NC STATE

Industry Expansion Solutions

ISO 9001:2015 Revision

What you need to know, and how your company can prepare.

ISO 9001 ✓

About the Update

ISO 9001 is the internationally recognized quality standard that has helped more than a million organizations from more than 160 countries improve their quality and operational performance. It is a management framework used across the world as a tool to inspire best practices and improve business performance.

ISO 9001-based standards are formally reviewed every five years to ensure they remain current with user needs and the most current management system practices. There are significant changes from the 2008 version of the standard to include:

- Increased emphasis on risk-based thinking, process approach and PDCA.

- Greater emphasis on producing desired results. Outcomes matter!

- More emphasis on organizational knowledge.

- Less explicit requirements for documented procedures, but more explicit requirements on documented information.

ISO 9001:2015 is the first revision of ISO 9001 since the year 2000. (The ISO 9001:2008 version was considered an amendment because only minor changes were made.) All organizations currently certified to ISO 9001:2008 will need to transition to the ISO 9001:2015 by September of 2018.

As you start your transition, NC State Industry Expansion Solutions (IES) can assist you with a solid game plan to ensure your successful transition.

Next Steps

1. Purchase and review a copy of ISO 9001:2015.

2. Contact your Registrar to ensure you understand their requirements
   for transition.

3. Identify members for your transition team.

4. Get training on the requirements of the standard.

5. Conduct a Gap Analysis to determine the level of effort and resources needed to transition.

6. Develop a transition plan.

7. Conduct a pre-assessment audit to ensure you are ready for the transition.

8. Schedule your official transition audit.

Questions?

- **When should our company start the transition process?**

  Sooner is better. We recommend getting a copy of the vocabulary standard, ISO 9000:2015, and familiarizing yourself with the terminology. Gaining fluency with the language before you begin the transition process will speed up the process. Then, make a game plan for your transition. If you are unsure of how to proceed, we can help.

- **When should we schedule our transition audit?**

  The most cost effective transition audit is in conjunction with your re-certification audit; however, the transition audit can take place during your surveillance audit or you can schedule a special transition audit. We strongly recommend you contact your Registrar to discuss your transition goals so they can provide you with guidance that is aligned with their transition strategy.

- **What is the new structure?**

  ISO 9001:2015 has been developed using Annex SL, the new high level structure created by ISO. There will now be structural constancy across ISO 9001-based standards going forward, which is great news for companies managing multiple quality systems.

- **What about our quality manual?**

  The new standard has no specific requirement for a quality manual ,but there is a requirement to provide evidence of "documented information" to support the QMS. Some organizations may opt to keep a dedicated quality manual, while others may take a less formal approach.

- **Will the ISO 9001:2015 certification audit be different?**

  There will be a greater emphasis on risk-based thinking, process approach and PDCA. In addition, metrics (objectives, KPIs, etc.) will play a big role in determining the effectiveness of your quality management system and its processes. There is a greater focus placed on management's responsibilities, including the responsibility of integrating the quality management system into the business strategy.

- **I am a small business. Is ISO 9001:2015 something to consider?**

  The requirements of ISO 9001:2015 are generic and intended to be applicable to any organization, regardless of size, industry or the products and/or services it provides.

- **Our company is currently implementing certification to ISO 9001:2008. Should we continue?**

  It depends on where you are in the implementation process. Some companies conduct a Gap Analysis to determine whether it will be beneficial to continue with the 2008 version or go forward with the 2015 version. If companies decide to continue with the 2008 version, they will have until September 2018 to transition to the 2015 version.

- **I have an integrated system including ISO 14001 and OHSAS 18001. How will the changes to ISO 9001 affect my system and transition?**

  The proposed changes to all three standards will make system integration much simpler. The anticipated publication dates and transitions are different, however, it is important to carefully plan your transitions to retain certification on each. We recommend you discuss transitions with your Registrar.

- **What if I want to transition more quickly than my surveillance audits allow?**

  Once the 2015 version of the standard was released, companies could begin their transition. The most cost effective way to transition would be during a recertification audit; however, if this does not coincide with your transition plan you can transition at any time. This, however, may require additional days and you may incur additional costs.

- **We are certified to ISO/TS 16949/AS9100. Will these standards be revised in line with ISO 9001:2015?**

  ISO/TS 16949 and AS 9100 will be revised using the same high level structure as ISO 9001:2015. These standards are still in the draft stages, so it is important to stay in contact with your Registrar to ensure you maintain your certifications.

- **Can I upgrade in 2016 during a re-certification audit?**

  Yes, provided your system meets all of the requirements of ISO 9001:2015.

- **Our company is certified to ISO 14001 as well as ISO 9001. Will we need training for both standards?**

  There are important changes to both standards, so we recommend getting training for both, to ensure you fully understand all requirements before transition.

- **I'm presently a qualified lead auditor/internal auditor. Do I need to retrain for the new version of the standard?**

  While your existing knowledge and experience is invaluable, it is crucial for you to understand the new requirements—this is the biggest change to the standard in a decade. We recommend that you attend our new auditor Upgrade training course which will help you feel confident about auditing to the new requirements of the standard.

How IES Can Help

IES offers training either onsite or in the classroom, depending on the needs of your company. Here are some of the training opportunities that can help your company make a smooth transition:

- ISO 9001:2015 Transition Overview (1 Day)
- ISO 9001:2015 Internal Auditor Upgrade Training (1 Day for existing auditors)
- ISO 9001:2015 Internal Auditor Training (2 Days for new auditors)
- ISO 9001:2015 Implementation Program (Support from start to finish)
- ISO 9001:2015 Coaching (Support Customized for your company's needs)
- ISO 9001:2015 Reassessment Audit to determine your company's readiness for a transition audit

Additionally, IES is continuing to offer all of the ISO 9001:2008 products for companies who are in the process and may need training and support for the 2008 version.

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Visit our website: www.ies.ncsu.edu to find the IES Regional Manager nearest you. Contact us by phone: 1.800.227.0264 or email: iesservices@ncsu.edu