application" is no longer restricted to chapter 7. However:

Everything which can be applied, should be applied.

Focus on customer satisfaction improvement.

4.4 QMS processes

Defining relevant processes and the resources required for them. NEW: Evaluate and describe (if necessary) the following items: Input, output, sequence, interfaces, resources, measurements, risks, opportunities, CIP.

8.2 Planning/8.4 External suppliers/8.4.2 Control of external provision

Monitoring of the outsourced processes e.g. suppliers.

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4.2 Documentation/4.2.2 QM manual

Creation and updating of a manual.

4.2.3 Documents/4.2.4 Records

Generation, checking, release, control

ISO 9001:2015

7.5 Documented information.

NEW: QM manual no longer explicitly required. It can, however, still be used.

Documented processes are mostly only necessary if the organization requires them for the effective running of its processes. Documented information can be found in 25 different positions.

7.5.2 Documented information

Generation, updating, etc.

NEW: Documents and records no longer distinguished between. Both are now referred to as "documented information". The terms can, however, still be used. Documented processes for the control of documents and records are no longer explicitly required.

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ISO 9001:2008

5 Responsibility of the management

5.1 Commitment

Top management must commit itself e.g. to providing resources. No concrete specifications.

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5 Leadership

5.1.1 Leadership and commitment to QMS

Strengthening of the responsibility of the top management and greater influence of the top management on executives and other members of the organization. Stronger emphasis on integrating QMS requirements in (existing) processes. Promotion of process-oriented approach and risk-based thinking.

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ISO 9001:2008

5.2 Customer orientation

Goal: increased customer satisfaction.

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5.1.2 Customer orientation

More detailed;

- Top management assumes responsibility and leadership in customer orientation
- More explicit: Customer needs and legal requirements need to be identified.
- Risks and opportunities are to be considered together with their consequences on products, services and customer satisfaction.
- Consider customer satisfaction improvement

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ISO 9001:2008

5.3 Quality policy

Including obligation to meet customer requirements and CIP. Must be communicated internally. Must be evaluated regularly. Framework for Q targets.

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ISO 9001:2015

5.2 Quality policy

No significant changes.
Plus: Information to interested parties.
Top management must define, implement and maintain Q policy. "Review" is omitted.

6.1 Measures for handling risks & opportunities

New chapter:
Weighing up risks and opportunities will now become an obligatory part of the planning process. Identify risks and opportunities, and take appropriate action.

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ISO 9001:2008

5.4 Planning/ 5.4.1 Quality targets

Measurable Q targets for relevant levels of the organisation.

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5.4.2 QMS planning

QM system planning.
Ensuring that QMS continues to work after changes.

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6.2 Quality targets

Quality targets as applied to relevant processes, not only to relevant functions and structure levels - taking relevant requirements into account.
Relevance of targets for the conformity of products and services.
No significant change.

6.2.2 Measures for achieving Q targets.

NEW: Concrete measures for achieving Q targets must be defined.

6.3 Planning changes

Changes to the QM system must be executed in a planned manner.
The QMS must work even after changes have been made.

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5.5 Responsibility & authorization/5.5.1 Responsibility

Establishment of clear areas of responsibility and authorization.

5.5.2 Senior management representative

Appointment of quality officer

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5.3 Organizational roles, responsibilities, authorities

Determination of responsibilities attached to relevant roles in the company.

Reporting to top management in conjunction with proposals.

Deleted.

NEW: Senior management representative no longer explicitly mentioned. The QMS roles (including the former role of the QM representative) must be defined.

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5.5.3 Internal communication

Ensuring suitable communication on Q topics.

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7.4 Communication

Internal and external communication on Q topics must be defined.

7.3 Awareness

Employees must have an awareness of Q topics.
NEW: Consequences of non-fulfilment and benefits of improved Q performance.

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5.6 Management review

Evaluation of the QM system by senior management at regular intervals.

Concrete input and action should be defined.

Records should be requested.

6 Resource management/6.1 Provision

Determining the necessary resources.

Goal: increased customer satisfaction.

6.2 Human resources

Competence, training, documentation of training.

ISO 9001:2015

9.3 Management review

Almost unchanged; additional entries on external and internal topics, interested parties, risks & opportunities, degree of Q targets achievement. QM system must be aligned with strategic orientation of the Company. Records should be kept of results.

7.1 Resources

Determining the required resources, including the qualifications and limitations of the internal resources and the resources to be obtained externally.

7.1.2 People

NEW: Target-oriented personnel planning instead of product-oriented existence of required persons.

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- 6.3 Infrastructure**
Identify and provide necessary infrastructure.

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- 7.2 Competence**
Competence, training, documentation of training (formerly 6.2).
The focus has now been expanded to include not only training of the company's own staff but also the commissioning of external resources.
Documented information on the competence of the deployed staff.
- 7.1.6 Organizational knowledge**
Completely new chapter: Knowledge management in the organization, From ISO 9004.
- 7.1.3 Infrastructure**
No significant changes.

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ISO 9001:2008

6.4 Working environment

Identify and provide necessary working environment.

7 Product realization & service provision/7.1 Planning

Create a Q plan for each product, project, service.

7.2 Customer-related processes/7.2.1 Identify requirements

Identification of customer needs.
Including implicit requirements and legal requirements.
Including after-delivery activities.

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7.1.4 Process environment

No significant changes

8 Operations/8.1 Planning

Almost unchanged. The term Q plan is no longer used. External processes must be handled as in 8.4 (Suppliers).

8.2.2 Determination of requirements

No significant changes

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7.2.2 Evaluation of requirements

Written feasibility assessment; exceptions e.g. for Web-based sales.

7.2.3 Communication with customers

Determining requests, contracts, complaints.

ISO 9001:2015

8.2.3 Determination of requirements

8.2.3 Determination of requirements
No significant changes.
Plus: Post-delivery activities

8.2.1 Communication with customers

No significant changes.
Plus: Customer views, complaints, handling of customer property, emergency measures.

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7.3 Development/7.3.1 Development planning

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Planning of developments in phases, responsibilities, reviews, verifications, validators

7.3.2 Inputs

Functional requirements, legal requirements, etc.

ISO 9001:2015

8.3 Development/8.3.1 General

Provision of service can also be viewed as development.

8.3.2 Development planning

Defining development stages, reviews, verification, validation.

Additional reference regarding inclusion of customers or interested parties in development process.

8.3.3 Inputs

Plus: Identification of consequences of possible errors, information on previous comparable development. Documented information necessary.

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7.3.3 Development results

Fulfilment of specifications, acceptance criteria, etc.

7.3.4 Development assessment

Evaluations in suitable phases by representatives of different functional areas, etc.

7.3.5 Verification

Verification based on planned arrangements.

7.3.6 Validation

Validation based on planned arrangements.

7.3.7 Development changes

Labelling of changes, evaluations.

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8.3.5 Development results

No significant changes
Documented information.

8.3.4 Development controls

Evaluation, verification, validation and measures in case of problems.
Documented information.

8.3.6 Development changes

Provision of further details for documented information in case of changes.

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7.4 Procurement/7.4.1 Procurement process

Monitoring of the procured products, selection and evaluation of suppliers, action.

7.4.2 Procurement data

Specifications for suppliers: regarding products, regarding staff requirements and regarding the supplier's QM system.

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8.4 Controls of externally provided products/services

No significant changes.

Only external suppliers are explicitly named.

Outsourced processes are monitored like suppliers.

In particular, monitoring must take place if the supplier delivers directly to the company's clients.

Documented information on supplier evaluation and measures for supplier evaluation.

8.4.3 Information for external providers

No significant changes.

Plus: Q controls at the supplier's site. Applicable requirements should be communicated to the provider.

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7.4.3 Verification of procured products

Checks for the procured products must be defined.

7.5 Production and service provision/7.5.1 Control of product and service provision

Provision under controlled conditions.

7.5.2 Validation processes

Validation of processes and services

ISO 9001:2015

8.4.2 Control of external provision

Q controls must be defined.

NEW: Outsourced processes remain within the scope of application of the company and must be explicitly monitored.

8.5.1 Control of production and service provision

No significant changes.

NEW: Expert staff now mentioned in addition to other resources.

8.5.1 Control of production and service provision

Shortened.

New: Measures to avoid human error.

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7.5.3 Identification and traceability

Identification of product status.

7.5.4 Property belonging to customers

Identification, protection,

7.5.5 Product preservation

Protection during processing e.g. transportation.
Packaging, labelling, etc.

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ISO 9001:2015

8.5.2 Identification and traceability

No significant changes.

8.5.3 Property belonging to customers or external providers

No significant changes.

Plus: Not only customers' property, but also that of suppliers.

8.5.4 Preservation

No significant changes. New wording: "process results" refers to applicability also to non-material process results

8.5.5 Post-delivery activities

New chapter: Determining activities after delivery, including consideration of risks etc.

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7.6 Control of monitoring and measuring equipment

Specification of necessary equipment, calibration, labelling, etc.

8 Measurement, analysis and improvement/8.1 General

Planning of measurement and improvement

8.2.1 Customer satisfaction

Measurement of customer satisfaction

ISO 9001:2015

8.5.6 Control of changes

New chapter: Change management; changes to production and service provision.

7.1.5 Monitoring and measuring resources

No significant changes.

9 Performance evaluation/9.1 Monitoring, measurement, analysis and evaluation

No significant changes.

9.1.2 Customer satisfaction

No significant changes.

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8.2.2 Internal audits

Audit programme, audit reports, etc.

8.2.3 Measurement of processes

Monitoring processes, corrections, corrective action.

8.2.4 Monitoring and measurement of products

Quality controls. Documentation.

8.3 Control of defective products

Identification, analysis of errors, corrections, action, etc.

ISO 9001:2015

9.2 Internal audit

No significant changes.

4.4 QM system and its processes c)

Performance indicators for processes.

9.1.3 Analysis and evaluation e)

Process performance, check of effectiveness, indication on risk and opportunities.

8.6 Release of products and services

Acceptance criteria must be verified.

8.7 Control of nonconforming process outputs

No significant changes.

Plus: Documented information on individuals who have issued special releases.

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8.3 a) Correction

Correction (immediate action).

8.4 Data analysis

Customer satisfaction, requirement fulfilment, process characteristics, suppliers.

8.5 Improvement/8.5.1 Continual improvement CIP

ISO 9001:2015

8.7 Control of nonconforming processes

Describe nonconformance as documented information, among others by defining the position deciding on actions.

9.1.3 Analysis and evaluation

No significant changes. Plus: Focus not only on evaluation of customer satisfaction but also on improving satisfaction.

10 Improvement/10.1 General

No significant changes. Focus on increasing customer satisfaction by improvement measures.

10.3 Continual improvement CIP

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8.5.2 Corrective action

Analysis of errors and derivation of action.

8.5.3 Preventive action

Analysis of potential errors and risks, preventive action.

ISO 9001:2015

10.2 Nonconformity and corrective action

No significant changes.

Corrections, immediate action, causes of errors, action, measurement of efficacy (including complaints).

New: Updating relevant risks and opportunities.

Deleted.

Note: Featured in chapter on risks and opportunities. These are preventive measures.

Thank you!



No Doubt.

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