ISO 9001:2015 Quality Standard Changes

Chris Anderson
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Structure of the ISO 9001:2015 Standard

Plan

1. Context of organization
   1.1 Understanding context
   1.2 Interested parties
   1.3 Scope

2. Leadership
   2.1 Leadership and commitment
   2.2 Customer focus

3. Planning
   3.1 Actions to address risk and opportunity
   3.2 Objectives and planning
   3.3 Planning of changes

4. Support
   4.1 Resources
   4.2 Competence
   4.3 Awareness
   4.4 Communication
   4.5 Documented information

Do

1. Operation
   1.1 Operational planning and control

Check

2. Performance and evaluation
   2.1 Monitoring, measurement, analysis and evaluation
   2.2 Internal audit
   2.3 Management review

Act

3. Improvement
   3.1 Nonconformity and corrective action
   3.2 Continual improvement
What Changed in ISO 9001:2015?

• Increased focus on the process approach, the foundation of an ISO 9001 Quality Management System (QMS)
• Management’s increased responsibility for:
  • Market and risk analysis
  • Risk-based thinking
  • Risk assessment/mitigation strategies
• Increased focus on Voice-of-the-Customer data collection, incorporating customer needs/expectations into your QMS
• The auditing implications of the new standard
ISO 9001:2015 Process Approach

• Aligning business and quality system measures/goals
• Achieving value for your organization with the decreased emphasis on documentation – what do you really need?
• Risks associated with the reduced emphasis on documentation
• Implementation of knowledge management
• Management accountability
### ANSI/ISO/ASQ Q9001 -2015

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<th><strong>9 Performance evaluation</strong></th>
<th><strong>8 Measurement, analysis and improvement</strong></th>
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<tr>
<td><strong>9.1 Monitoring, measurement, analysis and evaluation</strong></td>
<td><strong>8.1 General</strong></td>
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<tr>
<td><strong>9.1.1 General</strong></td>
<td><strong>8.1 General</strong></td>
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<tr>
<td>The organization <strong>shall</strong> determine:</td>
<td>The organization <strong>shall</strong> plan and implement the monitoring, measurement, analysis and improvement processes needed</td>
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<tr>
<td>a) What needs to be monitored and measured;</td>
<td>a) to demonstrate conformity to product requirements,</td>
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<td>b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;</td>
<td>c) to continually improve the effectiveness of the quality management system.</td>
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<tr>
<td>c) When the monitoring and measuring <strong>shall</strong> be performed;</td>
<td>b) to ensure conformity of the quality management system, and</td>
</tr>
<tr>
<td>d) When the results from monitoring and measurement <strong>shall</strong> be analyzed and evaluated.</td>
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<tr>
<td>The organization <strong>shall</strong> evaluate the performance and the effectiveness of the quality management system.</td>
<td>This <strong>shall</strong> include determination of applicable methods, including statistical techniques, and the extent of their use.</td>
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<tr>
<td>The organization <strong>shall</strong> retain appropriate <strong>documented information</strong> as evidence of the results.</td>
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### 8.2.3 Monitoring and measurement of processes

The organization **shall** apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.

These methods **shall** demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, correction and corrective action **shall** be taken, as appropriate.

The organization **shall** monitor and measure the characteristics of the product to verify that product requirements have been met.

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**Process Measures part of 4.4 and 9.1 above.**

**Emphasis on evaluation of results, measurement and analysis, and monitoring based on risk.**
QMS Processes

Focus on process:

- Process information
- Process control
- Process performance
- Process Improvement

• Identification of customers and other interested parties and their needs/expectations

• Incorporating these needs/expectations into the processes that make up the QMS
Consider the combination of internal and external factors and conditions that can have an effect on an organization’s approach to its products, services and investments and interested parties. { SWOT }

No requirement for a Quality Manual, per se, but some form of “documented information” is required.

Determining interested parties could be done through Voice of the Customer (VOC), Kano Analysis, Force Field Analysis, Quality Function Deployment (QFD), Balanced Scorecard,
Who Is The Customer?

- Team, department, management, shareholder, worker, end-user, supplier, interested party.
- Profile, persona, description.
- Characteristics, Levels, groups.
- Clause 4.1, 4.2
What Does the customer Need?

- Requirements
  - Stated needs
- Expectations
  - Implied needs
- Inputs/outputs
  - Communication needs
- Life-Cycle
  - Post-delivery needs
ISO 9001:2015 Risk Based Thinking

• Identifying the organization’s **risks and opportunities** and how they are related to the new standard

• Implementing risk-based thinking – **designing in quality**

• Using **risk assessment tools** such as Failure Modes Effects Analysis (FMEA)

• Reporting and assessing risks and opportunities as part of **management review**
What is Risk?

ISO 9001:2015 defines risk as

*the effect of uncertainty on an expected result.*

1. An effect is a deviation from the expected – positive or negative.
2. Risk is about what could happen and what the effect of this happening might be.
3. Risk also considers likelihood of occurrence.

The target of a quality management system is to achieve conformity and customer satisfaction.

_In other words..._

_It’s about minimizing surprises, building confidence in your plan, and ensuring you do what you said you were going to do._
Planning For Risk

- **Clause 4** - determine the risks affecting ability to meet objectives
- **Clause 5** - top management ensures clause 4 is followed
- **Clause 6** - take actions to address risks and opportunities
- Clause 8 - have processes which identify and address operation risks
- **Clause 9** - monitor, measure, analyze and evaluate risks and opportunities
- **Clause 10** - improve by responding to changes in risk

Useful documents
- ISO 31000:2009 Risk Management – Principles and guidelines

- **People and Risk**
  - Behaviors
  - Authority
  - Responsibility
  - Competency/training
  - (Customer) Awareness
  - Communication

- **Product and Risk**
  - Customer needs/expectations
  - Complexity
  - Criticality
  - Technology
  - Safety
  - Key Characteristics
  - Supplied products

- **Process and Risk**
  - Planning
  - Schedule
  - Capability
  - Outsourcing
  - Verification
Utilization of Risk Based Thinking as in Advanced Quality Planning (or APQP).

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<tr>
<td><strong>6 Planning</strong></td>
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<tr>
<td><strong>6.1 Actions to address risks and opportunities</strong></td>
<td><strong>8.5.3 Preventive action</strong></td>
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<tr>
<td>6.1.1 When planning for the quality management system, the organization <strong>shall</strong> consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the <strong>risks</strong> and opportunities that need to be addressed to:</td>
<td>The organization <strong>shall</strong> determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.</td>
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<tr>
<td>a) give assurance that the quality management system can achieve its intended result(s);</td>
<td>a) determining potential nonconformities and their causes,</td>
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<td>b) enhance desirable effects;</td>
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<tr>
<td>c) prevent, or reduce, undesired effects;</td>
<td>a) determining potential nonconformities and their causes,</td>
</tr>
<tr>
<td>d) achieve improvement.</td>
<td></td>
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<tr>
<td>6.1.2 The organization <strong>shall</strong> plan:</td>
<td></td>
</tr>
<tr>
<td>a) actions to address these <strong>risks</strong> and opportunities;</td>
<td>c) determining and implementing action needed.</td>
</tr>
<tr>
<td>b) how to:</td>
<td></td>
</tr>
<tr>
<td>1) integrate and implement the actions into its quality management system processes (see 4.4);</td>
<td>b) evaluating the need for action to prevent occurrence of nonconformities,</td>
</tr>
<tr>
<td>2) evaluate the effectiveness of these actions.</td>
<td>e) reviewing the effectiveness of the preventive action taken.</td>
</tr>
<tr>
<td>Actions taken to address <strong>risks</strong> and opportunities <strong>shall</strong> be proportionate to the potential impact on the conformity of products and services.</td>
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<tr>
<td>NOTE 1 Options to address <strong>risk</strong> can include: avoiding risk, taking <strong>risk</strong> in order to pursue an opportunity, eliminating the <strong>risk</strong> source, changing the likelihood or <strong>consequences</strong>, sharing the <strong>risk</strong>, or retaining <strong>risk</strong> by informed decision.</td>
<td>Preventive actions <strong>shall</strong> be appropriate to the effects of the potential problems.</td>
</tr>
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<td>NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization’s or its customers’ needs.</td>
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<tr>
<td>d) <strong>records</strong> of results of action taken (see 4.2.4), and</td>
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Bizmanualz, Inc.
“Risk-based Thinking”

- Analyze and prioritize risks and opportunities in your organization
  - What is acceptable?
  - What is unacceptable?

- Plan actions to address the risks
  - How can I avoid or eliminate the risk?
  - How can I mitigate the risk?

- Implement the plan
  - Measure your actions

- Check the effectiveness of the actions
  - Did it work?

- Learn from experience
  - Continual improvement

**Control Plan**
(Procedures/WI, PM)

SWOT, FMEA, MSA

SPC

Management Review
Dashboards, Audits

CAPA
8.5.5 Post-delivery activities

In determining the extent of post-delivery activities that are required, the organization shall consider:

- a) statutory and regulatory requirements.
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback;
### 9.3 Management review

**9.3.1 General**
Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.

### 5.6 Management review

**5.6.1 General**
Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.

### 9.3.2 Management review inputs

- **a)** the status of actions from previous management reviews;
- **b)** changes in external and internal issues that are relevant to the quality management system;
- **c)** information on the performance and effectiveness of the quality management system, including trends in:
  - c.1) customer satisfaction and feedback from relevant interested parties;
  - c.2) the extent to which quality objectives have been met;
  - c.3) process performance and conformity of products and services;
  - c.4) nonconformities and corrective actions;
  - c.5) monitoring and measurement results;
  - c.6) audit results;
  - c.7) the performance of external providers;
- **d)** The adequacy of resources;
- **e)** the effectiveness of actions taken to address risks and opportunities (see 6.1);
- **f)** opportunities for improvement.

### 5.6.2 Review input

- **a)** results of audits,
- **b)** customer feedback,
- **c)** process performance and product conformity,
- **d)** status of preventive and corrective actions,
- **e)** follow-up actions from previous management reviews,
- **f)** changes that could affect the quality management system, and
- **g)** recommendations for improvement.

### 9.3.3 Management review outputs

- **a)** opportunities for improvement;
- **b)** any need for changes to the quality management system;
- **c)** resource needs.

The outputs of the management review shall include decisions and actions related to:
- **a)** improvement of the effectiveness of the quality management system and its processes,
- **b)** improvement of product related to customer requirements, and
- **c)** resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

Records from management reviews shall be maintained (see 4.2.4).
ISO 9001:2015 Impacts to auditing

• **Auditor preparation** for and conduct of audits to the new standard
• Collecting **audit evidence** that may be harder to find due to the less prescriptive nature of the new standard – which alternative documents and records are acceptable
• Due to the new standard’s increased focus on process management, identifying the requirements and appropriate evidence that are needed to demonstrate compliance, **may be harder** for some auditors
Auditing ISO 9001:2015

Documentation Changes

• Similar to ISO 9001:1994 transition to ISO 9001:2000
  No longer required documented procedures in product realization, maintenance, purchasing, sales, calibration, training, storing, etc.

• ISO 9001 doesn’t throw procedures away
  “The organization shall maintain documented information to the extent necessary to support the operation of processes”

• Higher risk industries should have more documentation
  Just like in Aerospace, Automotive, Medical Device
## Documented Information

1. **4.3 Scope.** (same as old 4.2.2)
2. **4.4 QMS processes, as needed, to support the operation of processes.** (same as old 4.1)
3. **5.2.2 Quality policy** (same as old 5.3)
4. **6.2.1 Quality objectives** (similar to old 5.4.1)

### Data or Records

1. **7.1.5.1 Evidence of fitness for purpose of monitoring and measurement resources.** (similar to old 7.6)
2. **7.1.5.2 Basis for calibration/verification, where measurement traceability is a requirement/standards don’t exist.** (similar to old 7.6)
3. **7.2 Evidence of competence** (similar to old 6.2.2)
4. **8.1 confidence processes carried out as planned and demonstrate conformity of products/services to requirements.** (similar to 7.1d)
5. **8.2.3.2 Results of the review of requirements related to products and services.** (similar to old 7.2.2)
6. **8.3.2 Confirm that design and development requirements have been met.** (similar to old 7.3.1)
7. **8.3.4 Design and development controls** (similar to old 7.3.5/6)
8. **8.3.5 Design and development process outputs.** (similar to old 7.3.3)
9. **8.3.6 Design and development changes.** (same as old 7.3.7)
10. **8.4.1 Results of external provider evaluations, performance, and re-evaluations.** (same as old 7.4.1)
11. **8.5.1 Characteristics of the products and services, Activities to be performed and the results to be achieved** (similar as old 7.5.1)
12. **8.5.2 Unique identification of process outputs, where traceability is a requirement.** (same as old 7.5.3)
13. **8.5.3 Customer property damage notice.** (same as old 7.5.4)
14. **8.5.6 Results of the review of production changes, the personnel authorizing the change, and any necessary actions.** (new)
15. **8.6 person(s) authorizing release of products and services for delivery.** (same as old 8.2.4)
16. **8.7.2 Actions taken on nonconforming process outputs, products and services, including concessions obtained and the person or authority that made the decision dealing with the nonconformity.** (same as old 8.3)
17. **9.1.1 Evidence monitoring/measurement activities are implemented in accordance with determined requirements.** (new)
18. **9.2.1 Evidence of the audit program and audit results.** (similar to old 8.2.2)
19. **9.3.3 Evidence of the results of management reviews.** (same as old 5.6.1)
20. **10.2.2 Nonconformities, subsequent actions taken, and results of corrective action.** (same as old 8.5.2)
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<tr>
<td><strong>7.5 Documented information</strong></td>
<td><strong>4.2 Documentation requirements</strong></td>
</tr>
<tr>
<td><strong>7.5.1 General</strong></td>
<td><strong>4.2.1 General</strong></td>
</tr>
<tr>
<td>The organization’s quality management system <strong>shall</strong> include:</td>
<td>The quality management system documentation <strong>shall</strong> include:</td>
</tr>
<tr>
<td>a) <strong>documented information</strong> required by this International Standard;</td>
<td>c) <strong>documented procedures and records</strong> required by this International Standard, and</td>
</tr>
<tr>
<td>b) <strong>documented information</strong> determined by the organization as being necessary for the effectiveness of the quality management system.</td>
<td>d) documents, including records, determined by the organization as being necessary to ensure the effective planning, operation and control of its processes.</td>
</tr>
<tr>
<td><strong>No required procedures.</strong></td>
<td>a) documented statements of a quality policy and quality objectives,</td>
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<td>b) a quality manual.</td>
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</table>

NOTE the extent of **documented information** for a quality management system can differ from one organization to another due to:

| a) the size of organization and its type of activities, processes, products and services; | a) the size of organization and type of activities, |
| b) the complexity of processes and their interactions; | b) the complexity of processes and their interactions, and |
| c) the competence of persons. | c) the competence of personnel. |

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to:

| a) the size of organization and type of activities, |
| b) the complexity of processes and their interactions, and |
| c) the competence of personnel. |

NOTE 3 The documentation can be in any form or type of medium.

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<tr>
<th><strong>7.5.2 Creating and updating</strong></th>
<th><strong>4.2.3 Control of documents</strong></th>
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<tbody>
<tr>
<td><strong>documented information</strong> the organization <strong>shall</strong> ensure appropriate:</td>
<td>Documents required by the quality management system <strong>shall</strong> be controlled.</td>
</tr>
<tr>
<td>a) identification and description (e.g. a title, date, author, or reference number);</td>
<td>g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</td>
</tr>
<tr>
<td>b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);</td>
<td>b) to review and update as necessary and re-approve documents,</td>
</tr>
<tr>
<td>c) <strong>review and approval</strong> for suitability and adequacy.</td>
<td>Records are a special type of document and <strong>shall</strong> be controlled according to the requirements given in 4.2.4.</td>
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</table>

**A documented procedure shall** be established to define the controls needed

d) to ensure that relevant versions of applicable documents are available at points of use, |
e) to ensure that documents remain legible and readily identifiable,
### 7.5.3 Control of information

#### 7.5.3.1 Documented information

Required by the quality management system and by this International Standard shall be controlled to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organization shall address the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

**Documented information** of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and controlled.

**Documented information** retained as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view documented information only, or the permission and authority to view and change the documented information.

#### 4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

Records shall remain legible, readily identifiable and retrievable.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

4.2.3.c) to ensure that changes and the current revision status of documents are identified,

4.2.3.f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

4.2.3.a) to approve documents for adequacy prior to issue.
Process Approach Focus

• Auditor skills require interviewing techniques—similar to investigators
  i.e. use of checklists aligned with a set of standard clauses will no longer work. Instead, increased use of in-depth discussions and analyses against risk to determine whether customers will receive their expected outputs or services

• Auditor skills require process approach
  i.e. auditor will need to identify process concepts like process maps, value stream maps, PDCA, SIPOC or turtle diagrams.

• Auditor skills require process control—similar to quality engineers
  i.e. review of records, corrective action data, and quality policy is insufficient. Instead, increased use of process data, process control, process change resulting from improvement, and how it all correlates with quality objectives.
Example - Auditing ISO 9001:2015

Objective Evidence

• 1st pass yields and on-time delivery is tracked daily and discussed during daily production meetings with cross functional teams.

• This information is summarized and reported monthly by the quality manager to the general manager.

• The general manager goes over this information on a quarterly basis with all employees during state of the company meetings.

Question: What is wrong with this description?

• This description gives the evidence of compliance that was assessed. It does not address the effectiveness of the process.

Process Implemented?
Planned Results Achieved?
Appropriate Actions Taken?
Auditing ISO 9001:2015

Risk-Based Thinking

• Auditor skills require risk-based approaches
  
  i.e. auditor will need to identify risk concepts, tools, or methods for risk analysis and management. Although ISO 31000 or FMEA are not required, familiarity with risk-based approaches of some type will help.

• Auditor skills require customer and market risk
  
  i.e. auditor will need to identify interested parties (e.g. customers, shareholders, board members, competitors, regulators), what their relevant interests might be, and the risks as it relates to the organizational context.
Top Management must ensure that the management system requirements are integrated into the organization’s processes, that the policy and objectives are compatible with the strategic direction of the organization, and they have a grasp of the organization’s internal strengths and weaknesses and how these could impact on the ability to deliver their products or services.

Business process management, including the need now to allocate specific responsibilities for processes and demonstrate an understanding of the key risks associated with each process, is now squarely on Top Management.
Greater emphasis on documented Quality Objectives, ongoing performance, and responsibilities.
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<tr>
<td><strong>7.2 Competence</strong></td>
<td><strong>6.2.2 Competence, training and awareness</strong></td>
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<tr>
<td>The organization <strong>shall</strong> determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;</td>
<td>The organization <strong>shall</strong> determine the necessary competence for personnel performing work affecting conformity to product requirements.</td>
</tr>
<tr>
<td>b) ensure that these persons are competent on the basis of appropriate education, training, or experience;</td>
<td>b) where applicable, provide training or take other actions to achieve the necessary competence,</td>
</tr>
<tr>
<td>c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;</td>
<td>c) evaluate the effectiveness of the actions taken,</td>
</tr>
<tr>
<td>d) retain appropriate <strong>documented information</strong> as evidence of competence.</td>
<td>e) maintain appropriate <strong>records</strong> of education, training, skills and experience (see 4.2.4).</td>
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**NOTE**: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

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<th><strong>7.3 Awareness</strong></th>
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<tr>
<td>The organization <strong>shall</strong> ensure that persons doing work under the organization’s control are aware of:</td>
<td>d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and</td>
</tr>
<tr>
<td>a) the quality policy;</td>
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<tr>
<td>b) relevant quality objectives;</td>
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<tr>
<td>c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;</td>
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<tr>
<td>d) the implications of not conforming with the quality management system requirements.</td>
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<th><strong>7.4 Communication</strong></th>
<th><strong>5.5.3 Internal communication</strong></th>
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<tr>
<td>The organization <strong>shall</strong> determine the internal and external communications relevant to the quality management system including:</td>
<td>Top management <strong>shall</strong> ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.</td>
</tr>
<tr>
<td>a) on what it will communicate;</td>
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<td>b) when to communicate;</td>
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<td>c) with whom to communicate;</td>
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<td>d) how to communicate;</td>
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<tr>
<td>e) Who communicates.</td>
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Extended to include people under the organization’s control (agencies, contractors).

More prescriptive and includes external communications. Organizations must now determine what, when, with whom and how communications should take place.

More expansive and now applies to all persons doing work under the organization’s control. All people must be aware of policy, objectives, how they contribute and the implications of not conforming to the QMS.

Quality Plans, First Article Inspections (FAI), Part Submission Warrants (PSW), Production Part Approval Process (PPAP).

Extended to include implementation and control.
Transition Guidance

What do you need to do?

1. Take a fresh look at your QMS
   • ISO 9001:2008 certifications will not be valid after September 2018.
   • From March 2017 all initial certifications shall be to ISO 9001:2015

2. Highlight key changes as opportunities for improvement

3. Engage your certification body for transition arrangements

4. Review effectiveness of process/product controls (assume controls may have changed)

5. Implement new requirements on leadership, risk and context of organization

6. Make changes to your documented information to reflect new structure (as needed)