

Assess your readiness for ISO 9001:2015 or 14001:2015



Are you ready for ISO 9001:2015 or ISO 14001:2015?

If you haven't yet made the transition from ISO 9001:2008 or 14001:2004 to ISO 9001:2015 or 14001:2015, you're not the only one! Many businesses are still certified under the ISO 9001:2008 standard, which will become invalid as of September 15, 2018. Don't wait until September 14th, though. Transitioning will take some work and preparation, so it's important to be ready.

Key Steps

- 1** Identify Gaps
 - > What are the new requirements?
 - > What gaps need to be addressed to meet them?
- 2** Develop a Plan
 - > How will you implement the transition?
 - > What is your timeline?
- 3** Training
 - > Provide appropriate training to all parties
 - > Encourage awareness of the impact of changes
- 4** Update the QMS
 - > Meet new requirements
 - > Provide verification of effectiveness
- 5** Internal Audit
 - > Complete an internal audit to the new standard
 - > Perform a management review to the new standard
- 6** Transition Your Certification
 - > Complete the checklist (on back)
 - > Undergo the transition audit

Major Changes

The most noticeable change is the updated structure, known as Annex HLS. ISO 9001:2015, ISO 14001:2015, and more now follow the same overall structure, making it easier for anyone using multiple management systems.

Additional changes include:

- > An explicit requirement for risk-based thinking
- > Fewer prescribed requirements
- > Less emphasis on documentation
- > A requirement to define the boundary of the QMS
- > Increased emphasis on Organizational Context
- > Greater emphasis on achieving desired outcomes to improve customer satisfaction

We have included a self-assessment checklist on the next page to evaluate how ready you are for the transition, and to identify which processes still need to be implemented or updated.

Use this checklist as a beginning guide to many of the commonly overlooked points that are key to upgrading your quality management system to ISO 9001:2015 or ISO 14001:2015.

Context of the Organization

- Have you identified internal and external issues and interested parties?
- Is the QMS being assessed and reviewed to support the strategic direction of the organization?

Leadership

- Has top management demonstrated leadership and commitment to the QMS? Do you have evidence?

Planning

- When planning for change, have risks to achieving objectives been identified and considered?
- Have risks associated with externally provided products or services been identified?
- Have you determined the need for changes to the QMS and carried those out in a planned manner?

Support

- Have you determined and provided the resources to ensure valid and reliable monitoring and measuring of the conformity of products/services to the QMS requirements?
- Have you ensured that employees are aware of the quality policy and the quality management system?
- Have you determined the communications (internal and external) relevant to the QMS and the procedure for implementing these?

Operation

- Have you addressed the process risks that were identified during planning?
- Have the solutions to these risks been totally implemented?
- Have you applied criteria for evaluation, selection, monitoring, and reevaluation of external providers?
- Have you ensured that your product and service requirements define and consider applicable statutory and regulatory requirements?

Operation (cont'd)

- Have you ensured your organization is able to meet these product or service requirements?
- Have you established, implemented, and maintained an appropriate design and development process?
- Have you resolved conflicting design and development inputs and retained documentation of these?
- Have you met the requirements for post-delivery activities associated with your products or services?
- Have you reviewed and controlled changes for production or service provision, to the extent necessary to ensure continuing conformity?
- Have you implemented planned arrangements to verify that the product or service requirements have been met?
- Have you retained documented information of the release, including evidence of conformity and traceability to the authorizer of release?
- Have you identified and controlled nonconforming outputs by taking appropriate action?

Management Review

- Has top management regularly reviewed the QMS as planned, to ensure stability, adequacy, and effectiveness?
- Is the organization analyzing the effectiveness of actions taken to address product or service risks?
- After evaluation, have you modified controls applied to external providers?

Improvement

- When a nonconformity occurs, have you reacted as applicable and taken action to control and correct it?
- Have you evaluated the need to act to eliminate the cause or causes of the nonconformity to ensure it does not happen again?
- Is the QMS being updated as necessary to respond to nonconformities and their causes?

DEKRA Business Assurance

1120 Welsh Rd., Suite 210, North Wales, PA 19454

1-800-768-5362

Sales.US@DEKRA.com

www.DEKRA-Certification.US