ISO 9001:2015 Quality Management Systems - The 2008-to-2015 Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating your Quality Management System (QMS) against the requirements of ISO 9001:2015. As you transition from ISO 9001:2008 to ISO 9001:2015 each requirement is expressed as a question that the user (auditor / assessor) can ask to evaluate your QMS capabilities. You will need to have copies of the ISO 9001:2015 and ISO 9001:2008 standards to use along with this checklist so that you can refer to the requirements if necessary.

While the two versions of the standard do not line up when comparing the requirements:

New requirements and / or new terminology are highlighted in yellow.

The intent of the main clauses of the new standard is shown in bold blue font.

The right hand column in green shade is intended to provide reference / comparison / similarities to the ISO 9001:2008 requirements, and to identify and locate where in the new clauses, the former requirements are relevant.

Comments highlighted in bold red font indicate removed / missing requirements.

After you have prepared an audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed. In the space for 'currently in place', list or reference the procedures or other documents, or evidence that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, that is, will they need to be revised for the new system, or can they be used as is? Also note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if documented information is in place and if procedures and processes are being complied with, compliance is not your main focus for this audit. Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with ISO 9001:2015.

ISO 9001:2015 Quality Management Systems - The 2008-to-2015 Gap Analysis Checklist

QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	If NO - % Complete	Items Needed	ISO 9001:2008 Requirements
4 CONTEXT OF THE ORGANIZATION					4.0 Quality management system
This clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the Quality Management System (QMS). In addition the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.					----
4.1 Understanding the organization and its context					----
Does your company determine the external and internal issues that are relevant to your purpose and strategic direction?					
Do you consider the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?					
Does your company monitor and review the information related to the external and internal issues?					
4.2 Understanding the needs and expectations of interested parties					----
With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable					

ISO 9001:2015 Quality Management Systems - The 2008-to-2015 Gap Analysis Checklist

_____

statutory and regulatory requirements, do you determine:					
The interested parties that are relevant to the QMS?					
The requirements of these interested parties that are relevant to the QMS?					
Does your company monitor and review the information about these interested parties and their relevant requirements?					
4.3 Determining the scope of the quality management system					4.1 General requirements
To establish the scope of the QMS, does your company determine the boundaries and applicability of the QMS?					4.2.2 a) The scope of the QMS is required in a quality manual
When determining the scope of the QMS, do you consider the:					
External and internal issues (per 4.1)?					
Requirements of relevant interested parties (per 4.2)?					
The products and services of your company?					
When a requirement of ISO 9001:2015 can be applied, is the requirement applied by your company?					

ISO 9001:2015 Quality Management Systems - The 2008-to-2015 Gap Analysis Checklist

When requirements cannot be applied, and in order to claim conformity to ISO 9001:2015, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected?					4.2.2 a) Justifications for exclusions are required to be included in the quality manual
Is the scope of the QMS available and maintained as documented information?					
Does the scope state the products and services covered by the QMS?					
Does your company provide justification for any instance where a requirement of the standard cannot be applied?					1.2 Application - Exclusions permitted with justifications for clause 7 only in ISO 9001:2008
4.4 Quality management system and its processes			----		
4.4.1 As required by the standard, do you establish, document, implement, maintain and continually improve the QMS?					4.1 Establish, document, implement and maintain a QMS and continually improve its effectiveness
Does your company determine the processes needed for the QMS, their interactions and applications throughout your company?					4.1 a) Determine the processes needed for the QMS and their application through out the organization
That is, for the QMS processes do you determine the :					
Inputs required and the outputs expected					