ISO 9001:2015
Transition Guide

An LRQA perspective

Introduction

The publication of the Draft International Standard (DIS) of the International Quality Management System (QMS) Standard (ISO/DIS 9001:2014) signified the first time all current and future users can access and review the proposed changes to ISO 9001.

As a result, organizations are able to start planning for their transition to the new standard when it is published (currently forecast by ISO to be September 2015).

The draft standard contains both new elements and existing elements that are changing and this document sets out to provide interested parties with insight into the potential impact of the changes on organizations.

What's new?

The International Organization for Standardization (ISO) normally reviews standards every five years to ensure that they are relevant to changing market demands. The publication of ISO/FDIS 9001:2015 will mark the next to final stage in revisions process towards publication of ISO 9001:2015.

What's new?

The proposed new elements can be separated into two types:
1) those inserted as part of the wider Annex SL introduction to all ISO Management System Standards (MSS) and
2) those specifically introduced as part of the revision process for ISO 9001.

Common terminology and structure

Annex SL (the new high level structure and common text for all new and revised ISO standards) is the single biggest change to the proposed new draft standard document. At first glance, Annex SL appears to make the standard writers lives 'much easier' but in reality, as organizations begin to understand and appreciate the value of different management systems all speaking a common language, it will be organizations - and in turn the consumer - who stand to be the true beneficiaries.

This structure will drive MSS integration, thereby delivering increased organizational benefits and efficiencies while providing a more complete view of an organization – often spanning multiple sites, geographies and involving multiple suppliers.

New terms and definitions

The proposed new version contains many definitions; they have been included to help the reader understand all the terms used. An understanding of the definitions is vital in order to fully grasp the new standards requirements. A decision will be made later as to which definitions remain in ISO 9001 and which are included in ISO 9000, which gives the fundamental concepts and vocabulary for quality MSS.

One term that is used extensively throughout is '*determine*'. Determination is defined in ISO 9001:2015 as: "Activity to find out one or more characteristics and their characteristic values".

Within the management systems environment, organizations will have to consider how they can provide evidence that a process of determination has taken place and that an output from that process exists.

Annex A has been introduced and is informative in nature. This Annex provides clarification for the new Structure, Terminology and Concepts contained within the proposed new standard.

While the structure and terminology has changed, there is **no requirement** for an organization to use these terms or to follow the numbering or structure within their management system.

Context

Context of the organization is new and requires an organization to determine the internal and external issues and requirements that can impact on the planning of the quality system. *Context* becomes an important consideration and helps to ensure that the management system is designed and suitably adapted for a specific organization.

Risk based approach

The incorporation of Annex SL into ISO 9001:2015 drives a risk based approach to thinking and acting. The requirements under a risk based approach affect quality planning and incorporate much of what was previously titled *preventive action*. Now an organization will need to determine the risks and opportunities that need to be addressed to give assurance that the QMS can achieve its intended results.

This greater focus on risk will mean that an organization will need to demonstrate how this requirement is met. The extent and formality of the approach needed in a particular organization will – of course – be influenced by its context.

Scope and applicability

The manner in which inclusion and exclusion of requirements for the proposed new draft standard is addressed is different from previous versions. Now organizations will have to determine the scope of the management system and maintain this as documented information. The scope will need to be determined from the boundaries of the organization, its context, its interested parties and its products and services.

Where requirements can be applied, it is expected that they will be unless there is a clear reason that they are not applicable.

Documented information

The terms '*documented procedure*' and 'record' have been replaced with '*documented information*'.

The nature and type of documented information that an organization needs to maintain or retain is dependent on the context and its operating environment. The way documented information is defined in ISO 9001:2015 provides more scope for an organization to determine what is appropriate for its unique set of circumstances, rather than just following a prescriptive format.

Organizational knowledge

An organization will now need to consider what knowledge it needs to achieve conformity of products and services along with how it will develop, maintain and retain such knowledge. While this is a new requirement, many organizations will already have a system to manage the information and knowledge required to perform successfully, which can be incorporated into their QMS.

Control of externally provided products and services

Purchasing has become '*control of externally provided products and services*' to make it clear that the requirements apply to both physical products and consumed services related to the end product of the organization. While not specifically a new requirement, there has always been some confusion around whether certain categories of externally provided products and services should be included within the scope of the QMS. Now it is clear that however provided, an organization will need to apply a risk based approach and determine the type and extent of controls necessary.

What's changing?

In addition to several new focus areas, ISO 9001:2015 introduces a number of changes to existing requirements.

These changes often clarify the intent of a particular clause or make implicit requirements more explicit. These may not require an organization to change its management system in any way. However, it would be worthwhile for an organization to review whether the new wording of the standard aligns with their current organizational practices.

Leadership

The requirements relating to the relationship between the role *top management* plays in creating and supporting an effective QMS have been enhanced. There are now more areas where *top management* needs to demonstrate their involvement and engagement with the QMS, such as:

- Ensuring integration of QMS requirements into the organizations' business processes
- Promoting awareness of the process approach
- Assuring the QMS achieves its intended results
- Supporting other relevant management roles to demonstrate their leadership

Planning of changes

Another requirement that has been expanded and clarified is that of *planning of changes*. Where the need for change is identified there is now a much clearer requirement for such changes to be carried out in a planned and systematic manner. Again, an organization will need to review its own approach to managing changes to see if any revision of its QMS is necessary.

Analysis and evaluation

The proposed new draft standard text has expanded and enhanced the previous requirements to clarify what is expected. The performance, monitoring and review definitions are all relevant here. Analysis and evaluation of appropriate data covering conformity of products and services, customer satisfaction, conformity to the management system, process performance, external provider performance and so on, are all areas where an organization will need to review its current approach and determine if any change is necessary. The output of the Analysis and Evaluation is now a defined input into the Management Review process.

Management review

Because of the incorporation of Annex SL and the revision to other areas within the proposed new draft standard, the scope of information to be considered at *management review* may also need to be extended. There is now an explicit requirement for management review to consider:

- how changes in its context affect the QMS and its strategic direction and
- the effectiveness of actions taken to address risks and opportunities.

Management representative

ISO 9001:2015 no longer requires a specific role of a management representative but defines roles where *top management* needs to assign appropriate responsibility and authority. If this can be achieved through assignment to one person, then it may be that no change is necessary. If, however, the range of roles is broader than that of one person, then an organization will need to show how they have been assigned to appropriate personnel.

Quality manual

The requirement for a specific document called a quality manual has been replaced with a clause titled Quality Management System and its Processes. Organizations are now required to determine the processes needed for the QMS – their inputs, outputs, sequence and interaction – then maintain documented information to the extent necessary to support the understanding and operation of those processes.

How can LRQA help?

LRQA, through our extensive range of public and on-site training courses, our client specific gap analysis tools and our informative and educational online services, offers organizations a tailored path to successful transition to ISO 9001:2015.

The degree of change necessary will depend on how an organization has developed and uses its existing management system. Consideration needs to be given to a] whether its ISO 9001:2008 is limited to strictly meeting the requirements as specified in the standard or b] whether it has systems and processes in place that, while not specifically required in ISO 9001:2008, are viewed as management best practice.

Our ISO 9001 new standard transition services have been designed so that they are about your organization and your management system. We are committed to providing robust insight into your systems that help you make an effective and efficient transition to ISO 9001:2015.

Gap analysis
Our range of gap analysis services assess your existing QMS against the requirements of the proposed new standard in order to help you develop your transition plan.

To help you prepare, we offer three Gap Analysis options against ISO 9001:2015:

Level 1
Analyzes your existing management system in relation to the significant **new requirements** in the proposed new standard only.

Level 2
Analyzes your existing management system in relation to the significant **new requirements** as well the **major changes** in the proposed new standard.

Level 3
Analyzes your existing management system against the new proposed standard **as a whole**, assessing your system's performance against it.

In line with accreditation requirements, please note that any new standard transition services (including gap analysis and training) are in addition to the existing contracted assessment duration visit.

Training
LRQA's range of customized and packaged training services offers organizations the best start to transitioning to the new ISO 9001 standard. Gain real-world standards transition experience from LRQA trainers who are practicing third-party IRCA and/or RAB certified auditors. Our range of training services include:

ISO 9001:2015 Workshop
This course is for management systems managers or management representatives responsible for managing the transition.

Preparing for ISO 9001:2015
This course is for management systems managers or management representatives responsible for managing the transition.

ISO 9001:2015 for Internal Auditors
This course provides knowledge on transitioning to the new and amended requirements and how the revisions affect your existing quality management system.

ISO 9001:2015 Lead Auditor Transition
Gain the technical assessment skills that will enable you to handle a variety of situations, including revisions to the standard and how they may be audited.

On-site Workshop
A course tailored specifically for your employees and your management system in relation to ISO 9001:2015.

All of LRQA's public training courses can be delivered on-site. We also offer topic specific courses to help organizations address the most relevant changes to ISO 9001.

LRQA's trainers are experts in risk based thinking and change management, among a range of other elements that are new or feature as significant changes in ISO 9001:2015.
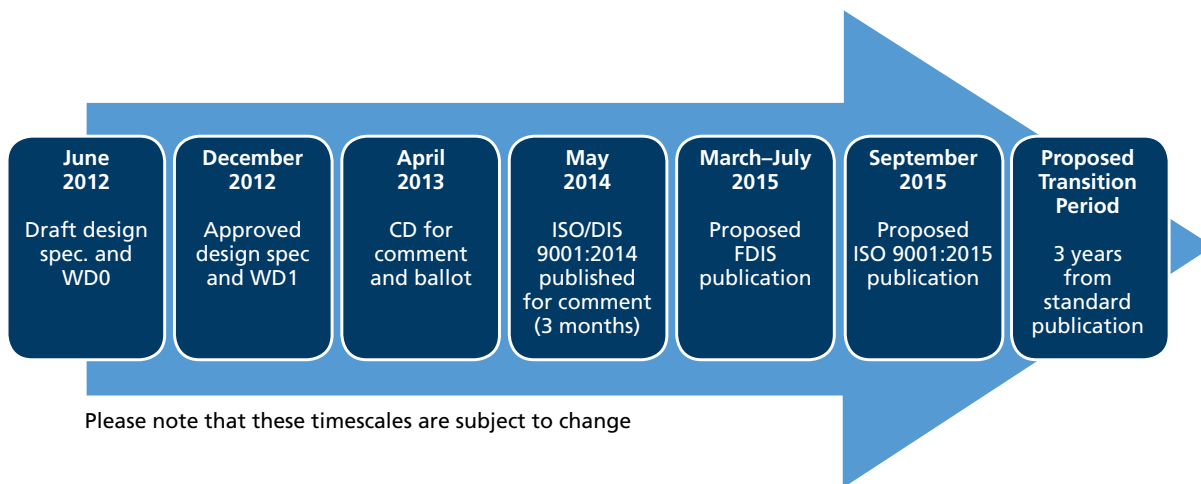
What's next?

Start with the current draft version and understand the proposed revisions that are completely new or have been revised. Those are the areas that are likely to be included in your transition plan. Also, make sure that quality managers and internal auditors understand the differences that Annex SL (common text and structure) will bring to the design, operation and performance of your QMS and any other management system standards in your organization.

Talk to LRQA; as a member of the Independent International Organization for Certification (IIOC), we are a member of all the major ISO technical committees helping to shape the new standards. We not only understand the DIS, but more importantly, we know what the DIS means to your QMS and wider organization - and how to apply it to best effect.

Engage with LRQA to find out how a gap analysis and training on specific areas of ISO 9001:2015 can benefit you personally, as well as your organization.

Begin formalizing a transition plan and process and ensure that top management is involved from the start.

June 2012	December 2012	April 2013	May 2014	March–July 2015	September 2015	Proposed Transition Period
Draft design spec. and WD0	Approved design spec and WD1	CD for comment and ballot	ISO/DIS 9001:2014 published for comment (3 months)	Proposed FDIS publication	Proposed ISO 9001:2015 publication	3 years from standard publication

Please note that these timescales are subject to change

LRQA at a glance

LR Management Systems (LRQA) is a member of the Lloyd's Register group, which provides independent assurance to companies operating high-risk capital intensive assets to enhance the safety of life, property, and the environment, so helping its clients ensure safe, responsible, and sustainable operations.

LRQA is a leading independent provider of assurance services including assessment, certification, validation, verification and training across a broad spectrum of standards, schemes and customized assurance programs. We are recognized by over 50 accreditation bodies and deliver our services to clients in more than 120 countries.

Applying our unique assessment methodology – Business Assurance – LRQA turns assessment into a powerful management tool. By understanding what really matters to your organization and stakeholders, we help you improve your management system and your business at the same time.

Independence

First Ever

LRQA holds **United Kingdom Accreditation Service** (UKAS) accreditation number 001 as the first ever certification body for both ISO 9001 (Quality) and ISO 14001 (Environmental) services

Recognition

Recognized by 50+ accreditation bodies worldwide

Technical Excellence

Shaping the Industry:

Through our membership of the **IIOC**, LRQA participates in all of the major committees helping to shape the future of the world' leading ISO standards.
Chair of the **FFSC**
Board Member of **IETA**
Member of **ISO** and
GFSI Technical Committees
Verification Partner of **CDP**

Best in Class

BT has won top accolades from ACCA (Association of Chartered Certified Accountants) for their LRQA verified Sustainability Reporting

Innovation

We build and deliver customized audit programs for organizations like **Mars** to add an additional level of assurance against client-specific criteria

Public Benefit

A Greener Planet

LRQA has verified around 1bn tons of CO_2 under the EU ETS. Assuring organizations' emissions are appropriately monitored and reported enables their management and reduction

Adding Value to Society

LRQA verified South Asia's first certified emission reductions under the United Nation's PoA framework, providing 57000 stoves to Bangladeshi families

First Ever

In the early 1990's, LRQA delivered the first ever Environmental Assurance Statement to **Norsk Hydro**

Scale

Global Reach - Local Focus

45000+ clients in
120+ countries
60000+ certificates issued

From Farm to Fork

5000+ food sector organizations from the world's best known brands to the smallest suppliers choose LRQA for their food safety assurance services

Size of Savings

LRQA's environmental insight saved **Shanghai Shipbuilding** £1.27m

CDP	Carbon Disclosure Project
FFSC	Foundation for Food Safety Certification
GFSI	Global Food Safety Initiative
IETA	International Emissions Trading Association
IIOC	Independent International Organization for Certification
ISO	International Organization for Standardization

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