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LRQA

Improving performance,
reducing risk

ISO 9001:2015 Overview and Comparison

Introduction

The purpose of this handout is to share LRQA insight into the newly revised international Quality Management System (QMS) Standard ISO 9001:2015, which was published on September 15, 2015.

Organizations certified to ISO 9001:2008 will have three years following publication of ISO 9001:2015 to transition to the revised standard. As a result, LRQA recognizes that there will be ongoing demand for knowledge of ISO 9001:2008 at least until September 2018.

ISO 9001:2015 Overview

Background

All Management System Standards (MSSs) are subject to regular review. The last significant revision to ISO 9001 was in 2000. ISO 9001:2008 clarified points and enhanced compatibility with ISO 14001 (EMS). More recently, ISO 9001 has been subject to a comprehensive rewrite to ensure that its aims and purpose appropriately support the changing needs of today's world and reflect the increasingly complex environments in which organizations operate.

Many organizations use and are certificated to multiple management system standards. This had led to organizations seeking to combine or integrate their management systems in an effective and efficient manner. The reality is that the continued proliferation of ISO MSSs has resulted in many apparently common requirements that are subtly or substantially different. This has caused confusion and inconsistent understanding and implementation.

In order to deliver consistent and compatible management system standards in the future, the ISO Technical Management Board has produced a common framework for all MSSs. This common framework is referred to as "Annex SL[1]".

[1] Specifically: Annex SL of ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2013

Essentially, Annex SL defines how all future new and revised MSS will be structured. The first standard to adopt this structure was the Business Continuity Management standard (ISO 22301). Similarly, the new version of ISO 9001 has been prepared using the "High-Level Structure" (i.e. clause sequence, common text and terminology provided in Annex SL).

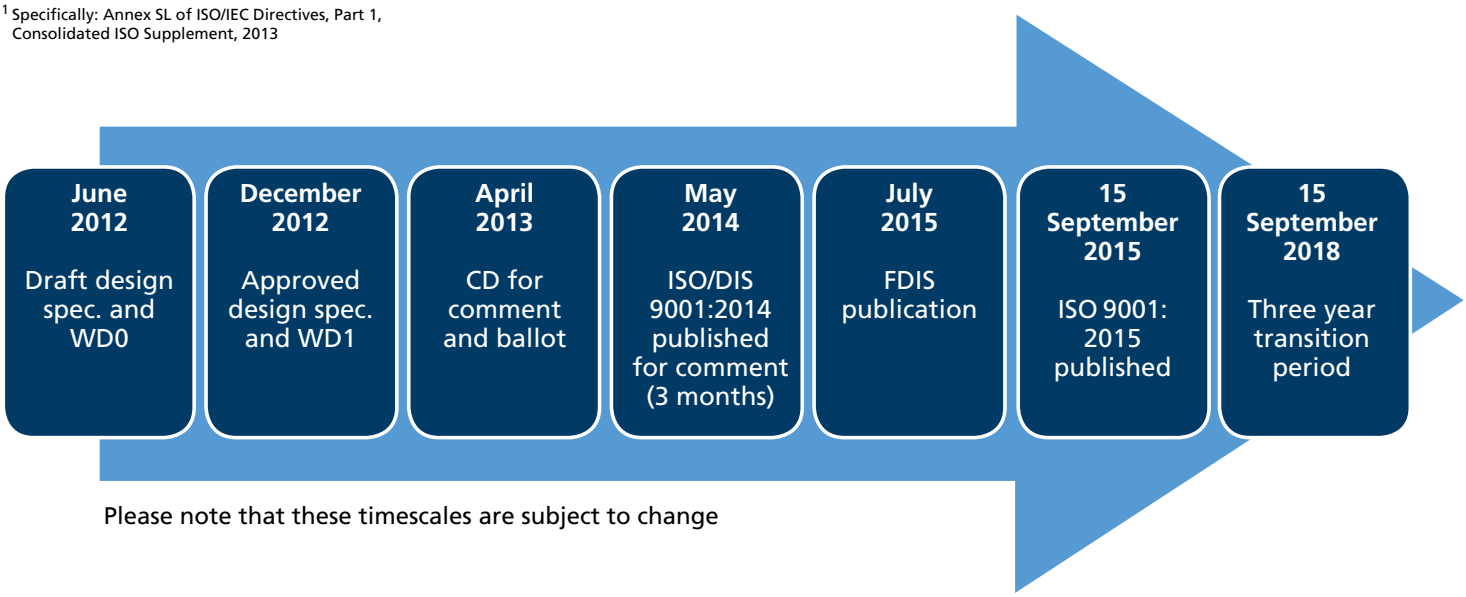
The development and approval of ISO MSSs follows an established process and sequence; Committee Draft (CD), Draft International Standard (DIS), Final Draft (FDIS) followed by publication of the Standard.

The significance of changes usually diminishes as development progresses. Once the FDIS is released the nature of any further change is normally minor.

In May 2014, the new version of ISO 9001 had reached the DIS stage.

ISO/DIS 9001:2014 was approved by the technical committee and released for public review and comment. The FDIS version was published in July 2015. The FDIS version was then adopted as the final published standard ISO 9001:2015 on September 15, 2015.

There will be a three year transition period for existing ISO 9001:2008 accredited certifications, giving a deadline of September 2018 for organizations to migrate their QMS to ISO 9001:2015 for their certification to remain valid.



Please note that these timescales are subject to change

The changes and what they mean

When comparing the current standard to ISO 9001:2008, the changes seem extensive. We know ISO 9001:2008 to ISO 9001:2015 adopts the High Level Structure of Annex SL, and that the main areas of change are:

- **Context of the organization**
- **Leadership**
- **Process approach**
- **Risk-based thinking**

Over the following pages, LRQA looks at the main differences and how they may require change within a QMS.

ISO 9001:2015 Overview

Structure of the standard in line with Annex SL

The first significant change in ISO 9001:2015 is that there are now ten sections instead of the existing eight in ISO 9001:2008.

If your QMS manual is written around and references the clauses of the current ISO 9001 then, if you decide to keep your quality manual, the numbers will need to be updated to match the new clause numbering. However, the structure and terminology of Annex SL and ISO 9001:2015 do not need to be reflected in the documentation of an organization's QMS.

So it is no surprise that the PDCA cycle is also very much evident in the way that the revised ISO 9001 standard is structured. Figure 1 of ISO 9001:2008 – Model of a process-based quality management system in the current standard is retained in an updated form showing the links to clauses of ISO 9001:2015.

Some of the above ten headings are familiar (Scope, Normative References, Terms and Definitions and Planning) but some are new (in particular, Context of the organization and Leadership). Furthermore, when some of the ten headings are expanded out for ISO 9001:2015, some of the familiar terms for the current ISO 9001 re-appear, all be it at times with some minor changes of wording, for example Internal Audit, Management Review and Design.

The following describes the High Level Structure of Annex SL in more detail:

0. Introduction
1. **Scope**
2. **Normative references**
3. **Terms and definitions**
4. **Context of the organization**
5. **Leadership**
6. **Planning**
7. **Support**
8. **Operation**
9. **Performance evaluation**
10. **Improvement**

Annex SL states the following:

> " An effective management system is usually based on managing the organization's processes using a Plan-Do-Check-Act approach in order to achieve the intended outcomes."

So, for these topics, the existing processes within your current QMS may well already address the new requirements since they have largely only been re-arranged to fit in with the Annex SL structure. Other familiar terms of the current ISO 9001 also reappear with subtle changes and/or enhancements; for example outsourcing and purchasing in the current standard reappear under control of externally provided products and services.

At the back of this handout we have included a useful correlation matrix between the clauses of ISO 9001:2008 and ISO/FDIS 9001:2015.

ISO 9001:2015 Overview

Context of the organization

Section 4 dedicates itself to the "organizational context".

This section is divided into four sub clauses:

4.1. Understanding the organization and its context.

4.2. Understanding the needs and expectations of interested parties.

4.3. Determining the scope of the quality management system.

4.4. Quality management system and its processes.

The latter two of these find counterparts in the General section 4.1 of ISO 9001:2008 but the former two are new requirements and they require an organization to think about the issues that can affect it as well as the parties that have an interest in it including how to garner these parties' relevant requirements.

Understanding the organization and its context

ISO 9001:2015 uses the term "context of the organization". This expands the concept of the organizational environment referenced in ISO 9001:2008 to include not only the business environment, but also internal factors, such as organizational culture, and external factors, such as socio-economic conditions under which it operates.

ISO 9001:2015 requires organizations to identify, monitor and review internal and external issues that are relevant to its purpose and strategic direction, and that have the ability to impact the QMS's intended results.

Understanding the needs and expectations of interested parties

ISO 9001:2015 requires organizations to go through a process initially to identify these groups and then to identify their needs and expectations that are relevant to the organization's quality management system.

Relevant interested parties are groups or individuals who have the ability to impact (or potentially impact or be impacted by) the organization's ability to supply consistently products and services that meet customer and applicable statutory and regulatory requirements. Customers, shareholders, board members and competitors would all fit into this classification.

ISO 9001:2015 Overview

Leadership

Section 5 dedicates itself to "Leadership".

This section is divided into three sub clauses:

5.1. Leadership and commitment.

5.2. Policy.

5.3. Organizational roles, responsibilities and authorities.

ISO 9001:2015 replaces "Management responsibility" with "Leadership", and repositions a number of ISO 9001:2008 requirements as leadership activities. This clause calls for the organization's top management to demonstrate their involvement and engagement with the quality management system though direct participation in, for example:

- Taking accountability for the effectiveness of the quality management system.
- Promoting the use of the process approach.
- Promoting improvement.

- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Thus, the top management assume an active role in the QMS by taking accountability for its success themselves (and not leaving it to the Management Representative – which, by the way, is no longer explicitly called for in the new version). The leaders must also integrate the QMS into the organization's processes; so the process approach is more to the fore in the new standard.

Process approach

Where ISO 9001:2008 promotes the adoption of a process approach ISO 9001:2015 requires the organization to establish a process-based quality management system.

ISO 9001:2015 Clause 4.4 states explicit requirements that need to be met in the design, operation and maintenance of a process-based management system. For example, determination of inputs required and outputs expected, resources needed, and assignment of responsibilities and authorities.

Much of what is given in clause 4.4 of ISO 9001:2015 can be found in ISO 9001:2008. However what was previously promoted is now a requirement, with requirements around processes appearing throughout ISO 9001:2015. For example, ISO 9001:2015 also states that organizations need to determine performance indicators that allow for the effective operation and control of processes, identify risks and opportunities for processes, and plan to address these.

Risk-based thinking

The concept of risk-based thinking is described in the Introduction of ISO 9001:2015.

Risk is about what could happen and what the effect of this happening might be. Risk also considers how likely it is to happen.

Risk is commonly understood to be negative. In risk-based thinking, when dealing with uncertainty, opportunity can also be found. The opportunity could be related to reducing the likelihood of something going wrong or improving conformity and customer satisfaction.

One of the key changes in ISO 9001:2015 is to establish a systematic approach to risk, rather than treating it as a single component of a QMS; as is the case with ISO 9001:2008 where preventive action is a standalone clause.

Now risk is considered and included throughout the standard and the term preventive action has disappeared.

ISO 9001:2015 requires the use of risk-based thinking to achieve conformity in the products and services provided by an organization, and thereby improve customer satisfaction, in the following way:

- Clause 4 (Context) the organization is required to determine the risks which may affect this (i.e. conformity in the products and services provided by an organization).
- Clause 5 (Leadership) top management is required to commit to ensuring the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed.
- Clause 6 (Planning) the organization is required to determine the risks and opportunities that need to be addressed and plan actions to address them.
- Clause 8 (Operation) the organization is required to implement processes to address risks and opportunities.
- Clause 9 (Performance evaluation) the organization is required to monitor, measure, analyze and evaluate the risks and opportunities.
- Clause 10 (Improvement) the organization is required to improve by responding to changes in risk.

Other changes

Most of the requirements of ISO 9001:2008 are carried forward to ISO 9001:2015. To improve consistency of interpretation and understanding, and aid translation, many requirements remain unchanged. Also the restructuring of the standard often means existing requirements have new clause numbers.

- The term 'product' is replaced by 'products and services'.
- 'Quality objectives' is expanded to 'Quality objectives and planning to achieve them' with more emphasis on planning how objectives will be achieved and making these planning requirements explicit rather than implicit.
- The phrase 'externally provided processes, products and services' replaces 'Purchasing'.
- References to a documented quality manual, documented procedures and to quality records are removed. Instead, throughout ISO/FDIS 9001:2015 there are specific references to "Documented Information".

This is information that the organization is required to keep, control and maintain.

- There is no longer a requirement to appoint a 'Management representative'.

There are other changes where aspects of a management system are more clearly described because the Annex SL format has a clause to address it.

Such as:

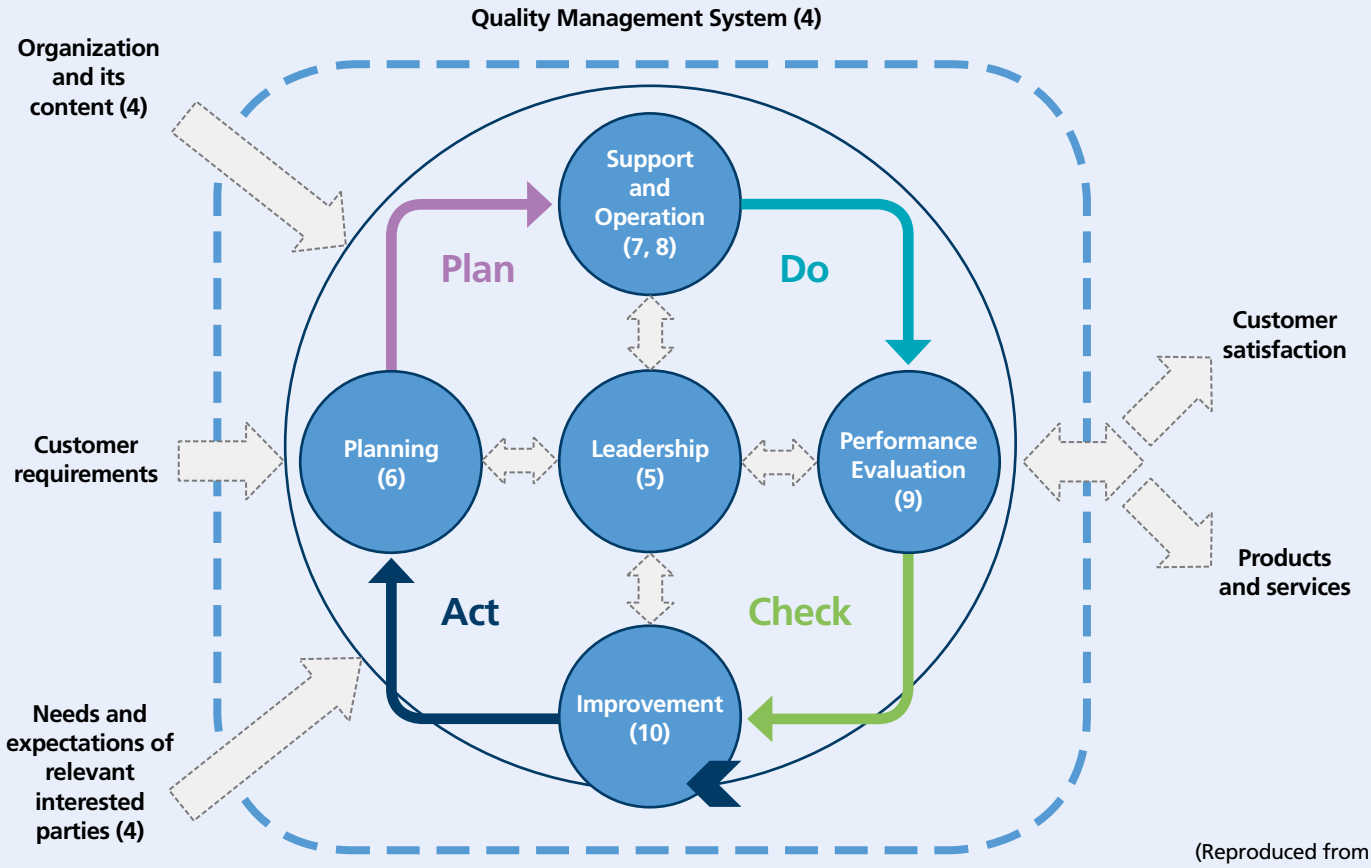
- Competence
- Awareness
- Scope
- Communication

This ensures that there is commonality with other management system standards and so you will be able to see the same headings in ISO 14001:2015 and ISO 45001 (the replacement for OHSAS 18001 when it is published) and group what you do for them together in your management system.

Lastly, there is clause 10 about Improvement. ISO 9001:2015 recognizes that incremental (continuous) improvement is not the only improvement profile. Improvement can also arise as a result of periodic breakthroughs, reactive change or as a result of reorganization.

Changes to the model of a process–based quality management system

The new version of the standard brings with it an updated version of the model, including the relevant clause numbers.



(Reproduced from ISO 9001:2015)

ISO 9001:2015 Overview

Conclusion

The most significant changes that ISO 9001:2015 will introduce come from adopting Annex SL.

Organizations will need to review fully their current QMS to ensure all the new and enhanced requirements of ISO 9001:2015 are met. For any organization the degree of change necessary will be dependent upon the maturity and effectiveness of the current management system, organizational structure and practices.

It will be September 2018 before certified organizations must complete transition to the new standard, however accredited certification bodies are advising that their clients start to make appropriate preparations as soon as practical and not delay until the last moment.

ISO 9001:2015 will build upon the current standard; it will not take quality management in a new and completely different direction. The course you are attending now will give you essential knowledge and skills and help lay the foundation for your further development and transition to ISO 9001:2015.

In preparation for the changes, LRQA can perform a Gap Analysis on your current system to determine how much work you need to do to bring it into line with the new standard.

We will also be offering a number of highly useful training courses to bring you, your management and your auditors up to speed on the new standard in readiness for a smooth transition to being certified to ISO 9001:2015.

We are offering:

- **ISO 9001:2015 – What's it all about?**
  A one day appreciation course.
- **Preparing for ISO 9001:2015**
  A two day implementation course for management system managers.

We will also offer transition courses which will bring your auditors up to speed with the new requirements and the types of evidence that you will be looking for to verify conformance.

These will be:

- **ISO 9001:2015 for internal auditors**
  A one day course for internal auditors.
- **ISO 9001:2015 Lead Auditor transition training**
  A two day course for those who have successfully completed QMS Auditor/Lead Auditor training based on ISO 9001:2008 or ISO 9001:2000, and want to upgrade to the new standard; including those auditors seeking re-registration with IRCA or another auditor certification body.

In the meantime we will continue to keep clients and delegates informed and ensure our courses remain current and relevant.

ISO 9001:2008 to ISO 9001:2015 Comparison Matrix

ISO 9001:2008	ISO 9001:2015
4 Quality management system	4.4 Quality management system and its processes
4.1 General requirements	4.4 Quality management system and its processes
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality manual	No longer a requirement
4.2.3 Control of documents	7.5.2 Creating and updating 7.5.3 Control of documented Information
4.2.4 Control of records	7.5.2 Creating and updating 7.5.3 Control of documented Information
5 Management responsibility	5 Leadership
5.1 Management commitment	5.1 Leadership and commitment 5.1.1 General
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Policy
5.4 Planning	6 Planning
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality management system planning	6 Planning 6.1 Actions to address risks and opportunities 6.3 Planning of changes
5.5 Responsibility, authority and communication	5 Leadership
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management representative	No longer a requirement
5.5.3 Internal communication	7.4 Communication
5.6 Management review	9.3 Management review
5.6.1 General	9.3.1 Management review
5.6.2 Review input	9.3.2 Management review inputs
5.6.3 Review output	9.3.3 Management review outputs
6 Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General
6.2 Human resources	Title removed 7.1.2 People 7.2 Competence
6.2.1 General	7.2 Competence
6.2.2 Competence, training and awareness	7.2 Competence 7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment	7.1.4 Environment for the operation of processes
7 Product realization	8 Operation
7.1 Planning of product realization	8.1 Operational planning and control
7.2 Customer-related processes	8.2 Requirements for products and services
7.2.1 Determination of requirements related to the product	8.2.2 Determining the requirements related to the products and services
7.2.2 Review of requirements related to the product	8.2.3 Review of requirements related to the products and services
7.2.3 Customer communication	7.4 Communication 8.2.1 Customer communication

ISO 9001:2008 to ISO 9001:2015 Comparison Matrix

ISO 9001:2008	ISO 9001:2015
7.3 Design and development	8.3 Design and development of products and services
7.3.1 Design and development planning	8.3 Design and development of products and services 8.3.1 General 8.3.2 Design and development planning
7.3.2 Design and development inputs	8.3.3 Design and development Inputs
7.3.3 Design and development outputs	8.3.5 Design and development outputs
7.3.4 Design and development review	8.3.4 Design and development controls
7.3.5 Design and development verification	8.3.4 Design and development controls
7.3.6 Design and development validation	8.3.4 Design and development controls
7.3.7 Control of design and development changes	8.3.6 Design and development changes
7.4 Purchasing	8.4 Control of externally provided processes, products and services
7.4.1 Purchasing process	8.4.1 General 8.4.2 Type and extent of control
7.4.2 Purchasing information	8.4.3 Information for external providers
7.4.3 Verification of purchased product	8.6 Release of products and services
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision 8.5.5 Post-delivery activities
7.5.2 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.3 Identification and traceability	8.5.2 Identification and traceability
7.5.4 Customer property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources
8.0 Measurement, analysis and improvement	9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Customer satisfaction	9.1.2 Customer satisfaction
8.2.2 Internal audit	9.2 Internal audit
8.2.3 Monitoring and measurement of processes	9.1.1 General
8.2.4 Monitoring and measurement of product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming outputs
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10 Improvement
8.5.1 Continual improvement	10.1 General 10.3 Continual Improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	Clause removed

ISO 9001:2015 to ISO 9001:2008 Comparison Matrix

ISO 9001:2015		ISO 9001:2008	
4	Context of the organization	1.0	Scope
4.1	Understanding the organization and its context	1.1	General
4.2	Understanding the needs and expectations of interested parties	1.1	General
4.3	Determining the scope of the quality management system	1.2 4.2.2a	Application Quality manual
4.4	Quality management system and its processes	4.1 4.2.2c	General requirements Quality manual
5	Leadership	5	Management responsibility
5.1	Leadership and commitment	5.1	Management commitment
5.1.1	General	5.1	Management commitment
5.1.2	Customer focus	5.2	Customer focus
5.2	Policy	5.3	Quality policy
5.3	Organizational roles, responsibilities and authorities	5.5.1 5.5.2	Responsibility and authority Management representative
6	Planning	5.4.2	Quality management system planning
6.1	Actions to address risks and opportunities	5.4.2 8.5.3	Quality management system planning Preventive action
6.2	Quality objectives and planning to achieve them	5.4.1	Quality objectives
6.3	Planning of changes	5.4.2	Quality management system planning
7	Support	6	Resource management
7.1	Resources	6	Resource management
7.1.1	General	6.1	Provision of resources
7.1.2	People	6.1	Provision of resources
7.1.3	Infrastructure	6.3	Infrastructure
7.1.4	Environment for the operation of processes	6.4	Work environment
7.1.5	Monitoring and measuring resources	7.6	Control of monitoring and measuring equipment
7.1.6	Organizational knowledge	New requirement	
7.2	Competence	6.2.1 6.2.2	General Competence, training and awareness
7.3	Awareness	6.2.2	Competence, training and awareness
7.4	Communication	5.5.3 7.2.3	Internal communication Customer communication
7.5	Documented information	4.2	Documentation requirements
7.5.1	General	4.2.1	General
7.5.2	Creating and updating	4.2.3 4.2.4	Control of documents Control of records
7.5.3	Control of documented Information	4.2.3 4.2.4	Control of documents Control of records
8	Operation	7	Product realization
8.1	Operational planning and control	7.1	Planning of product realization
8.2	Requirements for products and services	7.2	Customer-related processes
8.2.1	Customer communication	7.2.3	Customer communication
8.2.2	Determining requirements related to products and services	7.2.1	Determination of requirements related to the product

ISO 9001:2015 to ISO 9001:2008 Comparison Matrix

ISO 9001:2015	ISO 9001:2008
8.2.3 Review of requirements related to the products and services	7.2.2 Review of requirements related to the product
8.2.4 Changes to requirements for products and services	7.2.2 Review of requirements related to the product
8.3 Design and development of products and services	7.3 Design and development
8.3.1 General	7.3 Design and development
8.3.2 Design and development planning	7.3.1 Design and development planning
8.3.3 Design and development inputs	7.3.2 Design and development inputs
8.3.4 Design and development controls	7.3.4 Design and development review 7.3.5 Design and development verification 7.3.6 Design and development validation
8.3.5 Design and development outputs	7.3.3 Design and development outputs
8.3.6 Design and development changes	7.3.7 Control of design and development changes
8.4 Control of externally provided processes, products and services	7.4.1 Purchasing process
8.4.1 General	7.4.1 Purchasing process
8.4.2 Type and extent of control	7.4.1 Purchasing process 7.4.3 Verification of purchased product
8.4.3 Information for external providers	7.4.2 Purchasing information
8.5 Production and service provision	7.5 Production and service provision
8.5.1 Control of production and service provision	7.5.1 Control of production and service provision 7.5.2 Validation of processes for production and service provision
8.5.2 Identification and traceability	7.5.3 Identification and traceability
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property
8.5.4 Preservation	7.5.5 Preservation of product
8.5.5 Post-delivery activities	7.5.1 Control of production and service provision
8.5.6 Control of changes	7.3.7 Control of design and development changes
8.6 Release of products and services	8.2.4 Monitoring and measurement of processes 7.4.3 Verification of purchased product
8.7 Control of nonconforming outputs	8.3 Control of nonconforming product
9 Performance evaluation	New requirement
9.1 Monitoring, measurement, analysis and evaluation	8 Measurement, analysis and improvement
9.1.1 General	8.1 General
9.1.2 Customer satisfaction	8.2.1 Customer satisfaction
9.1.3 Analysis and evaluation	8.4 Analysis of data
9.2 Internal audit	8.2.2 Internal audit
9.3 Management review	5.6 Management review
10 Improvement	8.5 Improvement
10.1 General	8.5.1 Continual improvement
10.2 Nonconformity and corrective action	8.3 Control of nonconforming product 8.5.2 Corrective action
10.3 Continual Improvement	8.5.1 Continual improvement

Lloyd's Register Quality Assurance, Inc.
1330 Enclave Parkway, Suite 200
Houston, TX 77077 USA

E info-usa@lrqa.com
T +1 866 971 5772

www.lrqausa.com