

YOU'RE CLOSER THAN YOU THINK

ISO 9001:2015 **READINESS CHECKLIST**



**“THE TRANSITION
MAY BE MORE
STRAIGHTFORWARD
THAN YOU THINK”**

– Deborah Cox, D&D Rail Ltd

Read the full case study at
www.sgs.co.uk/DandDRail

Feedback from customers that have completed their ISO 9001:2015 transition audit with SGS indicates that, for many, they were much closer to meeting the requirements of the new standard than they had initially thought. As a result of this feedback, we have developed a Readiness Checklist to outline the changes contained in ISO 9001:2015.

The checklist has been designed to help you to understand exactly what is required in simple terms and to highlight the areas where your business activities may already comply. Working through the Readiness Checklist will provide you with valuable insights and guidance on your next steps.

It is important to note, however, that the Readiness Checklist cannot count as evidence for your transition audit, as our auditors will have to confirm compliance with the standard during your transition audit visit.

SGS

HOW DOES THE CHECKLIST WORK?

This checklist breaks each part of the new ISO 9001:2015 requirements down by clause. During each section you will be asked whether you feel you have fulfilled key elements of the new criteria. You have the choice to mark your response as:

Ready – this indicates that you feel you are ready to demonstrate this, and you should look to transition during your next visit from SGS.

Nearly Ready – this indicates that, with guidance or support on this matter, you would be able to demonstrate this. We would recommend looking to transition during your next SGS visit.

Work To Do – this option means that there will need to be further preparation for your audit, or perhaps even training with the SGS Academy.

You can find the relevant **next steps** at the end of the checklist, where you should have a much better idea on how close you are to transitioning.

CLAUSE 4 - CONTEXT OF THE ORGANISATION

The 'context' of the organisation (sometimes called its business or organisational environment) refers to the combination of internal and external factors and conditions that can have an effect on your organisation's approach to its products, services and investments.

HAVE YOU CONSIDERED	READY	NEARLY READY	WORK TO DO
the external and internal context issues?			
products and services of your organisation?			
boundaries and/or limits on the applicability of your QMS?			
identifying, monitored and reviewed the relevant internal and external issues of your organisation to establish whether the impact of any changes to them will affect your QMS?			
identifying the 'interested parties' that are relevant to your QMS?			
identifying what requirements these interested parties themselves have, which are relevant to your organisation's QMS?			
continually monitoring and reviewing these interested parties?			
adopting a process approach when developing, implementing and improving the effectiveness of your QMS?			
establishing the scope of your QMS?			

CLAUSE 5 - LEADERSHIP

Your Top Management are now required to demonstrate a greater direct involvement in your organisation's QMS. The removal of the need for a specific 'Management Representative' is partly an attempt to ensure that 'ownership' of your organisation's QMS is not simply focused on an individual person. Although the requirements in relation to your organisation's Quality Policy are broadly the same as previous, there are some new elements that now requires that your organisation's quality policy is appropriate to both its purpose and its 'context'.

QUESTIONS	READY	NEARLY READY	WORK TO DO
Are Top Management involved in the QMS preparation and continued review?			
Do they ensure that the Quality Policy is communicated within your organisation and to relevant parties?			
Are responsibilities and authorities assigned and communicated by Top Management?			
Are these understood within your organisation?			

CAN TOP MANAGEMENT DEMONSTRATE THAT THEY	READY	NEARLY READY	WORK TO DO
have taken responsibility for emphasising the importance of conforming to the requirements of your QMS?			
ensure that the QMS is achieving its intended results?			
drive continual improvement within your organisation?			
promote the use of risk based thinking and customer focus?			

CLAUSE 6 - PLANNING

Your organisation is now required to consider both its **context** and **interested parties** when planning and implementing the QMS. You are required to identify those risks and opportunities that have the potential to impact (positively or negatively) on the operation and performance of your QMS. Although risks and opportunities have to be determined and addressed, there is no requirement for a formal, documented risk management process and you are free to choose the assessment and evaluation mechanism you consider most appropriate.

QUESTIONS	READY	NEARLY READY	WORK TO DO
Have you established measurable quality objectives at relevant functions and levels?			
Are they consistent with your organisation's quality policy?			
Are they established for relevant processes and are they relevant to the enhancement of customer satisfaction?			
Is your organisation's QMS maintained when any changes to it are planned and implemented?			
When carrying out the changes, is consideration taken into account of why the change is being made and any potential consequence of those changes?			
Have you identified that there are resources necessary to carry out the changes?			

CLAUSE 7 - RESOURCES

You now need to consider both internal and external resource requirements and capabilities to be able to meet customer, and statutory and regulatory requirements. Greater emphasis on monitoring and measuring 'resources' rather than simply equipment is now required.

QUESTIONS	READY	NEARLY READY	WORK TO DO
Have you determined and maintained the knowledge obtained by your organisation (including by your personnel) to ensure that it can achieve conformity of products and services?			
Can you demonstrate that you have determined the competency requirements for personnel and that personnel meet those competency requirements, or you take action to ensure that they acquire any identified competence?			

A new addition to these requirements is that they now apply not only to your employees but to any person outside of your organisation, including sub-contract/agency personnel, as well as anyone undertaking outsourced processes and functions.

QUESTIONS	READY	NEARLY READY	WORK TO DO
Have you retained documented information to demonstrate that all personnel under your control are competent?			
Are all personnel under your control aware both of your organisation's quality objectives as well as the consequences of non-conformance with your QMS requirements?			

FOR PERSONS OUTSIDE OF YOUR ORGANISATION, HAVE YOU IDENTIFIED	READY	NEARLY READY	WORK TO DO
what needs to be communicated?			
when it needs communicating?			
how it will be communicated?			
who will receive such communications?			

FYI

The terms **documented procedure** and **record** have both been replaced by the term **documented information**. You will need to determine the level of documented information necessary to control your QMS. Control of **access** to documented information is now a specific requirement and can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

CLAUSE 8 - OPERATIONS

You are now required to control not only implementation and planned changes to processes, but also to unintended, unplanned changes. Where unintended changes are made, you will have to demonstrate that you have identified any actual or potential adverse effects and have taken action to mitigate them.

CAN YOU	READY	NEARLY READY	WORK TO DO
Demonstrate that you have specific processes in place for establishing the requirements for the products and services you intend to offer to customers?			
Substantiate any claims you make in respect of the products and services you offer?			
Have you implemented a design process where requirements for your products and services have not been established or defined, to the extent that enables product/service provision to take place?			

You are now required to include 'information derived from previous similar designs' as design inputs as well as the potential consequences of failure due to the nature of your products and services, and any standard(s) or code(s) of practice that you are committed to implement.

QUESTIONS	READY	NEARLY READY	WORK TO DO
Have you taken a risk-based approach when determining the type and extent of controls to apply to your external providers of processes, products and service?			
Do you communicate to your external providers any 'competence' requirements which will apply to their personnel?			

For identification and traceability, the emphasis is now on 'process outputs' rather than products and are a result of any activities which are ready for delivery to your customer or to your internal customers.

QUESTIONS	READY	NEARLY READY	WORK TO DO
Can you identify, verify, protect and safeguard property belonging to any customer and/or external providers used by your organisation?			
Do you retain documented information on the release of products and services, verifying that they have met customer requirements and traceable to the person(s) authorising the release?			

FYI

Process outputs that do not conform to their requirements must be identified and controlled. You will have to retain documented information describing the nonconformity, the actions taken, any concessions obtained and identify the authority who decided the course of action taken.

CLAUSE 9 - PERFORMANCE EVALUATION

You will find requirements have been better defined in respect of when monitoring and measuring shall be performed and when the results shall be analysed and evaluated.

QUESTION	READY	NEARLY READY	WORK TO DO
Can you demonstrate that you have sought out information relating to how customers view your organisation as well as your products and services?			

There is no fundamental change in the approach to internal audits however, you are now required to report the 'results of audits' to the relevant management within your organisation.

FYI

The key requirements of the **Management Review** process remain as before but additional requirements relating to changes in external and internal issues relevant to your QMS, external provider and relevant interested party issues, and the effectiveness of actions taken to address any risks and/or opportunities have been included as inputs.

CLAUSE 10 - IMPROVEMENTS

This is a new section that emphasises the general need to improve processes, products and services, as well as QMS results, in order to meet customer requirements and enhance customer satisfaction.

QUESTION	READY	NEARLY READY	WORK TO DO
Can you demonstrate that you are actively looking for opportunities to improve your processes, products and services, as well as the performance of your QMS?			

There is now an additional requirement for you to address the **consequences** of nonconformities, which is a recognition that not all of its processes and/or activities will represent the same level of risk in terms of your organisation's ability to meet its objectives.

QUESTIONS	READY	NEARLY READY	WORK TO DO
Can you identify whether any non-conformity could also exist elsewhere within your processes, products, services and/or systems, or whether they could potentially happen elsewhere?			
Can you demonstrate that you are continually improving the adequacy, suitability and effectiveness of your QMS?			

YOUR NEXT STEP

Hopefully this ISO 9001:2015 Readiness Checklist has helped you to understand more about the changes of the new standard, and what is required from you to achieve a successful transition. Below is an indication of what your results indicate in terms of your next step.

If the majority (or all) of your answers have covered Ready (with Nearly Ready making up the minority):	If the majority of your answers are Nearly Ready , with a mix of Ready and Work to Do making up the minority:	If the majority of your answers are returning Work to Do , with the minority showing either Ready or Nearly Ready :
<p>Congratulations! You are ready to book your transition audit with SGS. This can be done by heading to www.sgs.co.uk/transition-options and completing the form to register your interest.</p> <p>Alternatively, please get in contact with your regional office, who will be able to help progress your transition.</p>	<p>In this instance, your organisation would benefit from a gap analysis to help identify the areas that need to be addressed and to provide practical ways in which this can be achieved.</p> <p>To do this, please contact your SGS Auditor or regional office directly.</p>	<p>It seems there is still some areas of the new standard that you are not quite up-to-date with yet, but this can be resolved in a variety of ways.</p> <ul style="list-style-type: none"> • SGS Academy – The SGS Academy host a variety of transition training courses. Aimed at organisations already certified to the previous version of ISO 9001, the transition courses last for one day and offer a time-efficient way of understanding the recent changes. • SGS Product Expert Consultation – Another way to increase your knowledge of the new standard is to schedule a consultation with one of our product experts over the phone. • Gap Analysis Audit – A gap analysis is a great method of identifying areas that need attention and understanding the ways in which they can be addressed.

RESOURCE MATERIAL TO HELP SUPPORT YOUR TRANSITION

The decision to book your transition audit should be a simple one, however aspects surrounding the publication of a new standard can seem daunting. SGS is committed to making the transition as easy as possible for our customers, and provide continuously updated information and resources at www.sgs.co.uk/transition-options.

There you can find:

- ISO 9001:2015 pitfalls booklet
- Transition webinars
- Client case studies
- FAQs

NOT AN SGS CUSTOMER?

If you would like to know how easy it is to transfer your certification to SGS, and how we can support you through your transition process, please contact our support team on Freephone

0800 900 094

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WHEN YOU NEED TO BE SURE

