

Moving from ISO/TS 16949:2009 to IATF 16949:2016

**Transition Guide** 



# An effective Quality Management System is vital for organizations in the automotive industry. It helps them continually improve, meet customer requirements and ensure customer satisfaction.

This guide has been designed to help you meet the requirements of the new automotive standard for Quality Management Systems (QMS) IATF 16949:2016, which has replaced ISO/TS 16949:2009. IATF 16949:2016 is to be implemented as a supplement to, and in conjunction with, ISO 9001:2015 rather than being a standalone QMS. It specifies the requirements for establishing, implementing, maintaining and continually improving a QMS for any organization, in the automotive industry regardless of size.

So why is it changing?

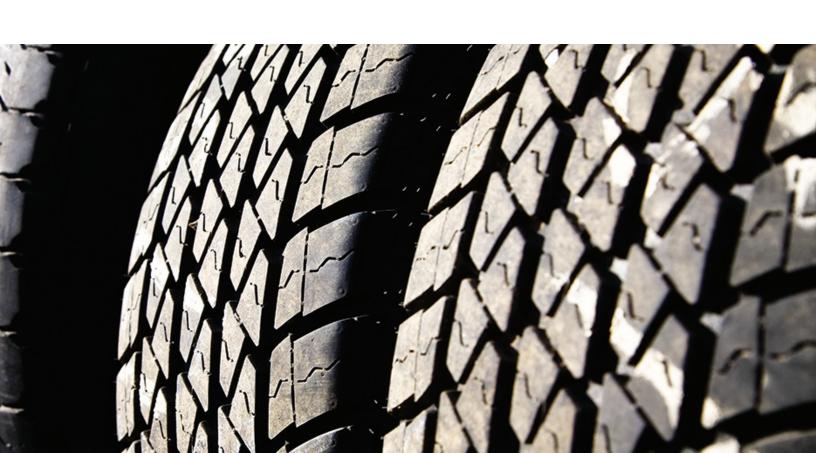
The International Automotive Task Force (IATF) who operate this standard have decided to base it on ISO 9001:2015 with some additional enhancements. This means that organizations in the automotive industry seeking IATF 16969 certification must also comply with ISO 9001:2015.

ISO 9001 was updated in 2015 to address the changes in the way we do business and maintain its relevance in today's world.

The new standard will help you to:

- 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 IATF 16949:2016 and ISO 9001:2015. 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 standard 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. IATF 16949:2016 builds on this to develop a robust QMS that facilitates continual improvement, emphasizes defect prevention, and helps reduce variation and waste in the supply chain; consideration of product safety and embedded software have also been included.

The new standard will help you 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
- Mitigate risk and improve opportunity management with a greater application of risk-based thinking

### One of the major changes in IATF 16949:2016 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 ISO/TS 16949. The new IATF 16949 standard will continue to do this and provide additional value.

The new IATF 16949 standard will:

- Facilitate continual improvement: Regular assessment will ensure you continually use, monitor and improve your processes
- Increase market opportunities so you can demonstrate to customers
  excellent levels of safety, reliability and 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 and a greater emphasis on awareness
- Help you trade as certification to this standard is mandatory for suppliers to most of the original equipment manufacturers in the automotive industry

## 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:

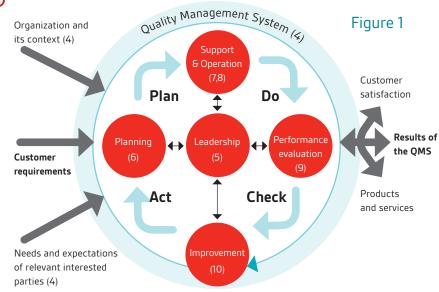
- 1 ISO 9000, Quality management systems Fundamentals and vocabulary
- 2 ISO 9004, Managing for the sustained success of an organization -A quality management approach
- 3 ISO 10001, Quality management Customer satisfaction Guidelines for codes of conduct for organizations
- 4 ISO 10002, Quality management Customer satisfaction Guidelines for complaints handling in organizations

- 5 ISO 31000, Risk management Principles and guidelines
- 6 ISO 10004, Quality management Customer satisfaction Guidelines for monitoring and measuring
- 7 ISO 10014, Quality management Guidelines for realizing financial and economic benefits
- 8 ISO 19011, Guidelines for auditing management systems

# Comparing IATF 16949:2016 with ISO/TS 16949:2009

The new standard is 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.



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	Refined planning process replaces preventive action and is defined as the 'effect of and opportunities 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.		
Product safety	fety Requirement to address the items defined within this new requirement in a documented and dedicated process for the management of product-safety related products and manufacturing processes.		
Embedded software	Detailed requirements for products with embedded software. Organizations must also implement and maintain a system for software quality assurance of these products.		
Corporate responsibility	uirement to have corporate responsibility policies including an anti-bribery policy, an employee code anduct, and an ethics escalation (whistle-blowing) policy.		
Supplier management	Additional requirements regarding the organization's supplier selection process have been added.		
Internal audits	Internal audit frequency requirements have been modified.		

## The key requirements of IATF 16949:2016

### Clause 1: Scope

Clause 1 details the scope of the standard and there is a supplementary note to cover products with embedded software.

#### 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 new standard contains additional terms and definitions relevant for the automotive industry including "accessory parts", "challenge part", "manufacturing services", "outsourced processes", "production shutdown", "special status", and "total productive maintenance".

### 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.

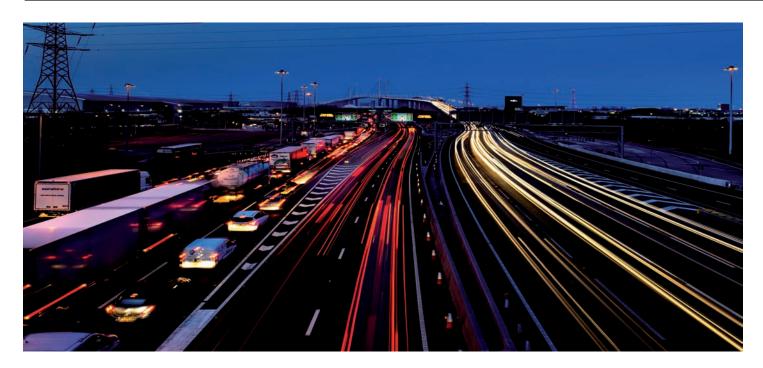
Secondly an organization will also need to identify the "interested parties" that are relevant to their QMS. These groups could include shareholders, employees, customers, suppliers, statutory and regulatory bodies and even pressure groups. Each organization will identify their own unique set of "interested 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 supporting outsourced functions or processes will also need to be considered in the organization's scope if they are relevant to the QMS.

You are required 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.

Product Safety is a new section in the standard. It has enhanced requirements designed to address current and emerging issues that the automotive industry is facing. The standard now lists the documented processes for the management of product-safety related products and manufacturing processes that an organization is required to have.





### 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. The ISO requirements have been supplemented by requiring organizations to adopt a corporate responsibility requirement. This reflects increasing market and governmental expectations for improved integrity in social and environmental matters. There is an increased emphasis on people "owning" the QMS rather than one individual. The new standard requires top management to identify "process" owners who must be competent and understand their roles in relation to the QMS.

Top management now has 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 is accountable and has 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. They 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 needs 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 they must remain ultimately accountable for the effectiveness of the QMS.

### Clause 6: Planning

Planning has always been a familiar element of TS 16949 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, while 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 include geographical expansion, new partnerships, or new technologies.

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

Another key element of this clause is the need to establish measurable quality objectives. Quality objectives now need to be consistent with the quality policy, relevant to the conformity of products and services as well as enhance customer satisfaction.

The new standard also contains several supplemental requirements in this clause. These cover: risk analysis recognizing the need to consider specific risks associated with the automotive industry, preventive action to reduce the negative effects of risk, and contingency plans, which is an enhanced requirement of what was found in ISO/TS 16949. The importance of addressing customer expectations was already present in the old standard, but this has now been enhanced so that it is done at all levels throughout the organization.

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.

There are additional requirements to meet applicable statutory and regulatory requirements. It continues to cover requirements for infrastructure and environment for the operation of processes. Where organizations are required to show their commitment to personnel safety, the new IATF standard makes reference to the forthcoming ISO 45001 as a way this can be demonstrated. Monitoring and measuring have been changed to include resources, such as personnel or training.

There are enhanced requirements in the new standard that cover calibration and verification records. This includes software installed on employee-owned or customer-owned equipment. There is also an additional requirement that covers internal and external laboratories that are used for inspection, test, or calibration services.

Organizational knowledge is a new requirement which deals with 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.

This clause also adds further requirements for on-the-job training and awareness, and requires that relevant people shall be informed about the consequences of nonconformities. Requirements for internal auditors are specified including minimum competencies and documentation relating to their training. Second-party auditor competencies are also specified.

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 of "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. 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 ISO/TS 16949:2009.

The new version of the standard acknowledges the importance confidentiality in relation to customer-contracted products and projects. It also specifies a requirement for verbal and written communication with the customer to be agreed in terms of language and in other formats such as computer languages used.

The clause continues to cover a number of requirements which have been strengthened in relation to ISO/TS 16949:2009. These include prototype programs, the product approval process where there is an emphasis on record retention and outsourced products and services, and statutory and regulatory requirements.

There are a number of new sub-clauses which cover the management, measurement and selection of suppliers. This recognizes the importance of effectively managing risk in the supply chain, particularly with regards to product quality. Reflecting the increasing application of computer technology in vehicles, there is a new requirement which covers the process for quality assurance of suppliers of embedded software products. The use of second—party audits is also new to the standard and is to be used in an organization's supplier management approach.

Finally, the new standard now has additional requirements regarding the control of nonconforming or reworked products. This includes being able to verify that products to be scrapped are determined as unusable prior to their disposal and that these products are not used elsewhere without the approval of the customer.

### Clause 9: Performance evaluation

Performance evaluation covers many of the areas featured in Clause 8 of the previous version.

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 analyzed, 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 and there is a supplemental clause covering customer satisfaction and performance indicators to be used to measure compliance with customer requirements. 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 conductedusing a risk-based approach. There are additional requirements relating to defining the "audit criteria" and ensuring the results of the audits are reported to 'relevant' management.

IATF 16949:2016 now contains new requirements that cover the qualifications of Internal Auditors, which will strengthen their development and competence. 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. These have now been moved to Clause 6. 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 exists 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. Preventive actions are also strengthened.

The new standard contains a new requirement that covers customer complaints and field failure test analysis. It requires organizations to perform analysis on field failures and returned parts. Where requested, this can extend to how embedded software in the organizations product performs within the system of the final customer's product.

### 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.

The table below shows where "Documented Information" is referred to in the new standard.

4.3 4.4	Scope of the QMS  QMS and its processes, including a manual  QMS policy		Control and verification of externally provided products and services including provider register.
5.2			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	5	
7.5	Documented information determined by the organization	9.2	Evidence of the audit program(s) and the audit results
	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	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		
8.3	Design and development		

## Transition guidance

IATF 16949:2015 transition timeline

2016 2017 2018

**Oct 2016** IATF 16949:2016 publication

**1 Nov 2016** New scheme rules to be published

Jan 2017 Transition assessments to IATF 16949:2016 may take place from this date Oct 1, 2017 All audits to be carried out to IATF 16949:2016 after this date

**Sept 14, 2018** Your transition must be complete

### Transition is an opportunity

- What do you need to do?
- 1. Take a completely fresh look at your QMS
- Attend our suite of transition training courses to understand the differences in more detail
- Highlight the key changes as an opportunity for improvement
- 4. Make changes to your documented system to reflect the additional requirement in the standard – a matrix to identify where in your QMS the requirement are covered is recommended
- 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

### Your transition journey

BSI has identified a step-by-step journey to help you through the transition and realize the benefits of the new IATF 16949:2016. 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, IATF 16949:2016 and the new scheme rules.

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.com/en-US including whitepapers which can help you understand the changes.

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



**Book a BSI transition training course** to make sure you fully understand the changes and core requirements.



**Start to revise your QMS** and perform an operational gap analysis to identify gaps and ensure your organization's QMS meets all the new requirements.



**Develop an implementation plan for your organization** and implement the changes. Consider other BSI services including business improvement software which may help with this.

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

Visit bsigroup.com/en-US

# Transition training from BSI

The BSI Training Academy will give you the skills and the knowledge to successfully transition to the new IATF 16949:2016 standard. Experts in their fields, our experienced instructors can help you get to grips with the new standard so you can be confident when you implement the changes in your organization.

#### IATF 16949:2016 transition training

Two-day classroom-based course

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

### IATF 16949:2016 Senior management briefing

Two hour face-to-face session

- Understand the purpose of ISO 9001:2015 and IATF 16949:2016 and the leadership responsibilities outlined in the standards
- Important for top management of organizations transitioning to IATF 16949:2016

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

### ISO 9001:2015 Transition

Two-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

Two-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 Deep dive

Two-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.
- These concepts are also relevant for IATF 16949:2016 so if you are involved in the transition this course may be useful to attend.

Find out more.

Call: **1-800-217-1390** 

Email: solutions.msamericas@

bsigroup.com.

or visit: bsigroup.com/en-US



### Additional resources

There are a variety of materials which can be accessed online at www.bsigroup.com/en-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.

### IATF 16949:2016 Frequently Asked Questions

Here we aim to address those initial questions that you may have as your 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 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.

#### **PLUS**:

- Old-to-new ISO 9001 Mapping Guide
- ISO 9001:2015 Self-assessment checklist
- IATF 16949:2015 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:

### 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 an IATF Contracted Certification Body since the conception of the TS standard. 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 centers 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 a range of services and differentiated management tools which help facilitate this process.



Find out more

Call: 1 800 862 4977 Visit: bsigroup.com/en-US