



➤ Moving to the
AS/EN 9100:2016 series

Transition Guide

Successful aviation space and defence businesses understand the value of an effective Quality Management System. It helps them continually improve, focus on meeting customer requirements, and ensure customer satisfaction.

This guide has been designed to help you meet the requirements of the new aerospace standard for Quality Management Systems (QMS) AS/EN 9100/9110/9120:2016, which replace the previous versions. These are based on ISO 9001:2015, which replaced ISO 9001:2008. They specify the requirements for establishing, implementing, maintaining and continually improving a QMS for any organization, in aviation, space and defence regardless of size.

So why is it changing?

The International Aerospace Quality Group (IAQG), who operate the AS/EN 9100 series of quality management standards have decided to continue to base the series on ISO 9001 with some additional enhancements.

All ISO management system standards are subject to a regular review under the rules by which they are written. Following a substantial user survey the

ISO 9001 committee decided that a review was appropriate to maintain its relevance in today's market place. The new standards will help you to:

- Ensure inclusion to the Online Aerospace Supplier Information System (OASIS) database
- Integrate with other management systems
- Provide an integrated approach to organizational management
- Reflect the increasingly complex international environment in which organizations operate in this industry
- Ensure the new standard reflects the needs of all potential user groups
- Enhance an organization's ability to satisfy its customers and continually improve

NB. This transition guide is designed to be read in conjunction with the 2016 versions of EN9100/9110/9120— Quality Management Systems: Requirements, which are due to be published toward the end of 2016. It does not contain the complete content of the standards and should not be regarded as a primary source of reference in place of the published standards. of reference in place of the published standard itself.



What's in the new standards and what are the benefits for organizations?

ISO 9001 is the world's most recognized management system standard and is used by over a million organizations across the world. The new version has been written to maintain its relevance in today's marketplace and to continue to offer organizations improved performance and business benefits. The revised AS/EN 9100 series of standards build on this revision to add clarity and enhance ease of use while addressing industry and stakeholder needs.

With the 2016 versions of AS/EN 9100 you will be able to:

- Introduce an integrated approach with other management system standards
- Bring quality and continual improvement into the heart of the organization
- Increase involvement of the leadership team
- Introduce risk and opportunity management

They will be much less prescriptive than the previous versions and can be used as more agile business improvement tools. This means that you can make the new standards relevant to the requirements of your organization to gain sustainable business improvements.

One of the major changes to the AS/EN 9100 series is that it brings quality management and continual improvement into the heart of an organization. This means that the new standard is an opportunity for organizations to align their strategic direction with their quality management system. The starting point of the new version of the standard is to identify internal and external parties and issues which affect the QMS. This means that it can be used to help enhance and monitor the performance of an organization, based on a higher level strategic view.

Our customers tell us they get multiple benefits as a result of implementing and adopting a system that meets the requirements of the AS/EN 9100 series. The new versions will continue to do this and provide additional value.

The new AS/EN 9100 series of standards will:

- **Facilitate continual improvement:** Regular assessment will ensure you continually use, monitor and improve your processes
- **Increase market opportunities** so you can demonstrate to clients excellent levels of traceability throughout the supply chain
- **Increase efficiency** that will save you time, money and resources
- **Ensure compliance** with a system supported by regulatory authorities that helps to mitigate your risks
- **Motivate, engage and involve staff** with more efficient internal processes
- **Help you trade** as it's often a requirement of the aerospace industry that you have implemented a QMS. It also independently demonstrates that you have in operation a management system accepted by the aerospace sector

Useful standards for your transition

ISO 9001 is part of a family of quality management related standards. You may find this section useful for further reference in addition to ISO 9001:

- | | |
|---|--|
| <p>1 ISO 9000, Quality management systems - Fundamentals and vocabulary</p> <p>2 ISO 9004, Managing for the sustained success of an organization - A quality management approach</p> <p>3 ISO 10001, Quality management - Customer satisfaction - Guidelines for codes of conduct for organizations</p> <p>4 ISO 10002, Quality management - Customer satisfaction - Guidelines for complaints handling in organizations</p> <p>5 ISO 31000, Risk management - Principles and guidelines</p> | <p>6 ISO 10004, Quality management - Customer satisfaction - Guidelines for monitoring and measuring</p> <p>7 ISO 10014, Quality management - Guidelines for realizing financial and economic benefits</p> <p>8 ISO 19011, Guidelines for auditing management systems</p> <p>Similarly, the AS/EN 9100 series is more than AS/EN 9100, 9110 and 9120. There are many complimentary standards which, though not for certification, will assist an organization. Refer to http://www.sae.org/iaqg/publications/standardsregister.pdf for more information.</p> |
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Comparing the 2016 revision of the AS/EN 9100 series with the previous versions

The new standards are based on Annex SL – the new high level structure. This is a common framework for all ISO management systems. This helps to keep consistency, align different management system standards, offer matching sub-clauses against the top level structure and apply common language across all standards. It will be easier for organizations to incorporate their QMS into core business processes and get more involvement from senior management.

The Plan-Do-Check-Act (PDCA) cycle can be applied to all processes and to the quality management system as a whole. The diagram here (Figure 1) illustrates how Clauses 4 to 10 can be grouped in relation to PDCA.

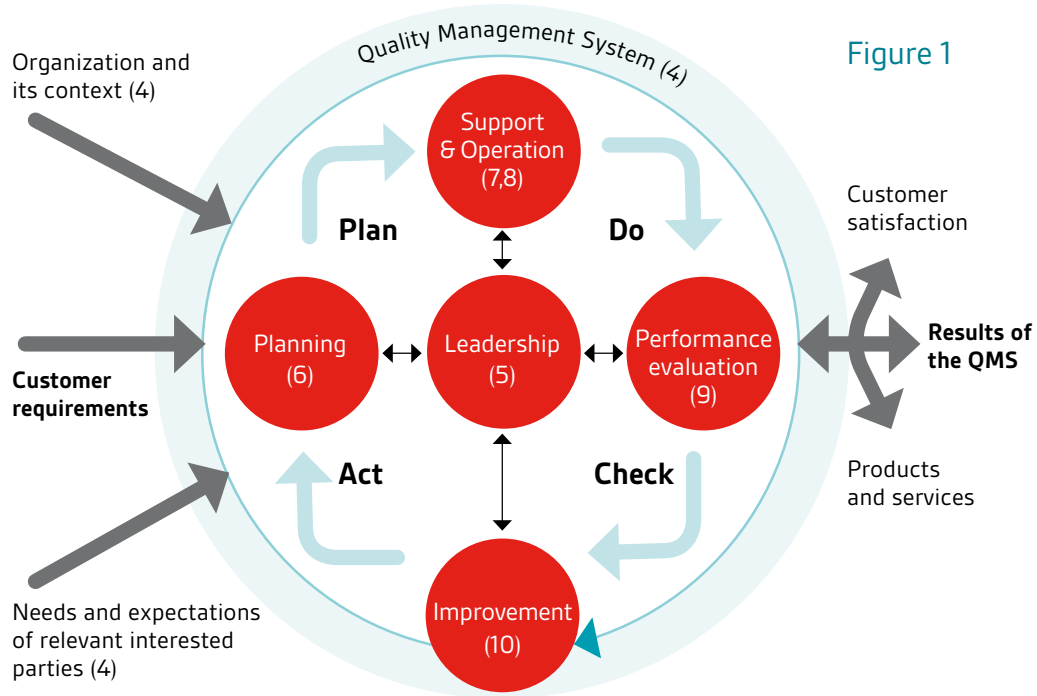


Figure 1

New/updated concept	Comment
Context of the organization	Consider the combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services, investments and interested parties.
Issues	Issues can be internal or external, positive or negative and include conditions that either affect or are affected by the organization.
Interested parties	Can be a person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity. Examples include suppliers, customers or competitors.
Leadership	Requirements specific to top management who are defined as a person or group of people who directs and controls an organization at the highest level.
Risk associated with threats and opportunities	Refined planning process replaces preventive action and is defined as the 'effect of uncertainty on an expected result.
Communication	There are explicit and more detailed requirements for both internal and external communications.
Documented information	Replaces documents and records. There are 2 types: maintained (i.e. procedures and work instructions) and retained (i.e. records)
Performance evaluation	The measurement of quality performance and the effectiveness of the QMS, covering the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results.
Nonconformity and corrective action	More detailed evaluation of both the nonconformities themselves and corrective actions required. Human factors have been added as an element of root cause analysis.
Management review	More detailed requirements relating to inputs and outputs of the review.

The key requirements of AS/EN 9100:2016 series

Clause 1: Scope

Clause 1 details the scope of the standard and there has been very little change to this clause from ISO 9001:2008.

Clause 2: Normative references

ISO 9000, Quality Management System - Fundamental and vocabulary is referenced and provides valuable guidance.

Clause 3: Terms and definitions

Terms and definitions are contained in ISO 9000:2015 - Quality Management - Fundamentals and vocabulary. The AS/EN 9100 series contains some additional terms in this clause including counterfeit part, "critical items", "key characteristics", "product safety", and "special requirements".

Clause 4: 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 rest of the new standard. It gives an organization the opportunity to identify and understand the factors and parties in their environment that support the quality management system.

Firstly, the organization will need to determine external and internal issues that are relevant to its purpose, i.e. what are the relevant issues, both inside and out, that have an impact on what the organization does, or that would affect its ability to achieve the

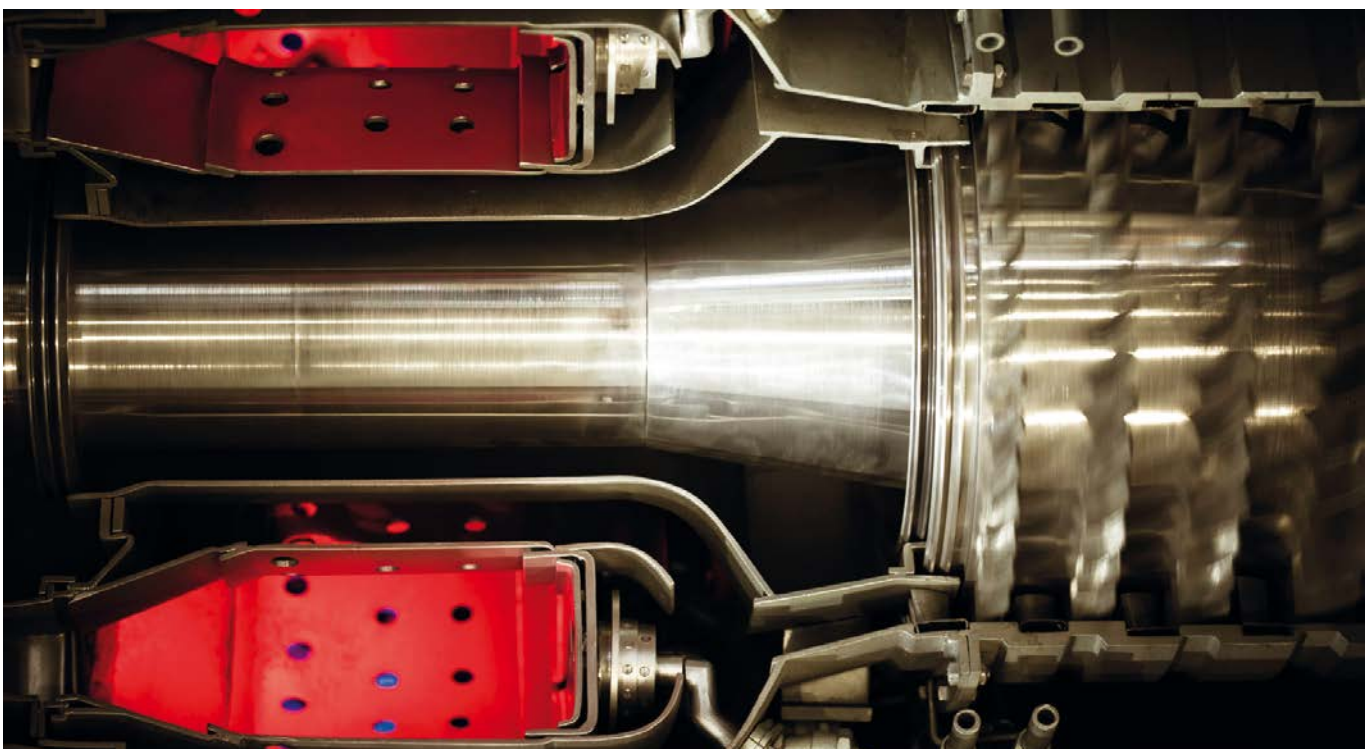
intended outcome(s) of its management system.

It should be noted that the term "issue" covers not only problems which would have been the subject of preventive action in previous standards, but also important topics for the management system to address, such as any market assurance and governance goals that the organization might set.

Secondly an organization will also need to identify the "interested parties" that are relevant to their QMS. These groups could include shareholders, employees, customers, suppliers, statutory and regulatory bodies and even pressure groups. Each organization will identify their own unique set of "interested parties" and over time these may change in line with the strategic direction of the organization.

Next the scope of the QMS must be determined. This could include the whole of the organization or specific identified functions. Any outsourced functions or processes will also need to be considered in the organization's scope if they are relevant to the QMS.

The final requirement of Clause 4 is to establish, implement, maintain and continually improve the QMS in accordance with the requirements of the standard. This requires the adoption of a process approach and although every organization will be different, documented information such as process diagrams or written procedures could be used to support this. The new AS/EN 9100 series of standards require the QMS scope, process definitions and application, plus the process sequence and interaction to be documented, along with responsibilities and authorities.





Clause 5: Leadership

This clause places requirements on “top management” which is the person or group of people who directs and controls the organization at the highest level. It is no longer the responsibility of the “Management Representative” who in the updated standards is retained and is responsible for oversight of the QMS, not its implementation. There is an increased emphasis on people “owning” the QMS rather than one individual. The purpose of these requirements is to demonstrate leadership and commitment from the top.

Top management now have greater involvement and responsibility in the management system and must ensure that the requirements of it are integrated into the organization's processes and that the policy and objectives are compatible with the strategic direction of the organization. The quality policy should be a living document, at the heart of the organization. To ensure this, top management are accountable and have a responsibility to ensure the QMS is made available, communicated, maintained and understood by all parties.

There is also a greater focus on top management to enhance customer satisfaction by identifying and addressing risks and opportunities that could affect this. Top management need to demonstrate consistent customer focus by showing how they meet customer requirements, regulatory and statutory requirements, and also how the organization maintains enhanced customer satisfaction.

In the same context, they need to have a grasp of the organization's internal strengths and weaknesses and how these could have an impact on delivery and conformity of products or services. This will strengthen the concept of business process management. In addition, top management need to demonstrate an understanding of the key risks associated with each process and the approach taken to manage, reduce or transfer the risk.

Finally, the clause places requirements on top management to assign QMS relevant responsibilities and authorities, but must remain accountable for the effectiveness of the QMS.

Clause 6: Planning

Planning has always been a familiar element of the AS/EN 9100 series but now there is an increased focus on ensuring that it is considered with Clause 4.1 ‘Context of the organization’ and Clause 4.2 ‘Interested parties’.

The first part of this clause concerns risk assessment whilst the second part is concerned with risk treatment. When determining actions to identify risks and opportunities these need to be proportionate to the potential impact they may have on the conformity of products and services. Opportunities could for example include new product launches, geographical expansion, new partnerships, or new technologies.

The organization will need to plan actions to address both risks and opportunities, to integrate and implement the actions into its management system processes and evaluate the effectiveness of these actions. Actions must be monitored, managed and communicated across the organization.

Another key element of this clause is the need to establish measurable quality objectives. This clause retains some of the requirements contained in Clause 5.4 of the previous version but is more specific. Quality objectives now need to be consistent with the quality policy, relevant to the conformity of products and services as well as enhancing customer satisfaction.

The last part of the clause considers planning of changes which must be done in a planned and systemic manner. There is a need to identify the potential consequences of changes, determine who is involved, when changes are to take place, what resource needs to be allocated.

Clause 7: Support

Clause 7 ensures there are the right resources, people and infrastructure to meet the organizational goals. It requires an organization to determine and provide the necessary resources to establish, implement, maintain and continually improve the QMS. Simply expressed, this is a very powerful requirement covering all QMS resource needs and now covers both internal and external resources.

Clause 7.1 builds on Clauses 6.1, 6.2, 6.3 and 7.6 from previous versions and splits into 5 sub-clauses. There are additional requirements to meet applicable statutory and regulatory requirements and for consideration of periodic review of competence. The sub-clauses continues to cover requirements for infrastructure and environment for the operation of processes. Monitoring and measuring has been changed to include resources, such as personnel or training.

Organizational knowledge is a new requirement which deals with requirements for competence, awareness, and communication of the QMS. Personnel must not only be aware of the quality policy, documented information and changes, but they must also understand how they contribute to product or service conformity and safety and the implications of not conforming. It also highlights the importance of ethical behavior.

There is a key requirement to maintain the knowledge held by an organization to ensure conformity of products and services. This could include the knowledge held by an individual as well as for example, the intellectual property of an organization. Organizations are required to examine whether the current knowledge they have is sufficient when planning changes and whether any additional knowledge is required. This includes internal and external feedback.

Finally there are the requirements for "documented information". This is a new term, which replaces the references in the previous standard to "documents" and "records". Organizations need to determine the level of documented information necessary to control the QMS. This will differ between organizations due to size and complexity. The revised series continues to require certain documented information, a variation from ISO 9001. In line with the increased importance of information security and data protection in organizations, there is also greater emphasis on controlling access to documented, current information such as use of passwords. Organizations should also have systems in place to provide a back-up should IT systems crash.

Clause 8: Operation

This clause deals with the execution of the plans and processes that enable the organization to meet customer requirements and design products and services. It includes much of what was referred to in Clause 7 of the previous version, but there is greater emphasis on the control of processes, especially planned changes and review of the consequences of unintended changes, and mitigating any adverse effects as necessary. It includes significant requirements over and above ISO 9001:2015 and the previous versions of the AS/EN 9100 series.

The clauses continues to cover 'requirements for products and services' and brings in more specific requirements such as coordinated review

by applicable functions, safety, producibility, sustainability, consideration of factors such as obsolescence, recycling etc. plus notification of change to customers. It now requires communication with regards to contingency actions where required and also the treatment of customer property. A new requirement for communicating with 'potential' customers is also included, useful for bringing new offerings or solutions to the market.

This clause details requirements such as operational risk management, joint planning of processes and controls for critical items and key characteristics. Additionally it covers operational risk, product safety, configuration, prevention of counterfeit parts, obsolescence, external providers, and the integration of processes such as scheduling events in sequence at acceptable risk within resource constraints. It also covers work transfers.

There are extensive requirements for design, including project management, stage approvals to proceed, planning and documentation of test requirements etc.

There are more explicit requirements in terms of the standards or codes of practice that the organization has committed to implement; internal and external resource needs for the design and development of products and services and finally the potential consequences of failure due to the nature of products and services.

Control of external providers is largely unchanged, but the application of risk is more rounded rather than focusing on provider selection. It also requires more flow down of controls on lower tier providers. Periodic testing of product or service is also added, based on risk.

The production elements are extensive, including calibration, special processes, FAI (First Article Inspection), traceability, configuration, preservation, FOD (Foreign Object Damage), shelf life and special handling,

There is a revised clause on post-delivery activities. This could include activities such as maintenance programmes or work carried out under warranty, and activities covering final disposal or recycling of the product. When determining the extent of these activities organizations must consider the risks associated with a product or service, customer requirements, customer feedback, and any statutory requirements.

Clause 9: Performance evaluation

Performance evaluation covers many of the areas featured in Clause 8 of the previous version. On time delivery performance is added as an input to Management Review; identified risks is an output.

Requirements for monitoring, measurement, analysis and evaluation are covered and you will need to consider what needs to be measured, methods employed, when data should be analysed and reported on and at what intervals. Documented information that provides evidence of this must be retained.

There is now an emphasis on directly seeking out information that relates to how customers view the organization. Organizations must actively seek out information on customer perception. This can be achieved in a number of ways including satisfaction surveys, analysis of market share, and through complaints logged. There is now an explicit requirement that organizations must show how the analysis and evaluation of this data is used, especially with regards to the need for improvements to the QMS.

Internal audits must also be conducted and this is largely unchanged from those in the previous version. There are additional requirements relating to defining the 'audit criteria' and ensuring the results of the audits are reported to 'relevant' management.

Management reviews are still required but there are additional requirements including the consideration of changes in external and internal issues that are relevant to the QMS. Documented information must be retained as evidence of management reviews.

Clause 10: Improvement

This clause starts with a new section that organizations should determine and identify opportunities for improvement such as improved processes to enhance customer satisfaction. There is also a need to look for opportunities to improve processes, products and services, and the QMS, especially with future customer requirements in mind.

Due to the new way of handling preventive actions, there are no preventive action requirements in this clause. However, there are some new corrective action requirements. The first is to react to the nonconformities and take action, as applicable, to control and correct the nonconformities and deal with the consequences. The second is to determine whether similar nonconformities exist or could potentially occur. Causal factors include human factors, so could be wide ranging. The requirement for documented information (procedure) for non-conformity and corrective action is retained. This must include flow down to providers as appropriate.

The requirement for continual improvement has been extended to cover the suitability and adequacy of the QMS as well as its effectiveness, but it no longer specifies how an organization achieves this. Improvement activities must be monitored and evaluated.

The change has brought some changes to the terminology used as is shown in the table below.

Major differences in terminology between the old and new standards

ISO 9001:2008	ISO 9001:2015 / AS/EN 9100 series
Products	Products and services
Exclusions	See Clause 4.3 for clarification of applicability
Management representative	See clause 5.3 of AS/EN 9100 series
Documentation, quality manual, documented procedures, records	Documented information Maintained = manuals and procedures Retained = records
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

Documented information

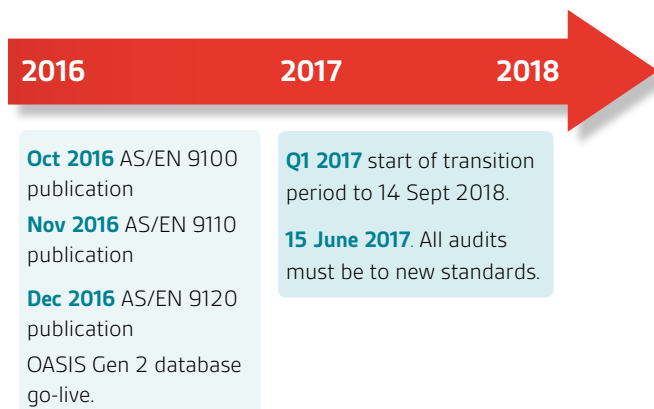
As part of the alignment with other management system standards a common clause on 'Documented Information' has been adopted. The terms "documented procedure" and "record" have both been replaced throughout the requirements text by "documented information". Where previous versions would have referred to documented procedures (e.g. to define, control or support a process) this is now expressed as a requirement to maintain documented information.

Where previous versions would have referred to records this is now expressed as a requirement to retain documented information. Requirements to maintain documented information are detailed throughout the standard and some examples are given. Please read the standard carefully particularly Clause 7.5.

4.3	Scope of the QMS	8.3	Design and development
4.4	QMS and its processes including a manual	8.4	Control and verification of externally provided products and services including provider register.
5.2	QMS policy	8.5	Production and service provision
6.2	QMS objectives	8.6	Release of products and services
7.1	Resources, including calibration register	8.7	Control of non conforming processes; including a maintained document (procedure)
7.2	Evidence of competence	9.1	Control of monitoring, measurement, analysis and evaluation
7.3	QMS documented information	9.2	Evidence of the audit programme(s) and the audit results
7.5	Documented information determined by the organization as being necessary for the effectiveness of the QMS	9.3	Evidence of the results of management reviews
8.1	Operational planning and control	10.1	Evidence of the nature of the nonconformities and any subsequent actions taken including a maintained document (procedure).
8.2	Determination of requirements for products and services		

Transition guidance

AS/EN 9100 series transition timeline



Transition is an opportunity – What do you need to do?

1. Take a completely fresh look at your QMS
2. Attend our suite of transition training courses to understand the differences in more detail
3. Highlight the key changes as an opportunity for improvement
4. Make changes to your documentation to reflect the new structure (as necessary)
5. Implement new requirements on leadership, risk and context of organization
6. Review effectiveness of current control set
7. Assume every control may have changed
8. Carry out an impact assessment

Compare the differences between ISO 9001:2008 and ISO 9001:2015 in our mapping guide.

Visit bsigroup.nl/iso9001revise

Your transition journey

BSI has identified a step-by-step journey to help you through the transition and realize the benefits of the new AS/EN 9100 series. We have mapped out a framework which guides you through the options and support available from BSI to ensure you have the knowledge and information you require.

Buy a copy of ISO 9001 and the AS/EN 9100 series of standards.

This will help you become familiar with the new requirements, terminology and layout



Visit the BSI website to access the most up-to-date support and transition material available at bsigroup.nl/AS9100-revision including whitepapers which can help you understand the changes.

N.B. This includes ISO 9001:2015 information.



Look at the wide range of BSI transition training courses available to make sure you fully understand the changes and core requirements.



Download our Implementation Toolkit based on the ISO 9001 revision which will help you to understand, implement and communicate the changes throughout your organization.



Start to revise your QMS based on the new High Level Structure and ISO 9001 clauses. **Caution:** The AS/EN 9100 series has requirements not included in ISO 9001 such as documented information. Your current QMS documents should be retained until publication of the revised AS/EN 9100 series of standards.



Buy the new AS/EN 9100 series standard when published. Further revise your QMS to meet the aerospace scheme requirements.



Consider further services to help implement the changes. BSI has a full range of services available including gap assessments and business improvement tools to help you manage your systems and transition. These can help you transition quickly and gain early adopter advantage.

Transition training from BSI

The BSI Training Academy will give you the skills and the knowledge to successfully transition to the new AS/EN 9100 series. Experts in their fields, our experienced tutors can help you get to grips with the new standards so you can be confident when you implement the changes in your organization.

AS/EN 9100 series transition training

2 day classroom based course

- Essential for anyone involved in the transition to the 2016 version of the AS/EN 9100 series, including managers, implementers and auditors
- Learn about the differences between the new and previous versions and what this means for your business

You may also find some of our ISO 9001:2015 training courses beneficial. These include:

ISO 9001:2015 Senior management briefing

2 hour face-to-face session

- Understand the purpose of ISO 9001:2015 and the leadership responsibilities outlined in the standard
- Important for top management of organizations transitioning to ISO 9001:2015

ISO 9001:2015 Transition

1 day classroom based training course

- Learn about the new ISO high level structure and the differences between ISO 9001:2008 and ISO 9001:2015
- Essential for anyone involved with an ISO 9001:2015 transition, from managers to implementers and auditors

ISO 9001:2015 Implementing changes

2 day classroom based training course

- Discover how to apply the key changes to ISO 9001:2015 and formulate a transition action plan
- Combines the one day transition course with an additional day of implementation activities
- Recommended for those responsible for transitioning an existing system to ISO 9001:2015

ISO 9001:2015 Auditor transition

2 day classroom based training course

- Learn how to audit the key changes to ISO 9001:2015
- Combines the one day transition course, with a supplementary day of ISO 9001:2015 auditing activities
- Ideal for existing internal and lead auditors who need to convert to ISO 9001:2015

ISO 9001:2015 Deep dive

2 day classroom based training course

- Gain a deeper insight into these important ISO 9001:2015 concepts: process approach, risk-based thinking, control of external provision and auditing leadership.
- Valuable for anyone involved with an ISO 9001:2015 transition, from managers to implementers and auditors.



Additional resources

There are a variety of materials which can be accessed online at www.bsigroup.nl 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 are now required to take a more active role in the QMS to ensure it is implemented, embedded, communicated and maintained.

AS/EN 9100 series Frequently Asked Questions

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

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.

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
- ISO 9001:2015 Self-assessment checklist
- AS/EN 9100 series CEO briefing

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 AS/EN 9100/9110/9120. 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 software

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 tools such as BSI Business Improvement Software. As one of our clients told us, "it's like having an extra member of the team". Clients have experienced up to a 50% reduction in the time taken to implement their management system.

Why BSI?



BSI has been at the forefront of the AS/EN 9100 series since the start. It is based on ISO 9001, the world's most widely adopted quality management system, for which BSI has held the Secretariat of the International Committee since 1994. That's why we are best placed to help you understand the standard.

At BSI we create excellence by driving the success of our clients through standards. We help organizations to embed resilience, helping them to grow sustainably, adapt to change, and prosper for the long term. We make excellence a habit.

For over a century our experts have been challenging mediocrity and complacency to help embed excellence into the way people and products work. With 80,000 clients in 182 countries, BSI is an organization whose standards inspire excellence across the globe.



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

The core of our business centres on the knowledge that we create and impart to our clients. In the standards arena we continue to build our reputation as an expert body, bringing together experts from industry to shape standards at local, regional and international levels. In fact, BSI originally created eight of the world's top 10 management system standards.

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 train our clients in world-class implementation and auditing techniques to ensure they maximize the benefits of standards.

Compliance

To experience real, long-term benefits, our clients need to ensure ongoing compliance to a regulation, market need or standard so that it becomes an embedded habit. We provide consultancy services and differentiated management tools to facilitate this process.



Find out more
Call: +31 (0)20 346 07 80
Visit: bsigroup.nl