



93% of organizations agree that QMS have been a significant driver of their success

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# HOW CAN YOU PREPARE FOR ISO 9001:2015?

ENHANCE YOUR TRANSITION WITH THIS READINESS CHECKLIST

**BE THE BENCHMARK**





**“THE  
TRANSITION  
MAY BE MORE  
STRAIGHT  
FORWARD  
THAN YOU  
THINK”**

Deborah Cox, D&D Rail Ltd

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 understand what is required and to highlight the areas where your business activities may already comply. Working through the Readiness Checklist will provide you with valuable insight and guidance on how you can begin your transition. 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. – Deborah Cox, D&D Rail Ltd  
Read the full case study at [www.sgs.com/DandDRail](http://www.sgs.com/DandDRail)

## HOW DOES THE CHECKLIST WORK?



### READY

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

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### 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.

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### WORK TO DO

This option means that you will need 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 ORGANIZATION

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

4. CONTEXT OF THE ORGANIZATION			
Have you considered	READY	NEARLY READY	WORK TO DO
The external and internal context issues?			
Products and services of your organization?			
Boundaries and/or limits on the applicability of your QMS?			
Identifying, monitoring and reviewing the relevant internal and external issues of your organization 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 organization’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 is now required to demonstrate a greater direct involvement in your organization’s QMS. The removal of the need for a specific ‘Management Representative’ is partly an attempt to ensure that ‘ownership’ of your organization’s QMS is not simply focused on an individual person. Although the requirements in relation to your organization’s Quality Policy are broadly the same as the previous version, there are some new elements that now require that your organization’s quality policy is appropriate to both its purpose and its ‘context’.

5. LEADERSHIP AND WORKER PARTICIPATION			
Questions	READY	NEARLY READY	WORK TO DO
Is top management involved in the QMS preparation and continued review?			
Do they ensure that the Quality Policy is communicated within your organization and to relevant parties?			
Are responsibilities and authorities assigned and communicated by top management?			
Are these understood within your organization?			
Can top management demonstrate that they			
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 organization?			
Promote the use of risk based thinking and customer focus?			



**CLAUSE 6 – PLANNING**

Your organization 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) 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.

<b>6. PLANNING</b>			
<b>Questions</b>	<b>READY</b>	<b>NEARLY READY</b>	<b>WORK TO DO</b>
Have you established measurable quality objectives at relevant functions and levels?			
Are they consistent with your organization’s quality policy?			
Are they established for relevant processes and are they relevant to the enhancement of customer satisfaction?			
Is your organization’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 – SUPPORT

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.

7. SUPPORT			
Questions	READY	NEARLY READY	WORK TO DO
Have you determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the EnMS and energy performance?			
Have you determined and maintained the knowledge obtained by your organization to ensure that your organization can control your energy performance and EnMS?			
There is now an additional requirement for you to address the consequences of non-conformities, which is a recognition that not all its processes and/or activities will represent the same level of risk in terms of your organization’s ability to meet its objectives.			
Questions			
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 organization’s quality objectives as well as the consequences of nonconformance with your QMS requirements?			
Questions			
What needs to be communicated?			
When it needs communicating?			
How will it be communicated?			
Who will receive such communications?			

### KEY NOTES

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 EnMS. 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 manage SEUs and implement action plans. It allows energy management (SEU) and energy performance improvement (action plans) to be linked to your organization’s business processes (competency, training, communication, operational controls, etc.).

8. OPERATIONS			
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 to the products and services you offer?			
Show a designed 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			
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			
Can you identify, verify, protect and safeguard property belonging to any customer and/or external providers used by your organization?			
Do you retain documented information on the release of products and services, verifying that they have met customer requirements and are traceable to the person(s) authorising the release?			

### KEY NOTES

**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 to when monitoring and measuring shall be performed and when the results shall be analysed and evaluated.

9. PERFORMANCE EVALUATION			
Question	READY	NEARLY READY	WORK TO DO
Can you demonstrate that you have sought out information relating to how customers view your organization, as well as your products and services?			
<p>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 organization.</p>			

### KEY NOTES

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 emphasizes the general need to improve processes, products and services, as well as QMS results, in order to meet customer requirements and enhance customer satisfaction.

10. IMPROVEMENTS			
Question	READY	NEARLY READY	WORK TO DO
Can you demonstrate that you are actively looking for opportunities to improve the performance of your EnMS?			
There is now an additional requirement for you to address the consequences of non-conformities, which is a recognition that not all its processes and/or activities will represent the same level of risk in terms of your organization’s ability to meet its objectives.			
Can you identify whether any non-conformity could also exist elsewhere within your facilities, equipment, systems and processes or whether they could potentially happen elsewhere?			
Can you demonstrate that you are continually improving the adequacy, suitability and effectiveness of your EnMS?			



## GETTING STARTED

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.

<b>IF THE MAJORITY (OR ALL YOUR ANSWERS ARE READY (WITH NEARLY READY MAKING UP THE MINORITY):</b>	<b>IF MAJORITY OF YOUR ANSWERS ARE NEARLY READY, WITH A MIX OF READY AND WORK TO DO MAKING UP THE MINORITY:</b>	<b>IF MAJORITY OF YOUR ANSWERS WORK TO DO, WITH THE MINORITY SHOWING EITHER READY OR NEARLY READY:</b>
<p>Congratulations! You are ready to book your transition audit with SGS. This can be done by emailing <a href="mailto:sustainable-development@sgs.com">sustainable-development@sgs.com</a></p>	<p>In this instance, your organization 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. To do this, please contact your SGS Auditor or local office directly.</p>	<p>It seems there are 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"> <li>• <b>SGS Academy</b> – SGS Academy hosts a variety of transition training courses. Aimed at organizations 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.</li> <li>• <b>SGS Product Expert Consultation</b> – Another way to increase your knowledge of the new standard is to schedule a consultation with one of our product experts over the phone.</li> <li>• <b>Gap Analysis Audit</b> – A gap analysis is a great method of identifying areas that need attention and understanding the ways in which they can be addressed.</li> </ul>

### 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 make the transition as easy as possible for our customers, and provide continuously updated information and resources on our website.

## CONTACT SGS

For an optimal transition towards ISO 9001:2015 contact:



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[www.sgs.com/iso9001-2015transition](http://www.sgs.com/iso9001-2015transition)



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WHEN YOU NEED TO BE SURE

