

ISO 9001:2015

How your ISO 9001 audit
will be different

Whitepaper



Introduction

The new ISO 9001 introduces some key changes to the way a quality management system (QMS) is incorporated into your organization's strategy and this will mean that the audit will focus on new areas. This whitepaper is intended to give you some guidance as to what to expect during your audit in relation to these new requirements and help you to prepare.

A key point to emphasise is that the purpose of ISO 9001 has not changed. It is defined in the scope section of the standard as follows: This International Standard specifies the requirements for a quality management system when an organization:

- a. Needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b. Aims to enhance customers satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Your management system must achieve these intended outcomes. Your BSI client manager will be looking for objective evidence to demonstrate that your organization's systems and processes are able to deliver not only what your customers want and/or need but also any relevant statutory or regulatory requirements.





What to expect during your **ISO 9001:2015** audit

The new ISO 9001:2015 has a number of new requirements which will change the focus of your audit. One of the major changes is that it brings quality management and continual improvement into the heart of an organization. This means that your quality management system must be aligned with the strategic direction of your organization.

There will be more emphasis on discussions and a need for process

owners to be available so they can explain the processes.

Open questions have always been part of the assessment and there will be greater emphasis on open discussions with the organization following the move away from documented procedure.

An important feature of the assessment is the ability to follow the line of sight linking the strategic direction and

leadership from senior management throughout the organization.

When auditing various processes the organization may not have a traditional document or even process flow diagram. However there will be a process owner, process objectives and interactions with other processes in the system. Using this information to review the effectiveness of the processes to meet the intended outcomes of the system is key.

Context of the organization

This is a new clause that establishes the context of the QMS and how the business strategy supports this. The 'context of the organization' is the clause that underpins the new standard. Organizations need to identify and understand the internal and external factors and interested parties which could influence its purpose and objectives and the purpose of the standard.

Firstly, your client manager will evaluate how you identify the external and internal issues which are relevant to your organization. You'll need to demonstrate how you identify,

monitor and review the information. Secondly, you'll need to demonstrate how you have identified and understood the needs and expectations of interested parties that are relevant to the services you deliver or the products you manufacture. Interested parties could include shareholders, employees, customers, suppliers, and even pressure groups and regulatory bodies and these may change over time. It's for your organization to decide if a particular requirement of a relevant interested party is important.

Leadership

Leadership is a new clause, but covers some requirements in ISO 9001:2008. Top management are now required to have greater involvement in the QMS and must ensure 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.

There is also greater focus on top management to enhance customer satisfaction and they must have a grasp of the organization's internal strengths and weaknesses and how these can impact the delivery of products or services.

Auditing Leadership is a process which usually begins with a discussion with top management. Your client manager will discuss many things that you will have discussed in previous assessments but there will be some new elements. These will include how they ensure the QMS is compatible with the strategic direction of the organization as well as how they take responsibility and promote risk-based thinking, customer focus and improvement throughout the organization.

Your client manager will use this information throughout the organization to evaluate if there is

unity of purpose and direction and to determine if people are engaged in achieving the quality objectives. This will involve a number of audit trails including:

- talking to employees at different levels and in different areas about their objectives and how they contribute to customer satisfaction and improving the system
- how change is managed in the organization and if departments work together to ensure they don't have an adverse effect on each other when making change.



Planning

Planning has always been an element of ISO 9001, but now there is an increased focus on ensuring that it is considered with the 'context of the organization' and 'interested parties'. There is a requirement to identify risks and opportunities, the impact these may have on the conformity of products and services and customer satisfaction and how you plan to address these.

You also need to be proactively looking for opportunities to improve your performance, your products and services, your processes and the overall effectiveness of your QMS.

Although there is an increase focus on risk-based thinking there is no requirement for formal methods for risk

management or a documented risk management process. It is entirely up to you how you identify risks within your organization; this may be through a more extensive risk management methodology or through something less formal.

Your client manager will test how you have used the information relating to your internal and external issues and interested parties to determine your risks and opportunities as well as the decision making process you have gone through to decide what actions you are going to take.

Support

Support ensures that you have the right resources, people and infrastructure required to meet your organizational goals. Organizational knowledge is a new requirement in addition to competence, awareness, and communication of the QMS.

Your client manager will be looking for evidence on how you determine and provide the resources needed for the quality management system including external providers.

In relation to competence, there has been a shift from people in the organization to anyone under the organizations control who can not only affect the product or service but can affect the performance of the QMS. There will be no difference to the

approach in auditing this requirement but there may be a wider sampling pool from which the objective evidence is selected. In addition, you need to consider changing needs and trends and how you will maintain existing knowledge and acquire additional knowledge. Your client manager will discuss how you determine the knowledge you need in your organization and how you protect it. This may include looking at areas such as CRM systems or succession planning.

For example there is less documentation required in the 2015 version of the standard. There is no requirement for a quality manual or documenting the procedures for

control of documents, or for internal audit. However there is a need to ensure there are the documents and records you need to ensure the system is effective. Your client manager will establish how you have decided what documentation and records you need. They will then test this throughout the organization to see that they are available and that they provide confidence that the processes have been carried out as planned and to demonstrate that your product or service meets your customer requirements and any regulatory or statutory requirements.

Operations

This part of the standard will feel very familiar to the 2008 version, it covers the execution of plans and processes from the initial customer interaction to the delivery of their products and services. There are some differences in this clause. The key ones being; the link with the actions to address risks and opportunities from Clause 6, the expansion of the purchasing clause to include control of externally provided processes, products and services, and the introduction of a clause to address control of changes.

Your client manager will use the information gathered from the audit of Planning as an audit trail for these requirements. They will test how the actions which have been identified to address risks and opportunities have been implemented and controlled. Your client manager may audit the requirements relating to change by selecting examples of change activities. They will then follow this throughout the organization looking at the requirements of leadership, risk, communication, awareness, resources, competence, organizational knowledge and evaluation of performance to test its effectiveness.





Performance evaluation

Performance evaluation covers many of the areas previously featured in Clause 8 of the 2008 version. Requirements for monitoring, measurement, analysis and evaluation are covered and you'll need to consider what needs to be measured, the

methods employed, when data should be analysed and when it should be reported on. The standard places more emphasis on the output of the monitoring and measuring activity and your client manager will do the same during the audit. They will review how

you use this data to establish if you have achieved the intended outcomes of the standard in relation to customer satisfaction and delivering products and services that meet customer, statutory and regulatory requirements.

Improvement

There is no significant change here in relation to the requirements of the standard. The main change is the requirement for corrective action is more explicit. It breaks down the various stages of action i.e. correction, investigation and corrective action. You should not see any significant change in how your client manager approaches this clause.

Your audit is nothing to be scared of, and your client manager will not review all elements in one audit. The major changes are the clauses on the context of the organization, leadership and risk. The content of the top management discussion will be a key change and your leadership team should prepare for this.

Additional resources

There are a variety of materials which can be accessed online at www.bsigroup.com/iso-9001 and consists of:

The importance of leadership whitepaper

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

REVISED: ISO 9001 Frequently Asked Questions

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

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 this whitepaper.

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.

PLUS:

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

Additional services

We also have a wide range of services to help you to implement the changes and understand how well you are doing. These include:

Gap assessment

A transition gap assessment is a pre-assessment service where we take a closer look at your transition plan and quality management system comparing it with the requirements of ISO 9001:2015. As a first step in your transition journey with BSI, the gap assessment can help confirm the areas of your system already compliant and any gaps in your system, saving you time and money.

Business improvement tools

When you implement the revised standard it's extremely important to manage and maintain it in the most efficient manner possible. Best practice organizations do this by deploying business improvement tools such as BSI Action Manager or Entropy software, as one of our clients told us, 'it's literally like having an extra member of the team'. Clients have experienced 50% reduction in the time to implement their management system.



To find out more
about BSI's solutions
to help you with the
new ISO changes
visit: **bsigroup.com**

Why BSI?

BSI has been at the forefront of ISO 9001 since the start. And it was originally based on BS 5750 which was developed by BSI. Since 1994 BSI has held the Secretariat of the International Committee developing and evolving ISO 9001 to where it is today. 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

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 14001, Environmental 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.

To find out more
visit: **bsigroup.com**

