ISO 9001:2015 TRANSITION GUIDANCE AND EXPECTATIONS

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Planning a smooth transition starts with understanding the new standard and your options!

As you are hopefully aware, the scheduled revision of the ISO 9001 standard was published as planned, in September 2015. This was the first significant revision to this document since the 2000 version was released 15 years ago.

With these current changes to the standard, many of you will have questions with regards to how the changes will affect your company and how the transition process is going to be undertaken.

In alignment with IAF and ANAB guidance, NQA, USA believes these changes to be significant in nature and thus will require an evaluation of companies' existing management systems to confirm the degree of conformity with the new risk based approach as detailed in ISO 9001:2015.

This document will discuss NQA, USA's philosophy associated with the changes to the standard, the options available to you, our client, and explain the expectations for registered organizations during the transition process.

Background for the Change- The Impact of Annex SL

In April 2012, the International Organization for Standardization (ISO) published Annex SL (previously ISO Guide 83) of the Consolidated ISO Supplement of the ISO/IEC Directives. This document provides identical structure, text and common terms and definitions for management system standards to follow for future revisions.

Over the years, ISO has published many management system standards for topics ranging from quality and environment to information security, business continuity management and records management. Despite sharing common elements, ISO management system standards come in many different shapes and structures. This, in turn, results in some confusion and difficulties at the implementation stage. This new approach will ensure consistency among future and revised management system standards and make integrated use of these standards far simpler. It will also make the standards easier to read and better understood by the users.
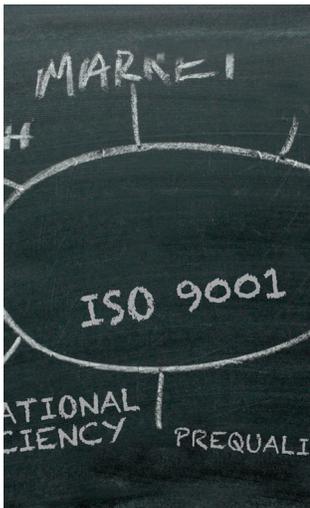
Three management system standards have already been published in this new harmonized format with another seven on the way. Both ISO 9001 and ISO 14001 will follow the new outline during their revision process.

Annex SL Structure

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

General Guidelines for Transition

1. The ISO 9001:2015 standard allows for fewer documented procedures than ISO 9001:2008. As you prepare for the transitioning of your QMS documentation for conformity to the new standard, it is acceptable to change the wording to comply with ISO 9001:2015. However, you must not delete procedures required by ISO 9001:2008 until ISO 9001:2015 conformity is achieved.

2. All NQA clients will be required to complete the ISO 9001:2015 checklist (TR002) to list process, procedure or work instruction references pertinent to the new requirements. This exercise serves both to ensure that all requirements have been addressed in the management system and to provide easy reference to requirements during future audits.

3. All current existing certificates to ISO 9001:2008 will expire on September 14, 2018, three years after the publication of the 2015 version of ISO 9001.

4. Until the transition is complete, the organization's QMS must maintain conformity to the 2008 standard. Where a lack of conformity is identified, a non-conformity will be raised and must be addressed per the current corrective action process.

5. If your organization's current ISO 9001 certificate expires before you are able to fully transition to the 2015 standard, you may be re-registered to the 2008 version. This new certificate will only remain valid for the remainder of the three year period after release of the 2015 version, September 14, 2018, as mentioned above.

6. A new certificate to the 2015 version will be issued when it can be satisfactorily shown that your organization has fully met the requirements of the new standard. As is the current practice, no major non-conformances can be in place and corrective actions for any minor non-conformances must be received and reviewed at NQA, USA prior to issuance of a certificate.

7. The International Accreditation Forum (IAF) ID 9:2015, Transition Planning Guidance for ISO 9001:2015 states that where transition audits are carried out in conjunction with scheduled surveillance or recertification, additional time is likely to be required to ensure that all activities are covered for the existing and new standards.

Transition Process

For the transition process to run smoothly, NQA, USA has created a Customer Transition Package. The Transition Package is comprised of 3 documents:

- This document, Transition Guidance (TR001)
- Transition Checklist (TR002)
- ISO 9001:2008- ISO 9001:2015 comparison

Transition Checklist

With the ISO 9001:2015 standard being restructured and reworded, NQA, USA feels it is important to provide clarity as to which of the clauses are new and significantly modified requirements from the previous revision. With this in mind, the Transition Checklist (TR002) was developed. We ask that your organization use this document to perform evaluations to determine the areas within your QMS that are in need of revision. Also note that there are several documents, articles and discussions on the new standard that are available on the NQA website.

By evaluating the identified topics and areas, your organization should be able to develop a fairly simple implementation plan that addresses any procedural or system changes, as well as, identify training and improvement needs. Once the Transition Checklist is completed, forward it to your Client Support Representative (CSR) and Lead Auditor prior to your organization's transition audit. This form can be downloaded from the NQA website: www.nqa.com

Pre-Assessment

Once your transition plan is completed, you may want to have the plan evaluated by an NQA, USA auditor in a Pre-assessment.

During the implementation of the ISO 9001:2015 transition process, NQA, USA can provide a Pre-assessment of your organization's revised Quality Management System. This activity would determine the level of conformity of your QMS to the requirements of the standard. This may be discussed with the auditor; however, the preferred method would be to contact your CSR for details and cost if a Pre-Assessment is desired.

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Auditor Interactions

NQA, USA is providing formal transition training to all auditors and office staff. The auditor will have the knowledge and authority to deal with most areas of the transition process. As always, there will be unique situations that develop that your auditor may not be able to support. In these cases, the NQA, USA office is at your disposal to support any of your unique transition needs.

Transition Audit Timing & Cost

Based on guidance from the IAF, NQA, USA is encouraging all clients to transition at the next Reassessment visit. Additional audit time will be required to ensure that all activities are covered for the existing and new standards. Other options such as transitioning during a surveillance or via a special audit are also available. If you have any questions regarding the timing or duration of your ISO 9001:2015 transition audit, please contact your CSR to discuss other arrangements.

Sector Scheme Impacts

Many customers registered by NQA, USA have customers which require registration to a specific industry scheme standard (AS9100, ISO 13485, TS16949, and TL9000). The industry working groups that sponsor these standards are currently evaluating the impact of the ISO 9001:2015 changes on their requirements. Organizations with sector scheme certifications will want to understand the scheme transition timelines, but becoming familiar with the ISO 9001:2015 changes may help such organizations get a head-start on their sector.

Multi-sites

For customers that are registered with a multisite certification, the transition approach will be similar. Due to the added complexity of the multiple facilities requiring transition support, the process will be coordinated differently. The Transition process for the organizations that are covered by the Multisite program will be handled by your assigned NQA, USA Multisite CSR/ Program Manager. This individual will be contacting your organization in the near future to assist in the planning effort.

We appreciate the effort your organization will go through to implement the requirements of the new standard. The staff here at NQA, USA looks forward to providing you the service you have come to expect in supporting your efforts in this transition process. If you have any questions or concerns regarding the transition process or the Transition Package, please contact your Client Support Representative.