



ISO Revisions



Final
Standard

➤ ISO 9001:2015 Revision **Frequently Asked Questions**

bsi.

...making excellence a habit.™

Introduction

ISO 9001, the world's leading international quality standard has helped millions of organizations to improve their quality and operational performance since it was first published as BS 5750 in 1979. The new version ensures ISO 9001 maintains relevance in today's market place and continues to offer organizations improved performance and business benefits.

All organizations currently certified to ISO 9001:2008 will need to transition to the new requirements by September 2018.

The new standard provides a great opportunity for your organization to review your quality management system and ensure that it's aligned with the strategic priorities of your organization.

This could help your business grow, increase customer satisfaction and increase profitability. It is now a powerful business improvement tool for organizations of all sizes and in manufacturing or service industries to use to help them remain resilient and achieve sustainable growth.

Here we aim to address those initial questions that you may have as you begin your journey towards the revised standard.

➤ About the Standard

How can I get access to the final standards ISO 9000:2015 and ISO 9001:2015?

ISO 9000:2015 and ISO 9001:2015 have been published and are available through the [BSI Shop](#).

Where can I get information about the new structure?

ISO 9001 has been developed using Annex SL, the new high level structure introduced by ISO. We have produced a short on-demand webinar which can be downloaded from our website, www.bsigroup.com/iso9001revision-us. Alternatively, download our informative whitepaper "Introduction to Annex SL" which can help you to understand the new structure in more detail.

➤ Changes to the Standard

I've heard that PDCA is no longer a part of the new ISO standard structure, is this true?

The new standard is still built around the process approach, which incorporates the PDCA cycle. Additionally the new version is more explicit about the meaning of the process approach.

How can I get a summary of the changes between ISO 9001:2008 and ISO 9001:2015?

BSI has produced a mapping guide which compares the clauses between both versions of the standard. This is a useful document that will help you to quickly identify the key changes and which clauses they refer to. You can download this at www.bsigroup.com/iso9001revision-us.

There are new requirements on identifying risks and opportunities – how can I do this?

Risk has always been a feature of ISO 9001, however now it has become more explicit and is expanded to include the whole management system. It uses a risk-based approach throughout and requires that each organization identifies, plans for and takes actions on those risks and opportunities which are relevant to achieving the intended outcomes of the management system.

A full risk assessment isn't required; however, it could be useful to use ISO 31000:2009, which can provide a framework for managing risk.

The standard does not contain a requirement for there to be a management representative - how will this affect the relationship with BSI and also the management of BSI visits?

The new standard now requires top management to have a greater involvement in the management system, that the requirements are integrated into the organization's processes and that the policy and objectives are compatible with the strategic direction of the organization. During a visit, your client manager will need to conduct an interview with top management to understand how this is achieved. BSI will still require a key contact for the management system.

I am a small business with less than 50 employees. Is ISO 9001:2015 relevant for me?

Definitely. The revised version of the standard is as relevant to small businesses as it is for large multinational organizations. Irrespective of your size, it will enable you to drive improvement in your business and increase customer satisfaction.

➤ Changes to the Standard

Do I still need to maintain a quality manual?

While there is no specific requirement for a quality manual in ISO 9001:2015, there is a requirement to provide evidence of “documented information” to support the QMS. As long as the information needed to evidence the management system is kept and available, how an organization does it is not important. While some organizations may choose to keep a dedicated quality manual, others can use a less centralized approach. This recognizes changes in technology and the differing media now used to record and monitor information.

Now that the standard has been published what tips would BSI offer to begin preparation?

Some activities that would make sense in preparation for the changes include:

- Review your current approach and spring clean where appropriate

- Engage with the leaders of the business as many of the proposed changes will impact them and help them understand those issues which they must manage and those they can delegate
- Review your approach to identification, management and control of your processes
- Start to consider how you can adopt and benefit from the concept of risk and opportunity management.
- If you have certification to more than one standard, start to consider the benefits to be gained from management system integration
- Read the introduction section of the standard, it contains some very valuable guidance on the concepts contained in the standard.

➤ Changes to other related standards

Which standards are currently aligned to the new Annex SL (high level structure)?

ISO 22301 – Business Continuity Management was the first standard to be structured in line with Annex SL. Other key standards in this structure include: ISO/IEC 27001:2013 – Information Security, and ISO 14001 - Environmental Management.

We are certified to ISO 22000 – the quality standard for food – what can we expect to happen?

The revision process for ISO 22000 began in September 2014 and the new standard will be brought in line with the new high level structure. More information will be available when that process begins but for now, visit www.ISO.org to find out more.

We are certified to TS 16949/AS9100 – will these be revised in line with the new version?

We are still awaiting information from the committees for these standards on their decision about revision. This means

that you must ensure that your system continues to meet the requirements of the current standards until the situation is clarified. We are expecting that the revision process for these standards may start in 2016.

What will happen to the Medical Devices standard ISO 13485?

A revision is currently being planned and however unlike all other ISO standards, it is NOT expected to follow the high level structure (Annex SL). The revised standard is expected towards the end of 2015, although this may change.

Will ISO 9004 continue to be available?

Yes, this document continues to offer very useful information on how to apply the principles of a quality management approach to the wider issues of business management and building a sustainable business for the future

➤ The transition process

How soon can I start the transition process?

You can start preparing for the transition immediately, educating the relevant people in your business and re-structuring your processes in line with the new high level structure. We have a downloadable internal communications pack that you may find useful for this. We suggest that you build new processes outside of your existing system.

How long will ISO 9001:2008 continue to be recognized and audited to?

ISO 9001:2008 will be recognized and can be audited to until September 2018, which will be the end of the 3 year transition period for ISO 9001:2015. It's best to get started with your transition planning as soon as possible so that you can pro-actively manage this process. Please note, all organizations must transition to the new standard by the transition deadline at which point certificates for ISO 9001:2008 will no longer be valid.

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

Yes – providing your system meets all of the requirements of ISO 9001:2015.

Will the transition mean additional days and additional costs?

It is expected that clients will transition during the course of their surveillance audits and there will be a requirement for additional time to review and assess your implementation of the new requirements.

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

You are more than welcome to transition as soon as the 3 year transition period begins; however, this may require additional days and as such, you may incur additional costs.

Will my assessments to ISO 9001:2015 be any different?

Although there will be some similarities to the way assessments are carried out, there are some important differences. We will need to meet with top management during your audits, so they should be available on assessment days. Before an assessment, our client managers will provide you with an agenda for the day(s) so you can prepare.

Will there be a cost for certificate renewal?

We are not expecting to charge for certificate renewals.

How do I find out how far we are through the transition process?

We will be working closely with clients and tracking their progression towards the new standard over the coming months. Your BSI client manager will discuss your transition progress at each visit to see where you are on your journey.

What if I want an extension to scope. Does that have to be to the 2015 version of the standard?

No, you can extend the scope of your existing certificate against the 2008 version of the standard. You must, however, transition by September 2018, otherwise your certificate will be invalid.

I'm currently implementing/considering certification to ISO 9001, what should I do?

If you have already started implementing ISO 9001:2008, continue as planned - you still have until September 2018 to transition to the new standard. We would recommend familiarizing yourself with the new high level structure so that you can keep this in mind.

If you haven't started implementation yet, we would recommend that you obtain a copy of the 2015 version and implement this version.

I have an integrated system including ISO 14001 and OHSAS 18001, how will the changes to ISO 9001 and these standards affect my system and transition?

The proposed changes to all three standards will make system integration much easier as there is greater alignment between the documents. However as they have different projected publication dates and transitions, you will need to plan your transitions carefully to retain certification on each. Talk to your BSI client manager who will help you plan this process.

Transitioning to the new standard provides a great opportunity to integrate your systems into one. Obtaining a copy of PAS 99 may be of benefit as it contains valuable guidance on the design and structure of an Integrated Management System

Have questions about your transition?
Call us at 1-800-862-4977

➤ Support from BSI

How can my BSI client manager support me through this process?

Should you have any questions, your client manager has been kept fully updated with the ISO 9001 revision process. All our client managers have undertaken a rigorous and robust training program on ISO 9001:2015, so you can be confident that assessments delivered to the new standard will deliver maximum benefit to your organization.

There are lots of supporting material available from BSI to help you during this time including training, whitepapers and transition guides. However, it will be up to you to plan and implement the changes within your business.

What training will be available?

Our experts have developed a comprehensive range of training courses to help you understand the key changes to ISO 9001:2015 and start your transition. They contain not only the information, but also the practical skills to apply this information effectively.

This includes a course specifically for senior management which introduces their new responsibilities; transition training covering the new high level structure and key changes to the standard and key changes to the standard; a new course for auditors as there are important new requirements for them to know.

There is also training available on some of the key new areas of the standard such as “process approach”, “risk-based thinking”, “external provision” and “auditing leadership”. Visit bsigroup.com/iso9001revisions-us for more information.

I'm presently a qualified lead auditor/auditor, do I need to retrain for the new version of the standard?

While your existing knowledge and experience is invaluable, this is the biggest change to the standard in a decade. It's vital you understand the new requirements which won't be familiar. We would recommend that you book onto our new auditor transition training course as this will build on your existing knowledge and help you to feel confident about the new version of the standard.

We are also certified to both ISO 9001 and ISO 14001. Do I need to undergo training for both standards?

There are important changes to both standards. We would recommend that you book training for both standards to make sure you fully understand what this means to your organization.

➤ Additional resources

There are a variety of materials which can be accessed online at www.bsigroup.com/iso9001revision-us and consists of:

The importance of leadership

The new standard has an entire clause devoted to leadership and is one of the most significant changes. This whitepaper explains why management is now required to take a more active role in the QMS to ensure it is implemented, embedded, communicated and maintained.

ISO 9001 Whitepaper: Managing risk in quality management

This whitepaper explains the background to the revision, how risk is being incorporated into the revised standard and the benefits for ISO 9001 clients.

Introducing Annex SL

The new generic framework with core text, common terms and definitions and the blueprint for all management system standards going forward – understand more about the structure in our whitepaper.

PLUS:

- Old-to-new ISO 9001 Mapping Guide
- Self-assessment checklist
- Transition Journey to the new ISO 9001:2015

➤ Our products and services

We provide a unique combination of complementary products and services, managed through our three business streams: Knowledge, Assurance and Compliance.

Knowledge

BSI works with business experts, government bodies, trade associations and consumer groups to capture best practice and structure the knowledge all organizations need to succeed. The majority of the widely used and implemented international standards were originally shaped by BSI, for example ISO 9001, Quality Management and ISO/IEC 27001 for Information Security.

Assurance

Independent assessment of the conformity of a process or product to a particular standard ensures that our clients perform to a high level of excellence. We help our clients understand how they are performing, thereby identifying areas of improvement from within.

Compliance

To experience real, long-term benefits, our clients need to ensure ongoing compliance to a standard so that it becomes an embedded habit. We train our clients to understand standards and how to implement them, as well as provide added value and differentiated management tools to facilitate the process of ongoing compliance.

➤ Why BSI?

BSI has been at the forefront of ISO 9001 since the start. It was originally based on BS 5750, the first quality management system standard which was developed by BSI in 1972.

That's why we're best placed to help you understand and transition to the new standard.

At BSI, we create excellence by driving the success of our clients through standards. We enable others to perform better, manage risk and achieve sustainable growth.

For over a century our experts have been challenging mediocrity and complacency to help embed excellence into the way people and products work. We make excellence a habit



BSI Group America Inc.
12950 Worldgate Drive, Suite 800
Herndon, VA 20170
USA
Tel: 1 800 862 4977
Fax: 1 703 437 9001
Email: inquiry.msamericas@bsigroup.com
bsigroup.com/en-us

To find out more visit:
bsigroup.com/isorevisions-us