1. **Why did the ISO 9001 standard change?**

Although there are a number of reasons that resulted in the revision of ISO 9001, however, we will explain two that hold the utmost importance. Firstly, the International Organization for Standardization i.e. ISO wants to develop a process by which organizations seeking to achieve a number of certifications can easily do so by working on a same set of quality and procedure manuals. That is why, it has started developing all of its management standards on the same pattern in order to bring integration. Secondly, the revised standard aims to bring simplicity and easy language so that all stakeholders can equally understand and comprehend the standard. In other words, it aims to bring auditors, accreditation bodies, certification bodies and clients, all on the same page by bringing consistency in the certification process.

1. **What is the expected timeline of ISO 9001:2015 implementation?**

The revised standard ISO 9001:2015 was published on 15th of September, 2015. ISO has given a time period of three years to companies to transition from ISO 9001:2008 to ISO 9001:2015. According to this, ISO 9001:2008 will no longer be valid after 14th of September, 2018. However, certification bodies have been emphasized to develop their own audit dates and all companies are allowed to undergo transition timeline according to their organizational objectives.

1. **Would it be better if we do the transition earlier?**

It is not recommended to wait for transition until the last moment. However, till the ISO 9001:2008 certificate remains valid, it holds the same importance as an ISO 9001:2015 certificate. But transition must be made at such a time that allows ample time to complete the post-audit process before the expiry of ISO 9001:2008 certificate. Transition audits should be completed at least 120 days ahead of the ISO 9001:2008 expiry date to be on the safe side. That means that all transition audits must be finished by 14th of May, 2018. This allows adequate time to take corrective actions in case of any nonconformities discovered during the audit.

1. **What if my organization is unable to transition on time?**

If your organization is unable to transition to ISO 9001:2015 before the end of cancellation of ISO 9001:2008, then you will not be certified any longer and your organization will need to restart the process of certification i.e. it will have to undergo Stage 1 and Stage 2 of initial audit as well.

1. **What is Annex SL?**

Annex SL is a document that is a part of the ISO/IEC Directives Part 1. It can be considered as an outline for all the revisions of ISO standards as it serves to regulate and control the process of making, updating and delivering published ISO standard. Among many other things, it includes common definitions and terms that are widely used in all ISO standards family. This can help organizations seek multiple certifications of various standards such as ISO 9001, OHSAS 18001 and ISO 14001, all at one time as all of them will have 10 same sections and same definitions and terms. The Directives 1 document, that includes Annex SL, can be found here:

<http://www.iso.org/iso/annex_sl_excerpt_-_2015__6th_edition_-hls_and_guidance_only.pdf>

1. **What is the risk-based approach and why was it included in the revised version?**

Risk-based approach in ISO 9001:2015 describes the way organizations should approach risk matters. It will enable organizations plan their processes to manage a risk-free business, thus avoiding undesired outcomes. Risk management varies according to the business context, hence each business needs to have risk-based thinking according to its needs.

1. **Which activities that we are already undergoing according to ISO 9001:2008 will help us demonstrate our Risk Management compliance according to ISO 9001:2015?**

Some of the requirements of ISO 9001:2008 that will help you demonstrate your organization’s Risk Compliance include:

* 5.6. Management Review (your quality system assessment)
* 7.2.2 Review of Requirements related to Product (customer expectations versus current capability)
* 8.5.3 Preventive Actions (problems assessment and taking actions to avoid these problems)
* 6.2.2 Training (competency needs assessment along with steps to train personnel for competency).

1. **Do we need to provide transition training to our Staff?**

Yes. The level of transition training, though, depends upon the extent of revision that you bring to your quality management system. To the least, a training should be carried out to aware the staff about the new standard, along with its impact on the organizational processes and employees.

1. **Do we need to provide transition training to our internal auditors?**

Every organization must see its internal auditor as a competency and decide upon the extent to which they require to provide training to its internal auditors. However, it is most likely that a team of experienced internal auditors will undergo self-study and perform the transition audit successfully. The effectiveness of the internal audit will ultimately reveal the competency level of your internal auditors.

1. **What are the transition steps in brief?**

International Accreditation Forum (IAF) recommends following basic transitioning steps in its Informative Document (ID9).

1. Full review of ISO 9001:2015 to be performed by top management to identify and address gaps.
2. Development of implementation plan along with assigned roles and responsibilities.
3. QMS documents to be updated to reflect the revised processes.
4. Awareness sessions and transition trainings.
5. Internal audit along with management review.
6. Planning of transition arrangements.
7. **Is a quality manual still required, even though it is not mentioned in the standard?**

Although a quality manual is desirable, it is not required. According to the revised standard, documented information should be maintained to ensure the effectiveness of quality management system. Quality manual can be one of the preferable ways to explain its quality management system.

1. **What are some of the benefits of ISO 9001:2015?**

Following are some of the benefits of ISO 9001:2015:

* More flexible, but with strong focus on conformance of quality.
* More user friendly for knowledge-based and service organizations.
* More emphasis on engagement of leadership.
* Structured planning and consistency with other ISO management standards.
* Flexibility in presenting documented information.
* Structured approach to addressing risks and opportunities.

1. **What is meant by Documented Information?**

Documented information is a replacement of “documents” and “records” in ISO 9001:2008. Information does not fall under any specific category and both documents and records have been combined and collectively termed as documented information. Information that is subject to change, such as procedures, policies, etc. needs to be maintained and kept up to date. Information that is not expected to change, such as records, needs to be retained.

1. **Are any exclusions in ISO 9001:2015 allowed?**

ISO 9001:2015 revision does not refer to any possible exclusions in its requirements any more. However, the applicability of requirements can be determined by organizations and a requirement can be found inapplicable only if its absence does not affect the assurance of conformity to the quality of product or service for which the organization seeks the certification.

1. **What is meant by Organizational Context?**

Organizational context refers to all the internal and external factors that directly or indirectly have an effect on the quality of the organization’s product or service. Internal factors can be organizational information systems, structure, culture, governance, decision-making, etc. External factors can be social, cultural, political, legal, financial, technological, economic, etc. factors at national and/or international level, which can have an impact on the business of the organization.