



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

1. PURPOSE

The purpose of this document is to detail the gaps between the superseded standard ISO 9001: 2008 and the current standard ISO 9001: 2015, to assist existing and potential clients assess their current Quality Management System and make the necessary changes to ensure that their systems are compliant.

2. DETAIL

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

3. THINGS NOT TO DO

While this checklist does provide a comprehensive checklist that covers the transition, the following needs to be noted.

Organization's do not need to:

- Remove their management representatives - While there is no requirement in ISO9001:2015 for a management representative, this does not prevent organizations from choosing to retain this role if they so wish. Be aware, however, that some of the duties traditionally assigned to the management representative by top management will, in future, need to be undertaken directly by top management themselves.
- Throw out their Quality Manuals and Documented Procedures.
- While 9001:2015 sets out no requirement for organizations to hold either a Quality Manual or Documented Procedures, if this documentation is in place, needed and working well, there is no need for it to be withdrawn.
- Renumber existing QMS documentation to correspond to the new clause references - Although organizations may choose to carry out a renumbering exercise, it is down to each to determine whether the benefits gained from renumbering will exceed the effort involved in actioning the change. However, reference needs to be made to compliance with 9001:2015, if the organization wishes to demonstrate compliance to this standard.
- Restructure their management systems to follow the sequence of requirements as set out in the ISO9001:2015. Providing all of the requirements contained in the Standard are met, the organizations system will be compliant.
- Refresh existing documentation to use the new terms and definitions contained within ISO 9001:2015. Once again, organizations are free to make the judgment as to whether this effort would be worthwhile. If organizations are more comfortable using their own terminology, e.g. "records" instead of "documented information", or "supplier" rather than "external provider" then this is perfectly acceptable.



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		
<p>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.</p>					----
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 statutory and regulatory requirements, do you determine:					



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
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

QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	If NO - % Complete	Items Needed	ISO 9001:2008 Requirements
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 throughout the organization
That is, for the QMS processes do you determine the:					



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
<ul style="list-style-type: none"> Inputs required and the outputs expected from the processes? 					
<ul style="list-style-type: none"> Sequence and interaction of the processes? 					4.1 b) Determine the sequence and interaction of the processes
<ul style="list-style-type: none"> Criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of the processes? 					4.1 c) Determine criteria and methods to ensure the operation and control of processes
<ul style="list-style-type: none"> Resources needed and ensure their availability? 					4.1 d) Ensure the availability of resources and information needed to support the operation and monitoring of processes
<ul style="list-style-type: none"> Assignment of the responsibilities and authorities for these processes? 					5.5.1 Ensure that responsibilities and authorities are defined and communicated
<ul style="list-style-type: none"> Risks and opportunities (per 6.1), and plans to implement the appropriate actions to address them? 					Risk management is not required in ISO 9001:2008.
<ul style="list-style-type: none"> Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results? 					4.1 e) Monitor, measure and analyze processes. 8.2.3 Apply suitable methods for monitoring and measuring of the QMS processes



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
<ul style="list-style-type: none"> Opportunities for improvement of the processes and the QMS? 					4.1 f) Implement actions to achieve planned results and continually improve processes
<p>Does your company maintain the necessary documented information to support the operation of processes?</p>					4.2.1 QMS documentation includes a) Documented statements for the quality policy and quality objectives b) Quality manual c) Documented procedures and record d) Documents and records required as necessary
A quality manual is removed as a requirement from clause 7.5.1 of ISO 9001:2015.					
Throughout ISO 9001:2015, documents and records are replaced with the term documented information.					
4.4.2 Does your company retain the necessary documented information to provide the confidence that the processes are being carried out as planned?					4.2.4 Records to provide evidence of conformity are controlled
5 LEADERSHIP			5.0 Management Responsibility		
<p>This clause requires that your top management demonstrates leadership and commitment with respect to the QMS. In addition, top management is required to demonstrate leadership and commitment with respect to customer focus. This section also asks top management to establish, implement and maintain a quality policy that is appropriate to your company and to ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood.</p>					----



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
5.1 Leadership and commitment					5.1 Management commitment
5.1.1 General					----
Does top management demonstrate leadership and commitment with respect to the QMS by:					5.1 Top management provide evidence of its commitment to the QMS and continually improving
<ul style="list-style-type: none"> • Taking accountability of the effectiveness of the QMS? 					
<ul style="list-style-type: none"> • Ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the strategic direction and the context of the organization? 					5.1 b) Establish the quality policy 5.4.1 Establish quality objectives at relevant functions and levels
<ul style="list-style-type: none"> • Ensuring that the quality policy is communicated, understood and applied within the company? 					5.3 d) Ensure the quality policy is communicated
<ul style="list-style-type: none"> • Ensuring the integration of the QMS requirements into the company's business processes? 					
<ul style="list-style-type: none"> • Promoting awareness of the process approach? 					0.2 Promote the adoption of the process approach for the QMS
<ul style="list-style-type: none"> • Ensuring that the resources needed for the QMS are available? 					5.1 e) Ensuring the availability of resources



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
<ul style="list-style-type: none"> Communicating the importance of effective quality management and of conforming to the QMS requirements? 					5.1 a) Communicating the importance of meeting customer and statutory and regulatory requirements
<ul style="list-style-type: none"> Ensuring that the QMS achieves its intended results? 					5.1 d) Conduct management reviews
<ul style="list-style-type: none"> Engaging, directing and supporting persons to contribute to the effectiveness of the QMS? 					6.2.2 d) Ensure that personnel are aware of how they contribute to the quality objectives
Promoting continual improvement?					8.5.1 Continually improve the effectiveness of the QMS
<ul style="list-style-type: none"> Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility? 					
5.1.2 Customer focus			5.2 Customer focus		
Does top management demonstrate leadership and commitment with respect to customer focus by ensuring that the:					
<ul style="list-style-type: none"> Customer requirements and applicable statutory and regulatory requirements are determined and met? 					5.2 Top management ensure that customer requirements are determined and met to enhance customer satisfaction



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
<ul style="list-style-type: none"> Risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed? 					Risk management is not required in ISO 9001:2008.
<ul style="list-style-type: none"> Focus on consistently providing products and services that meet customer and applicable statutory and regulatory requirements are maintained? 					5.1 a) Communicating the importance of meeting customer, statutory and regulatory requirements
<ul style="list-style-type: none"> Focus on enhancing customer satisfaction is maintained? 					5.2 Top management aim at enhancing customer satisfaction
5.2 Policy			5.3 Quality policy		
5.2.1 Developing the quality policy			----		
Has your top management established, implemented and maintained a quality policy that:					5.3 Top management ensure that the quality policy
<ul style="list-style-type: none"> Is appropriate to the purpose and context of the organization? 					5.3 a) Is appropriate to the purpose of the organization 5.3 e) Is reviewed for continuing suitability
<ul style="list-style-type: none"> Provides a framework for setting and reviewing quality objectives? 					5.3 c) Provides a framework for quality objectives
<ul style="list-style-type: none"> Includes a commitment to satisfy applicable requirements? 					5.3 b) Includes a commitment to comply with requirements



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
<ul style="list-style-type: none"> Includes a commitment to continual improvement of the QMS? 					5.3 b) Includes a commitment to continually improve the QMS
5.2.2 Communicating the quality policy		----			
Is your quality policy:					
<ul style="list-style-type: none"> Communicated, understood and applied within your company? 					5.3 d) Is communicated and understood
<ul style="list-style-type: none"> Available as documented information? 					4.2.1 a) Documented statement of quality policy-
<ul style="list-style-type: none"> Available to relevant interested parties? 					
		<p style="color: red;">Missing in clause 5.2 of ISO 9001:2015 is the requirement in clause 5.3 e to ensure that the quality policy is reviewed for continuing suitability.</p>			
5.3 Organizational roles, responsibilities and authorities		5.5 Responsibility, authority and communication			
----		5.5.1 Responsibility and authority			
Does the top management ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the company?					5.5.1 Top management ensure that responsibilities and authorities are defined and communicated
Does top management assign the responsibility and authority for:					5.5.2 Top management appoint a management representative



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
<ul style="list-style-type: none"> Ensuring that the QMS conforms to the requirements of ISO 9001:2015 standard? 					4.1 Processes managed in accordance with the requirement of the international standard
<ul style="list-style-type: none"> Ensuring that the processes are delivering their intended outputs? 					5.5.2 a) Ensuring that processes for the QMS are established, implemented and maintained – through the management representative
<ul style="list-style-type: none"> Reporting on the performance of the QMS on opportunities for improvement and for reporting to top management? 					5.5.2 b) Reporting to top management on the performance of the QMS and the need for improvement – through the management representative
<ul style="list-style-type: none"> Ensuring the promotion of customer focus throughout your company? 					5.5.2 c) Ensuring The promotion of customer awareness – through the management representative
<ul style="list-style-type: none"> Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented? 					5.4.2 b) Integrity of the QMS is maintained when changes are planned and implemented
The appointment of a management representative is removed as a requirement in clause 5.5.2 of ISO 9001:2015.					
6 PLANNING			5.4 Planning		
<p>This clause talks about the planning for the QMS, where your company needs to consider the issues referred to in 4.1, the requirements of 4.2 and determine the risks and opportunities that need to be addressed. In addition, this section covers the quality objectives that will need to be established for the relevant functions and the plans to achieve them</p>					----



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
determined. You will also need to carry out changes in a planned and systematic manner when it is determined that change to the QMS is required.					
6.1 Actions to address risks and opportunities			----		
----			5.4.2 Quality management system planning		
6.1.1 When planning for the QMS, does your company consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed?					5.4.2 a) Top management ensure the planning is carried out in order to meet the requirements
Is this performed to:					
<ul style="list-style-type: none"> Give assurance that the QMS can achieve its intended results? 					
<ul style="list-style-type: none"> Enhance desirable effects? 					
<ul style="list-style-type: none"> Prevent, or reduce undesired effects? 					
<ul style="list-style-type: none"> Achieve improvement? 					
<ul style="list-style-type: none"> Does the company plan: 					
<ul style="list-style-type: none"> Actions to address these risks and opportunities? 					



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
<ul style="list-style-type: none"> How to integrate, implement the actions into the QMS processes and evaluate the effectiveness of these actions? 					
6.1.2 Do you take actions to address risks and opportunities that are proportionate to the potential impact on the conformity of products and services?					
6.2 Quality objectives and planning to achieve them					5.4.1 Quality objectives
6.2.1 Does your company establish quality objectives at relevant functions, levels and processes?					5.4.1 Top management ensure that quality objectives are established at relevant functions
Do you consider the following:					
<ul style="list-style-type: none"> Are the quality objectives consistent with the quality policy? 					5.4.1 Quality objectives consistent with the quality policy
<ul style="list-style-type: none"> Are the objectives measurable? 					5.4.1 Quality objectives measurable
<ul style="list-style-type: none"> Do they take into account applicable requirements? 					
<ul style="list-style-type: none"> Are they relevant to conformity of products and services and the enhancement of customer satisfaction? 					



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
• Are they monitored; communicated, and updated as required?					
Do you retain documented information for the quality objectives?					
6.2.2 When planning how to achieve the quality objectives, does your company determine:					
• What will be done?					
• What resources will be required?					
• Who will be responsible?					
• When it will be completed?					
• How the results will be evaluated?					
6.3 Planning of changes					5.4.2 Quality management system planning
When your company determines the need for changes to the QMS, do you carry out the changes in a planned and systematic manner?					5.4.2 a) Planning of the QMS is carried out to meet requirements 5.4.2 b) Integrity of QMS is maintained
Do you consider the:					
• Purpose of the change and any of its potential consequences?					



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
• Integrity of the QMS?					
• Availability of resources?					
• Allocation or reallocation of responsibilities and authorities?					
7 SUPPORT	6.0 Resource management				
<p>This clause requires that your company determine and provide the resources needed to establish, implement, maintain and continually improve the QMS. This section covers the resources that support the QMS and include people, infrastructure, environment for the operation of processes, monitoring and measuring resources, and organizational knowledge. In addition, competence, awareness of the human resources / personnel and methods for communication among the personnel along with systems for documented information need to be determined.</p>					----
7.1 Resources	6.1 Provision of resources				
7.1.1 General	----				
Does your company determine and provide the resources needed to establish, implement, maintain and continually improve the QMS?					6.1 Provide resources needed to 6.1 a) Implement and maintain the QMS 6.1 b) Resources to enhance customer satisfaction
	<p>Missing in clause 7.1.1 of ISO 9001:2015 is the requirement (6.1 b) to provide resources to enhance customer satisfaction.</p>				
Do you consider:					



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
<ul style="list-style-type: none"> The capabilities of, and constraints on, existing internal resources? 					
<ul style="list-style-type: none"> What needs to be obtained from external providers? 					
7.1.2 People	6.2 Human resources				
To ensure that your company can consistently meet customer and applicable statutory and regulatory requirements, do you determine and provide the persons necessary for the effective operation of the QMS, including the processes needed?					6.2.1 General Personnel performing work affecting conformity are competent
7.1.3 Infrastructure	6.3 Infrastructure				
To achieve conformity of products and services, does your company determine, provide and maintain the infrastructure for the operation of the processes?					6.3 Infrastructure Determine, provide and maintain the infrastructure
Is the following considered as infrastructure:					
<ul style="list-style-type: none"> Buildings and associated utilities? 					6.3 a) Buildings, workspace, utilities
<ul style="list-style-type: none"> Equipment including hardware and software? 					6.3 b) Process equipment
<ul style="list-style-type: none"> Transportation? 					8.3 c) Supporting services



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
<ul style="list-style-type: none"> Information and communication technology? 					8.3 c) Supporting services
7.1.4 Environment for the operation of processes			6.4 Work environment		
Does your company determine, provide and maintain the environment necessary for the operation of the processes and to achieve conformity of products and services?					6.4 Determine and manage the work environment needed to achieve conformity to product requirements
For the environment for the operation of processes, do you consider the applicable physical, social, and psychological factors?					6.4 Note - Work environment relates to conditions under which work is performed including factors such as noise, temperature, humidity, lighting or weather
7.1.5 Monitoring and measuring resources			7.6 Control of monitoring and measuring equipment		
7.1.5.1 General			-----		
When measuring or monitoring is used for evidence of conformity of products and services, does your company determine the resources needed to ensure valid and reliable monitoring and measuring results?					7.6 Determine the monitoring and measurement to be undertaken and the equipment needed to provide evidence of conformity
Do you ensure that resources provided are:					
<ul style="list-style-type: none"> Suitable for the type of monitoring and measurement activities being undertaken? 					7.6 Establish processes to ensure that monitoring and measurement can be carried out



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
<ul style="list-style-type: none"> Maintained to ensure their continued fitness for their purpose? 					7.6 b) Adjusted or readjusted as necessary. 7.6 e) Protected from damage and deterioration during handling, maintenance and storage
What documented information does your company retain as evidence of fitness for purpose of monitoring and measurement resources?					7.6 Records of the results of calibration and verification maintained
7.1.5.2 Measurement traceability			-----		
When measurement traceability is a requirement, such as with a statutory or regulatory requirement; a customer or relevant interested party expectation; or considered by your company to be an essential part of providing confidence in the validity of measurement results, do you manage the measuring instruments as follows:					7.6 Where necessary to ensure valid results, the measuring equipment is:
<ul style="list-style-type: none"> Verified or calibrated at specified intervals or prior to use against measurement standards traceable to international or national measurement standards. 					7.6 a) Calibrated or verified against standards traceable to international or national standards
<ul style="list-style-type: none"> Where no such standards exist, do you retain documented information for the basis used for calibration or verification? 					7.6 a) Where no such standards exist, the basis used for calibration or verification is recorded
<ul style="list-style-type: none"> Identified in order to determine their calibration status? 					7.6 c) Identification to determine calibration status



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
<ul style="list-style-type: none"> Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results? 					7.6 d) Safeguarded from adjustments that invalidate results
When an instrument is found to be out of calibration, does your company determine if the validity of previous measurement results has been adversely affected					7.6 Assess and record validity of prior measuring results when equipment is found not to conform to requirements
Do you take corrective action in such cases?					7.6 Take action on the equipment and any product affected
					7.6 Ability of computer software is confirmed and is required prior to initial use and reconfirmed as needed. Note - Confirmation include its verification and configuration management to maintain its suitability for use
	Missing in clause 7.1.5 of ISO 9001:2015 is the requirement in 7.6 that, when used for monitoring and measurement, the ability of computer software to satisfy the intended application is confirmed and is required prior to initial use and reconfirmed as needed.				
	Missing in clause 7.1.5 of ISO 9001:2015 is the note to clarify that confirmation of ability to satisfy intended application would include its verification and configuration management to maintain its suitability for use.				
7.1.6 Organizational knowledge					----



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
Does your company determine the knowledge necessary for the operation of the processes and to achieve conformity of products and services?					6.2.2 a) Determine necessary competence of personnel performing work affecting conformity to requirements
Is this knowledge maintained and made available as necessary?					
When addressing changing needs and trends, does your company consider its current knowledge and determine how to acquire or access the necessary additional knowledge?					
For organizational knowledge do you consider information such as intellectual property and lessons learned?					
To obtain needed knowledge, do you consider:					
<ul style="list-style-type: none"> Internal sources, such as learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the company? 					
<ul style="list-style-type: none"> External sources, such as standards, academia, conferences, gathering knowledge with customers or providers? 					
7.2 Competence					6.2 Human resources



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
----					6.2.1 General
----					6.2.2 Competence, training and awareness
Does your company determine the necessary competence of the personnel doing work that affects quality performance?					6.2.2 a) Determine necessary competence for personnel performing work affecting conformity to requirements
Do you ensure that these persons are competent on the basis of appropriate education, training, or experience?					6.2.1 Personnel performing work affecting conformity to requirements competent on basis of education, training, skills and experience
Does your company take actions to acquire the necessary competence?					8.2.2 b) Provide training or take other actions to achieve needed competence
Do you consider, for example, the provision of training to, the mentoring of, or the re assignment of employees, or the hiring or contracting of competent persons, as relevant actions?					
Do you evaluate the effectiveness of the actions taken?					6.2.2 c) Evaluate the effectiveness of action taken
Does your company retain documented information as evidence of competence?					6.2.2 e) Maintain records of education, training, skills and experience
7.3 Awareness					6.2.2 Competence, training and awareness



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
Does your company ensure that personnel performing work under your control are aware of:					
<ul style="list-style-type: none"> The quality policy and the relevant quality objectives? 					6.2.2 d) Ensure that personnel are aware of how they contribute to the quality objectives
<ul style="list-style-type: none"> Their contribution to the effectiveness of the QMS, including the benefits of improved quality performance? 					6.2.2 d) Ensure that personnel are aware of the importance of their activities
<ul style="list-style-type: none"> The implications of not conforming to the QMS requirements? 					
7.4 Communication					5.5.3 Internal communication
Does your company determine the internal and external communications relevant to the QMS that include:					5.5.3 Ensure communication processes are established and take place regarding the effectiveness of the QMS
<ul style="list-style-type: none"> On what it will communicate? 					
<ul style="list-style-type: none"> When to communicate? 					
<ul style="list-style-type: none"> With whom to communicate? 					
<ul style="list-style-type: none"> How to communicate? 					
7.5 Documented information					4.2 Documentation requirements



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
7.5.1 General			4.2.1 General		
Does your QMS include:					
<ul style="list-style-type: none"> Documented information required by the ISO 9001:2015 standard? 					4.2.1 a) Documented statements of a quality policy and quality objectives 4.2.1 b) Quality manual 4.2.1 c) Documented procedures and records required by the standard
<ul style="list-style-type: none"> Documented information determined by your company as necessary for the effectiveness of the QMS? 					4.2.1 d) Documents and records determined to be needed to ensure the effective planning, operation and control of processes
----			4.2.2 Quality manual		
					4.2.2 Maintain a quality manual that includes a) the scope and justification for exclusions, b) Documented procedures for the QMS, c) description of the process interactions
A quality manual is not a mandatory requirement in clause 7.5.1 of ISO 9001:2015					
For the documented information of the QMS, do you consider the:					4.2.1 Note 1 - Documented procedure means that a procedure s established, documented, implemented and maintained



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
<ul style="list-style-type: none"> Size of your company and the type of activities, processes, products and services? 					4.2.1 Note 2 - Extent of documentation depends on size and type of activities
<ul style="list-style-type: none"> Complexity of processes and their interactions? 					4.2.1 Note 2 - Extent of documentation depends on complexity of processes and their interactions
<ul style="list-style-type: none"> Competence of personnel? 					4.2.1 Note 2 - Extent of documentation depends on competence of personnel
7.5.2 Creating and updating			----		
When creating and updating documented information does the company ensure::					
Identification and description, such as a title, date, author, or reference number?					4.2.3 c) Ensure changes and revision status are Identified
<ul style="list-style-type: none"> Format, such as language, software version, graphics and media, such as paper, electronic? 					4.2.1 Note 3 - Documentation can be in any form or type of medium
<ul style="list-style-type: none"> Review and approval for suitability and adequacy? 					4.2.3 a) Approve documents for adequacy prior to issue
7.5.3 Control of documented Information			4.2.3 Control of documents		
-----			4.2.4 Control of records		
In ISO 9001:2015 documents and records are replaced with documented information.					



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
	Removed from clause 7.5.3 of ISO 9001:2015 is the requirement for a documented procedure for 4.2.3, Control of records.				
7.5.3.1 Do you control the documented information required by the QMS and by ISO 9001:2015 to ensure that it is:					4.2.3 Documents required by the QMS controlled with 4.2.4 4.2.3 Documented procedure established to define controls 4.2.4 Documented procedure to define controls of records
	Removed from clause 7.5.3 of ISO 9001:2015 is the requirement for a documented procedure for 4.2.4, Control of documents.				
<ul style="list-style-type: none"> Available and suitable for use, where and when it is needed? 					4.2.3 d) Ensure relevant versions of documents are available at points of use
<ul style="list-style-type: none"> Adequately protected, such as from loss of confidentiality, improper use, or loss of integrity? 					4.2.3 e) Ensure documents remain legible and readily identifiable
7.5.3.2 For the control of documented information, does your company address the following:					
<ul style="list-style-type: none"> Distribution, access, retrieval and use? 					4.2.3 d) Ensure relevant versions of documents are available at points of use
<ul style="list-style-type: none"> Storage and preservation, including preservation of legibility? 					4.2.4 Documented procedure to define controls for the identification, storage, protection, retrieval, retention and



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
					disposition of records 4.2.4 Records remain legible, identifiable and retrievable
<ul style="list-style-type: none"> Control of changes (e.g. version control)? 					4.2.3 b) Review and update as needed and re-approve documents 4.2.3 d) Ensure relevant versions of documents are available at points of use 4.2.3 g) Prevent the unintended use of obsolete documents and identified if they are retained
	Missing in clause 7.5.3 of ISO 9001:2015 is a requirement (4.2.3 b) to ensure the update and re-approval of documents.				
	Missing in ISO 9001:2015 is a requirement (4.2.3 g) to ensure that obsolete documents are prevented from unintended use.				
<ul style="list-style-type: none"> Retention and disposition? 					4.2.4 Documented procedure to define controls for the identification, storage, protection, retrieval, retention and disposition of records
Does your company identify and control the documented information from external origin and determined by your company to be necessary for the planning and operation of the QMS?					4.2.3 f) Ensure that documents of external origin needed for the planning of the QMS are identified and distributed
8 OPERATION			7.0 Product realization		
This clause requires that your company plan, implement and control the processes required for the QMS and to implement the actions to address risks and opportunities associated with them. Operational planning and control include					----



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
<p>systems for customer related processes, design and development, control of external providers, control of production and service provision, and including identification and traceability, preservation of products, and control of nonconforming outputs.</p>					
<p>8.1 Operational planning and control</p>			<p>7.1 Planning of product realization</p>		
<p>Does your company plan, implement and control the processes needed to meet requirements for the provision of products and services and to implement the actions to address risks and opportunities by:</p>					<p>7.1 Plan and develop the processes for product realization Planning of product realization consistent with other processes and determines:</p>
<ul style="list-style-type: none"> Determining requirements for the product and services? 					<p>7.1 a) Quality objectives and requirements of products</p>
<ul style="list-style-type: none"> Establishing criteria for the processes and for the acceptance of products and services? 					<p>7.1 c) Test activities specific to the product and the criteria for acceptance</p>
<ul style="list-style-type: none"> Determining the resources needed to achieve conformity to product and service requirements? 					<p>7.1 b) Establish processes and documents and provide resources</p>
<ul style="list-style-type: none"> Implementing control of the processes in accordance with the criteria? 					<p>7.1 c) Required verification activities & criteria for acceptance</p>
<ul style="list-style-type: none"> Retaining documented information to provide the confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements? 					<p>7.1 d) Records needed to provide evidence of meeting requirements</p>



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
Do you provide the output of the planning in a format that is suitable to your operations?					7.1 Output of planning in a suitable format. Note 1 – Documents for quality plan. Note 2 - Requirements of design and development (7.3) may be applied to the development of product realization processes
	Missing in clause 8.1 of ISO 9001:2015 is the note 1 that defines quality plans.				
	Missing in clause 8.1 of ISO 9001:2015 is the note 2 where requirements of design and development may be applied to the development of production processes.				
Does your company control planned changes and review the consequences of unintended changes?					
When required, do you take action to mitigate any adverse effects?					
Does your company ensure that outsourced processes are controlled in accordance with clause 8.4)?					4.1 Outsourced processes that affect product conformity are controlled. The type and extent of control applied to outsourced processes defined within the QMS
8.2 Requirements for products and services			7.2 Customer related processes		
8.2.1 Customer communication			7.2.3 Customer communication		



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
Does your company establish the processes for communicating with customers in relation to:					7.2.3 Determine and implement means of communicating with customers in relation to:
<ul style="list-style-type: none"> Information relating to products and services? 					7.2.3 a) Product information
<ul style="list-style-type: none"> Enquiries, contracts or order handling, including changes? 					7.2.3 b) Enquiries, contracts, orders, amendments
<ul style="list-style-type: none"> Obtaining customer feedback, including customer complaints (9.1.2)? 					7.2.3 c) Customer feedback and complaints
<ul style="list-style-type: none"> The handling or treatment of customer property, when applicable (per 8.5.3)? 					7.5.4 Exercise care with customer property
<ul style="list-style-type: none"> Specific requirements for contingency actions, when relevant? 					
8.2.2 Determining the requirements related to products and services			7.2.1 Determination of requirements related to the product		
Does your company establish, implement and maintain a process to determine the requirements for the products and services to be offered to customers?					7.2.1 Determine requirements, 7.2.2 Review requirements, 7.2.3 Customer communication
Do you ensure that product and service requirements (including those considered necessary by your company), and applicable statutory and regulatory requirements, are defined?					7.2.1 a) Determine customer requirements including post-delivery activities 7.2.1 b) Determine not stated requirements 7.2.1 c) Determine statutory and



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
					regulatory requirements 7.2.1 d) Determine any other necessary requirements
Do you ensure that your company has the ability to meet the defined requirements and substantiate the claims for the products and services offered?					Ability to meet requirements as reviewed in 7.2.2 c)
8.2.3 Review of requirements related to products and services			7.2.2 Review of requirements related to the product		
8.2.3.1 To ensure that you have the ability to meet requirements, does your company review:					7.2.2 Review requirements prior to the commitment to supply a product to the customer. and ensure that:
<ul style="list-style-type: none"> Requirements specified by the customer, including the requirements for delivery and post-delivery activities (8.5.5)? 					7.2.2 a) Product requirements are defined 7.2.1 a) Delivery and post-delivery activities are determined
<ul style="list-style-type: none"> Requirements not stated by the customer, but necessary for the customers' specified or intended use, when known? 					Requirements not stated as determined in 7.2.1 b)
<ul style="list-style-type: none"> Requirements specified by your company? 					
<ul style="list-style-type: none"> Additional statutory and regulatory requirements applicable to the products and services? 					Statutory & regulatory requirements as determined in 7.2.1 c)
<ul style="list-style-type: none"> Contract or order requirements differing from those previously expressed? 					7.2.2 b) Contract or order requirements differing from previous requirements



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
Do you conduct the review prior to your company's commitment to supply products and services to the customer?					7.2.2 Review conducted prior to commitment to supply a product
Does the review ensure that contract or order requirements differing from those previously defined are resolved?					7.2.2 b) Contract or order requirements differences resolved
When the customer does not provide a documented statement of their requirements, do you confirm the customer requirements before accepting an order?					7.2.2 Where no customer documented statement is provided, requirements confirmed before acceptance
8.2.3.2 Does your company retain documented information describing the results of the review, including any new or changed requirements for the products and services?					7.2.2 Records of results of reviews and actions taken maintained
8.2.4 Changes to requirements for products and services			----		
When requirements for products and services are changed, does your company ensure that relevant documented information is amended?					7.2.2 When product requirements are changed ensure that relevant documents are amended
Do you make the relevant personnel aware of the changed requirements?					7.2.2 Personnel made aware of changes. Note – Impractical reviews for situations such as internet sales
<p>Missing in clause 8.2.3 of ISO 9001:2015 is the note to clarify situations such as internet sales and product information through catalogues and advertising materials.</p>					



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
8.3 Design and development of products and services					7.3 Design and development
8.3.1 General					----
Has your company established, implemented, and maintained a design and development process to ensure the subsequent provision of products and services?					----
8.3.2 Design and development planning					7.3.1 Design and development planning
In determining the stages and controls for design and development, does your company consider the:					7.3.1 Plan and control design and development of product and determine a, b, c below:
<ul style="list-style-type: none"> Nature, duration and complexity of the design and development activities? 					
<ul style="list-style-type: none"> Requirements that specify particular process stages, including applicable design and development reviews? 					7.3.1 a) Design and development stages
<ul style="list-style-type: none"> Required design and development verification and validation? 					7.3.1 b) Review, verification and validation appropriate to each stage
<ul style="list-style-type: none"> Responsibilities and authorities involved in the design and development process? 					7.3.1 c) Responsibilities and authorities for design and development



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
<ul style="list-style-type: none"> Internal and external resources needed for the design and development process? 					
<ul style="list-style-type: none"> Need to control interfaces between individuals and parties involved in the design and development process? 					7.3.1 Manage the interfaces between the groups involved for effective communication and clear responsibilities
<ul style="list-style-type: none"> Need for involvement of customer and user groups in the design and development process? 					7.3.4 Participants in design and development reviews include representatives from concerned functions.
<ul style="list-style-type: none"> Requirements for subsequent provision of products and services? 					
<ul style="list-style-type: none"> Level of control expected by customers or other interested parties? 					
<ul style="list-style-type: none"> Necessary documented information to confirm that design and development requirements have been met? 					7.3.1 Planning output updated as the design progresses
8.3.3 Design and development Inputs			7.3.2 Design and development Inputs		
Does your company determine the:					7.3.2 Inputs to be determined and records maintained and include:
<ul style="list-style-type: none"> Requirements essential for the specific type of products and services being designed and developed, including, as required, functional and performance requirements? 					7.3.2 a) Functional and performance requirements



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
• Applicable statutory and regulatory requirements?					7.3.2 b) Applicable statutory and regulatory requirements
• Information derived from previous similar design and development?					7.3.2 c) Information derived from previous similar designs
• Standards or codes of practice that your company is committed to implement?					7.3.2 d) Other requirements essential for design and development
• Internal and external resource needs for the design and development of products and services?					.7.3.2 d) Other essential requirements
• Potential consequences of failure due to the nature of the products and services?					.7.3.2 d) Other essential requirements
• Level of control expected of the design and development process by customers and other relevant interested parties?					7.3.2 d) Other essential requirements
Do you ensure that the inputs for design and development purposes are complete and not ambiguous and resolve conflicts in inputs?					7.3.2 Inputs reviewed for adequacy. Requirements to be complete, not ambiguous and not in conflict with each other
Has your company retained documented information on design and development inputs?					7.3.2 Inputs to be determined and records maintained.
8.3.4 Design and development controls					----



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
----					7.3.4 Design and development review
----					7.3.5 Design and development verification
----					7.3.6 Design and development validation
Do the controls you apply to the design and development process ensure that the:					----
<ul style="list-style-type: none"> Results to be achieved by the design and development activities are clearly defined? 					As determined in 7.3.2 a)
<ul style="list-style-type: none"> Design and development reviews are conducted as planned to evaluate the ability of results of design and development to meet requirements? 					7.3.4 Design and development review at suitable stages. 7.3.4 a) reviews to evaluate ability of results to meet requirements.
<ul style="list-style-type: none"> Verification is conducted to ensure that the design and development outputs have met the design and development input requirements? 					7.3.5 Verification performed to ensure that the outputs meet the design and development inputs
<ul style="list-style-type: none"> Validation is conducted to ensure that the resulting products and services are capable of meeting the requirements for the specified application or intended use? 					7.3.6 Validation performed to ensure that the product is capable of meeting requirements & intended use. 7.3.6 Validation performed prior to delivery or implementation
<ul style="list-style-type: none"> Necessary actions taken on problems determined during the reviews, verifications, validations? 					7.3.4 b) for the reviews to identify problems and actions.



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
Do you retain documented information on design and development control activities?					
As suitable to your products and services, how do you conduct reviews, verifications, and validations? Are those activities conducted separately or in combination?					
Missing in clause 8.3.4 of ISO 9001:2015 is a requirement that, when practical, validation be performed prior to the delivery or implementation of the product.					
8.3.5 Design and development outputs			7.3.3 Design and development outputs		
Does your company ensure that design and development outputs:					7.3.3 Design and development outputs in a form suitable for verification and development input approved prior to release
<ul style="list-style-type: none"> Meet the input requirements for design and development? 					7.3.3 a) Meet input requirements for design and development
<ul style="list-style-type: none"> Are adequate for the subsequent processes for the provision of products and services? 					7.3.3 b) Provide information for purchasing, production and service provision and preservation of product
<ul style="list-style-type: none"> Include or reference monitoring and measuring requirements, and acceptance criteria, as applicable? 					7.3.3 c) Contain product acceptance criteria



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
<ul style="list-style-type: none"> Specify product or service characteristics essential for their intended purpose and their safe and proper provision? 					7.3.3 d) Specify characteristics for safe and proper use. 7.3.3 Note – Information can include details for preservation of product
	Missing in clause 8.3.5 of ISO 9001:2015 are requirements that outputs be in a form suitable for verification, and that development inputs be approved prior to release.				
	Missing in clause 8.3.5 of ISO 9001:2015 is the note that design and development output can include information and details for preservation of product.				
Does your company retain the documented information on the design and development outputs?					7.3.2 Records of inputs maintained 7.3.4 Records of results of reviews and actions taken maintained 7.3.5 Records of results of verification maintained 7.3.6 Records of results of validation maintained
8.3.6 Design and development changes			7.3.7 Control of design and development changes		
Does your company review control and identify changes made during, or subsequent to the design and development of products and services ?					7.3.7 Design and development changes identified and records maintained
Do you review, control and identify the changes to ensure that there are no adverse impacts on conformity to requirements?					7.3.7 Changes reviewed, verified, validated and approved before implementation



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
					7.3.7 Review includes evaluation of the changes on constituent parts
Have you retained documented information on: <ul style="list-style-type: none"> • Design and development changes? • Results of reviews? • Authorization of changes? • Actions taken to prevent adverse impacts? 					7.3.7 Records of results of review of changes and actions taken are maintained
	Missing in clause 8.3.6 of ISO 9001:2015 is a requirement for the evaluation of the effect of change on constituent parts and products already delivered.				
8.4 Control of externally provided processes, products and services				7.4 Purchasing	
8.4.1 General				7.4.1 Purchasing process	
Does your company ensure that externally provided processes, products, and services conform to specified requirements?					7.4.1 Ensure that purchased product conforms to specified purchase requirements
Do you apply the specified requirements for the control of externally provided products and services when:					
<ul style="list-style-type: none"> • Products and services are provided by external providers for incorporation into your own products and services? 					



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
<ul style="list-style-type: none"> • Products and services are provided directly to the customer(s) by external providers on behalf of your company? 					
<ul style="list-style-type: none"> • A process or part of a process is provided by an external provider as a result of your decision to outsource a process or function? 					
Do you establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with specified requirements?					7.4.1 Evaluate and select suppliers based on their ability to supply product to requirements Criteria for selection, evaluation, and re-evaluation are established
Does your company retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers?					7.4.1 Records of results of evaluations and actions arising from the evaluation maintained
8.4.2 Type and extent of control	7.4.3 Verification of purchased product				
How does your company ensure that externally provided processes, products and services do not adversely affect your ability to consistently deliver conforming products and services to customers?					4.1 Outsourced processes that affect product conformity are controlled. The type and extent of control applied to outsourced processes are defined in the QMS.



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
Does your company: <ul style="list-style-type: none"> Ensure that externally provided processes remain within the control of the QMS? Define both the controls that are intended to be applied to external providers and those that are intended to be applied to the resulting output? 					4.1 -- Note 3, Ensuring control over outsourced processes does not absolve the organization of the responsibility to conform to requirements 7.4.1 The type and extent of control applied to suppliers and purchased products depend on the effect of the purchased product on subsequent product realization and the final product.
When determining the type and extent of controls to be applied, do you consider: <ul style="list-style-type: none"> The potential impact of the externally provided processes, products and services on your ability to consistently meet customer and applicable statutory and regulatory requirements? The effectiveness of the controls applied by the external provider? 					4.1 Extent of control applied to outsources influenced by: Note 3 Responsibility to conform to customer, statutory and regulatory requirements and influenced by Note 3 a) b) c). Note 1 – Processes needed for the QMS. Note 2 – Process performed by external party.
Has your company determined the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements?					7.4.3 Establish and implement inspection or other activities needed to ensure that purchased product meets requirements
Missing in clause 8.4.2 of ISO 9001:2015 are notes 1, 2, 3 that clarify / define outsourced processes.					
8.4.3 Information for external providers			7.4.2 Purchasing information		



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
How does your company ensure the adequacy of specified requirements prior to their communication to the external provider?					7.4.2 Ensure adequacy of specified purchase requirements prior to issue to the supplier
Does your company communicate to external providers the following requirements:					----
<ul style="list-style-type: none"> The products and services to be provided or the processes to be performed? 					7.4.2 Information to describe the product to be purchased
Approval or release of products and services, methods, processes or equipment?					7.4.2 a) Requirements for approval of product, procedures, processes and equipment
<ul style="list-style-type: none"> Competence of personnel, including necessary qualification; their interactions with your QMS? 					7.4.2 b) Requirements for the qualification of personnel 7.4.2 c) QMS requirements
<ul style="list-style-type: none"> The control and monitoring of the external provider's performance to be applied by your company? 					7.4.3 Establish and implement inspection or other activities --
<ul style="list-style-type: none"> Verification activities that your company or your customer intends to perform at the external provider's premises? 					7.4.3 Where verifications are performed at supplier's premises, the intended verifications and methods of product release are stated in purchasing information
8.5 Production and service provision		7.5 Production and service provision			



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
8.5.1 Control of production and service provision		7.5.1 Control of production and service provision			
----		7.5.2 Validation of processes for production and service provision			
Does your company implement the controlled conditions for production and service provision?					7.5.1 Plan and carry out production and service provision under controlled conditions.
Do the controlled conditions include the:					7.5.1 Controlled conditions are:
<ul style="list-style-type: none"> • Availability of documented information that defines the characteristics of the products and services? 					7.5.1 a) Availability of information to describe product characteristics
<ul style="list-style-type: none"> • Availability of documented information that defines the activities to be performed and the results to be achieved? 					7.5.1 b) Availability of work instructions as needed
<ul style="list-style-type: none"> • Monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met? 					7.5.1 e) Implementation of monitoring and measurement.
<ul style="list-style-type: none"> • Use and control of suitable infrastructure and process environment? 					7.5.1c) Use of suitable equipment
<ul style="list-style-type: none"> • Availability and use of suitable monitoring and measuring resources? 					7.5.1 d) Availability and use of monitoring and measuring equipment



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
<ul style="list-style-type: none"> Appointment of competent personnel, including any required qualifications? 					7.4.2 b) Requirements for qualification of personnel
<ul style="list-style-type: none"> Validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement? 					7.5.2 Validate any processes --outputs cannot be verified by subsequent monitoring and measurement 7.5.2 Validation demonstrates the ability of such processes to achieve planned results. Controls for such processes are: 7.5.2 a) Criteria for review and approval of processes 7.5.2 b) Approval of equipment and qualification of personnel 7.5.2 c) Use of specific methods and procedures 7.5.2 d) Requirements for records 7.5.2 e) Revalidation
Missing in clause 8.5.1 of ISO 9001:2015 are the validation of processes requirements for above 7.5.2 a, b, c, d.					
<ul style="list-style-type: none"> Implementation of actions to prevent human errors? 					
<ul style="list-style-type: none"> Implementation of products and services release, delivery and post-delivery activities? 					7.5.1 f) Implement product release, delivery and post-delivery activities
8.5.2 Identification and traceability			7.5.3 Identification and traceability		



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
When required to ensure conformity of products and services , does your company use suitable means to identify process outputs ?					7.5.3 Identify the product by suitable means throughout product realization
Do you identify the status of process outputs with respect to monitoring and measurement requirements throughout production and service provision?					7.5.3 Identify product status with respect to monitoring and measurement requirements
When traceability is required, do you control the unique identification of process outputs ?					7.5.3 When traceability is a required, control the unique identification of the product
Do you retain the documented information needed to maintain traceability?					7.5.3 Maintain records for unique identification. Note - Configuration management can be a means of identification and traceability
Do you consider process outputs as the results of any activities which are ready for delivery to the customer or to an internal customer, such as a receiver of the inputs to the next process?					
	Missing in clause 8.5.2 of ISO 9001:2015 is a note where configuration management can be a means of identification and traceability.				
8.5.3 Property belonging to customers or external providers	7.5.4 Customer property				



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
Does your company exercise care with property belonging to the customer or external providers while it is under your control?					7.5.4 Exercise care with customer property while being used or in control of the organization
Do you identify, verify, protect and safeguard the external property provided for use or incorporation into the products and services?					7.5.4 Identify, verify, protect, safeguard customer property
When external property is incorrectly used, lost, damaged or otherwise found to be unsuitable for use, do you report this to the customer or external provider?					7.5.4 Report lost, damaged or otherwise unsuitable for use and maintain records
Do you retain documented information on such events?					7.5.4 Report -- and maintain records
Do you consider customer property as including material, components, tools and equipment, customer premises, intellectual property and personal data?					7.5.4 Note - Customer property can include intellectual property and personal data
8.5.4 Preservation			7.5.5 Preservation of product		
Does your company ensure preservation of process outputs during production and service provision, as needed to maintain conformity to requirements?					7.5.5 Preserve the product during internal processing and delivery to intended destination in order to maintain conformity



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
Do you consider preservation as including identification, handling, packaging, storage, transmission or transportation , and protection?					7.5.5 Preservation includes identification, packaging, storage and protection 7.5.5 Preservation applies to constituent parts
Missing in clause 8.5.4 of ISO 9001:2015 is a requirement (7.5.5) that preservation also applies to constituent parts of a product.					
8.5.5 Post-delivery activities			----		
Does your company meet requirements for post-delivery activities associated with the products and services?					7.2.1 a) Determine requirements for delivery and post-delivery activities 7.5.1 f) Implementation of product release, delivery and post-delivery activities
When determining your post-delivery activities, do you consider the:					
• Potential undesired consequences associated with the products and services?					
• Nature, use and intended lifetime of the products and services?					
• Customer feedback?					
• Statutory and regulatory requirements?					



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
Do you consider post-delivery activities as including actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal?					7.2.1 Note - Post delivery activities may include warranty, contract items such as maintenance, recycling or final disposal
8.5.6 Control of changes			----		
Does your company review and control changes for production or service provision in order to ensure continuing conformity with specified requirements?					
Do you retain documented information describing the results of the review of those changes, the personnel authorizing the change, and any necessary actions?					
8.6 Release of products and services			----		
----			8.2.4 Monitoring and measurement of product		
Does your company implement the planned arrangements at appropriate stages to verify that product and service requirements have been met?					8.2.4 Monitor and measure the characteristics of the product to verify that requirements are met. Carried out at appropriate stages of product realization
Do you retain evidence of conformity with the acceptance criteria?					8.2.4 Evidence of conformity with criteria maintained



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
Do you ensure that the release of products and services to the customer does not proceed until the planned verification of conformity has been satisfactorily completed?					7.5.1 f) Implementation of product release, delivery and post-delivery activities 8.2.4 Release of product not to proceed until planned arrangements are satisfactorily completed
Do you release unverified products or services only after obtaining a relevant internal authority or as required by the customer?					8.2.4 Released after approved by relevant authority or customer
Does documented information provide traceability to the person(s) authorizing release of products and services for delivery to the customer?					8.2.4 Records indicate person(s) authorizing release of product for delivery to customers
----					8.2.3 Monitoring and measurement of processes
QMS and its processes – Ref. 4.4 g) For the QMS processes do you determine the methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results?					8.1 Plan and implement the monitoring, measurement, analysis & improvement processes needed to: a) Demonstrate conformity to product requirements b) Ensure conformity to QMS requirements c) Continually improve the effectiveness of the QMS
For the QMS processes do you determine the methods for monitoring, measuring, and evaluation of processes?					8.2.3 Apply suitable methods for monitoring and measuring of the QMS processes that demonstrate ability to achieve planned results. Consider impact



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
					on conformity, take action when results not achieved
	Missing in clause 8 of ISO 9001:2015 is a specific clause for the requirements for the monitoring and measurement of processes.				
	Missing in clause 8 of ISO 9001:2015 is the requirement that suitable methods used for monitoring and measuring of processes demonstrate the ability of processes to achieve planned results.				
	Missing in clause 8 of ISO 9001:2015 is the note that when determining suitable methods for the monitoring and measurement of processes, consideration be given to the type and extent appropriate to impact on the conformity to product requirements and on the effectiveness of the QMS.				
	Missing in clause 8 of ISO 9001:2015 is the requirement that when planned monitoring and measurement of processes results are not achieved, correction and corrective action are taken.				
8.7 Control of nonconforming outputs				8.3 Control of nonconforming product	
	Removed from clause 8.7 of ISO 9001:2015 is the requirement for a documented procedure for 8.3, Control of nonconforming product.				
8.7.1 Does your company ensure that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery?					8.3 Ensure non conforming product is identified and controlled to prevent unintended use or delivery
Do you take corrective action based on the nature of the nonconformity and the impact on the conformity of products and services ?					8.3 a) Taking action to eliminate the nonconformity



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
Do you also apply corrective action to non-conforming products and services detected after delivery of the products or during the provision of the service?					3 d) Take action appropriate to the effects of the nonconformity when nonconforming product is detected after delivery or use
Does your company deal with non conforming outputs in one or more of the following:					8.3 Deal with nonconforming product in one or more ways:
<ul style="list-style-type: none"> • Correction? 					8.3 a) Taking action to eliminate the nonconformity
<ul style="list-style-type: none"> • Segregation, containment, return or suspension of provision of products and services? 					8.3 c) Taking action to preclude its original intended use or application
<ul style="list-style-type: none"> • Informing the customer? 					
<ul style="list-style-type: none"> • Obtaining authorization for acceptance with a concession? 					8.3 b) Authorizing the use, release under concession by a relevant authority or by the customer
After correcting nonconforming process outputs, products and services , do you verify that the requirements are met?					8.3 Corrected nonconforming product is subject to re-verification to demonstrate conformity to requirements
8.7.2 Do you retain documented information of actions taken on nonconforming process outputs, products and services ?					8.3 Records of the nature of non conforming product maintained
Do you retain documented information on any concessions obtained and on the person or					8.3 Records of the nature on nonconformities and subsequent actions



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
authority that made the decision regarding dealing with the nonconformity?					taken including information on concessions obtained are maintained
9 PERFORMANCE EVALUATION			8.0 Measurement, analysis and improvement		
<p>This clause requires that your company plan, implement and control the monitoring, measurement, analysis, and evaluation processes. Performance evaluation includes systems for the evaluation of customer satisfaction, analysis and evaluation of data, internal audits, and management review, aimed at improved quality performance and an effective QMS.</p>					----
9.1 Monitoring, measurement, analysis and evaluation			----		
9.1.1 General			8.1 General		
Does your company determine:					
• What needs to be monitored and measured?					
• The methods for monitoring, measurement, analysis and evaluation to ensure valid results?					
• When the monitoring and measuring are to be performed?					
• When the results from monitoring and measurement are analyzed and evaluated?					



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
Do you ensure that monitoring and measurement activities are implemented to meet the determined requirements?					8.1 Plan and implement the monitoring, measurement, analysis & improvement processes needed to: a) Demonstrate conformity to product requirements b) Ensure conformity to QMS requirements c) Continually improve the effectiveness of the QMS. 8.2.3 Apply suitable methods for monitoring and measuring of the QMS processes.
Does your company evaluate the quality performance and the effectiveness of the QMS?					5.6.1 Management review of QMS to ensure continuing suitability, adequacy and effectiveness
Do you retain appropriate documented information as evidence of the results?					
				8.2 Monitoring and measurement	
9.1.2 Customer satisfaction				8.2.1 Customer satisfaction	
Does your company monitor customer satisfaction to determine the perception of the degree to which their needs and expectations have been met?					8.2.1 As a measurement of performance, monitor information relating to customer perception to meet requirements
Do you obtain information relating to customer views and opinions of your company and your products and services?					As monitored in 8.2.1



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
Do you determine the methods for obtaining and using this information?					8.2.1 Determine the methods for obtaining and using information
Do you consider information related to customer views as including customer satisfaction or opinion surveys, customer data on the quality of delivered products or services, market-share analysis , warranty claims, dealer reports and compliments?					8.2.1 Note – Monitoring can include customer satisfaction or opinion surveys, customer data, opinion surveys, lost business analysis, compliments, warranty claims and dealer reports
9.1.3 Analysis and evaluation			8.4 Analysis of data		
Does your company analyze and evaluate the data and information resulting from monitoring, measurement?					8.4 Determine, collect and analyze data to demonstrate suitability and effectiveness of the QMS and to evaluate where continual improvement can be made 8.4 Include data generated from monitoring and measurement and other sources
Do you use the results of analysis to evaluate:					8.4 Analysis of data to provide information on:
• Conformity of products and services to requirements?					8.4 b) Conformity to product requirements
• Degree of customer satisfaction?					8.4 a) Customer satisfaction
• Performance and effectiveness of the QMS?					



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
• Planning has been effectively implemented?					
• Effectiveness of actions taken to address risks and opportunities?					8.4 c) Characteristics and trends of processes and products including opportunities for preventive action (8.5.3)
• Performance of external providers?					8.4 d) Supplier performance
• Need for improvements to the QMS?					8.4 Evaluate for continual improvement
Do you consider statistical techniques as a method for the analysis of data					8.1 For measurement, analysis and improvement, determine suitable methods, including statistical techniques & the extent of their use
9.2 Internal audit			8.2.2 Internal audit		
9.2.1 Does your company conduct internal audits at planned intervals to determine whether the QMS:					8.2.2 Conduct internal audits at planned intervals to determine:
• Conforms to your own QMS requirements and to the ISO 9001:2015 requirements?					8.2.2 a) Conforms to planned arrangements
• Is effectively implemented and maintained?					8.2.2 b) Is effectively implemented and maintained
9.2.2 Does your company::					



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
<ul style="list-style-type: none"> Plan, establish, implement and maintain an audit program that includes the frequency, methods, responsibilities, planning requirements and reporting? 					8.2.2 A documented procedure defines responsibilities and requirements for planning, conducting audits and reporting results
<p>Removed from clause 9.2 of ISO 9001:2015 is the requirement for a documented procedure for 9.2 internal audits.</p>					
<ul style="list-style-type: none"> Consider the importance of the processes concerned, changes impacting on your company, and the results of previous audits? 					8.2.2 An audit program planned taking into consideration status and importance of processes, areas to be audited and results of previous audits
<ul style="list-style-type: none"> Define the audit criteria and scope for each audit? 					8.2.2 Audit criteria, scope, frequency, and methods to be defined
<ul style="list-style-type: none"> Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process? 					8.2.2 Selection of auditors and conduct of audits to be objective and impartial
<p>Missing in clause 9.2 of ISO 9001:2015 is the requirement that auditors can not audit their own work.</p>					
<ul style="list-style-type: none"> Ensure that the results of the audits are reported to relevant management? 					8.2.2 Documented procedure to establish records and report results
<ul style="list-style-type: none"> Take timely correction and corrective actions without undue delay? 					8.2.2 Management responsible for the audited area take prompt corrections and actions to eliminate nonconformities and their causes



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
Missing in clause 9.2 of ISO 9001:2015 is the requirement for follow-up activities including verification of action taken and reporting of results.					
Do you retain documented information as evidence of the implementation of the audit program and the audit results?					8.2.2 Records of audits and results maintained
9.3 Management review			5.6 Management review		
9.3.1 General			5.6.1 General		
Does the top management review the QMS at planned intervals, to ensure that it continues to be suitable, adequate and effective and aligned with the strategic direction of your company?					5.6.1 Top management review of QMS at planned intervals to ensure suitability, adequacy, and effectiveness
9.3.2 Management review inputs			5.6.2 Review input		
As inputs for the planning and conducting management reviews, do you consider the following:					5.6.2 Inputs for management review include information on:
<ul style="list-style-type: none"> • The status of actions from previous management reviews? 					5.6.2 e) Follow-up on actions from previous management reviews
<ul style="list-style-type: none"> • Changes in external and internal issues that are relevant to the QMS? 					5.6.2 f) Changes that could affect the QMS



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
Do you also consider information on the quality performance, including trends in:					
<ul style="list-style-type: none"> • Customer satisfaction and feedback from interested parties? 					5.6.2 b) Customer feedback
<ul style="list-style-type: none"> • Extent to which quality objectives have been met? 					5.6.1 Management review include assessing opportunities for improvement and the need for changes to QMS including the quality policy and quality objectives
<ul style="list-style-type: none"> • Process performance and conformity of products and services? 					5.6.2 c) Process performance and product conformity
<ul style="list-style-type: none"> • Nonconformities and corrective actions? 					5.6.2 d) Status of preventive and corrective actions
<ul style="list-style-type: none"> • Monitoring and measurement results? 					
<ul style="list-style-type: none"> • Audit results? 					5.6.2 a) Results of audits
<ul style="list-style-type: none"> • Performance of external providers? 					
<ul style="list-style-type: none"> • Adequacy of resources? 					As reported as output in 5.6.3 c)
Does the management review include the review of the effectiveness of actions taken to address risks and opportunities (per 6.1)?					



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
Do you include new potential opportunities for continual improvement?					5.6.2 g) Recommendations for improvement
9.3.3 Management review outputs			5.6.3 Review output		
As outputs of your management reviews do you include decisions and actions related to:					5.6.3 Output from management review include and decisions and actions related to:
<ul style="list-style-type: none"> Continual improvement opportunities? 					5.6.3 a) Improvement of effectiveness of QMS and its processes. 5.6.3 b) Improvement of product related to customer requirements
<ul style="list-style-type: none"> Any need for changes to the QMS, including needs for resources? 					5.6.3 c) Resource needed
.Does your company retain documented information as evidence of the results of management reviews?					5.6.1 Records of management reviews maintained
10 IMPROVEMENT			8.5 Improvement		
<p>This clause requires that your company determine and select opportunities for improvement and implement the actions needed to meet customer requirements and to enhance customer satisfaction. The improvement process includes systems for nonconformity and corrective action and for continual improvement.</p>					
10.1 General			----		



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
Does your company determine and select opportunities for improvement and implement actions needed to meet customer requirements and enhance customer satisfaction?					
Do you include:					
<ul style="list-style-type: none"> Improving products and services to meet requirements as well as to address future needs and expectations? 					
<ul style="list-style-type: none"> Correcting, preventing or reducing undesired effects? 					
<ul style="list-style-type: none"> Improving the performance and effectiveness of the QMS? 					
Do you consider improvement as events:					
<ul style="list-style-type: none"> That can be effected reactively, such as corrective action? 					
<ul style="list-style-type: none"> Incrementally, such as continual improvement? 					
<ul style="list-style-type: none"> By-step-change, such as breakthrough? 					
<ul style="list-style-type: none"> Creatively, such as innovation? 					
<ul style="list-style-type: none"> Re-organization such as transformation? 					



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
10.2 Nonconformity and corrective action			8.5.2 Corrective action		
10.2.1 When nonconformities occur, including those resulting from complaints, does your company:					
<ul style="list-style-type: none"> React to the nonconformity, and as needed take action to control and correct it; and deal with the consequences of the nonconformity? 					8.5.2 Take action to eliminate causes on non conformities in order to prevent recurrence. 8.5.2 A documented procedure defines requirements
<ul style="list-style-type: none"> Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: <ul style="list-style-type: none"> -- Reviewing and analyzing the nonconformity? -- Determining the cause of the non conformity? -- Determining if similar nonconformities exist, or could potentially occur? 					8.5.2 a) Review nonconformities including customer complaints 8.5.2 b) Determine causes of non conformities 8.5.2 c) Evaluate the need for action to ensure that non conformities do not recur
<ul style="list-style-type: none"> Implement any action needed? 					8.5.2 d) Determine and implement action needed
<ul style="list-style-type: none"> Review the effectiveness of any corrective action taken? 					8.5.2 f) Review effectiveness of corrective action taken
<ul style="list-style-type: none"> Update risks and opportunities identified during the planning? 					



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
<ul style="list-style-type: none"> Make changes to the QMS if needed? 					
Does your company take corrective actions that are appropriate to the effects of the nonconformities encountered?					8.5.2 Corrective actions to be appropriate to the effects of the non conformity encountered
10.2.2 Does your company retain documented information as evidence of the:					
<ul style="list-style-type: none"> Nature of the nonconformities and any subsequent actions taken? 					
<ul style="list-style-type: none"> Results of any corrective action? 					8.5.2 e) Records of the results of action taken
	Removed from clause 10.2 of ISO 9001:2015 is the requirement for a documented procedure for 8.5.2, Corrective action.				
10.3 Continual improvement			8.5.1 Continual improvement		
Does your company continually improve the suitability, adequacy, and effectiveness of the QMS?					8.5.1 Continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results analysis of data, corrective and preventive actions & management review
Do you consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs and					8.5.1 Continually improve the effectiveness of the QMS through the use of management review.



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
opportunities to be addressed as part of continual improvement?					
Does your company select and make use of applicable tools and methodologies for the investigation of the causes of under-performance and for supporting continual improvement?					
----				8.5.3 Preventive action	
In ISO 9001:2015, the concept of preventive action is expressed through a risk-based approach where risks are determined and actions to address opportunities and risks are taken.			Removed from clause 10.3 of ISO 9001:2015 is a requirement for a documented procedure for 8.5.3 Preventive action.		

Additional Notes:



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

END OF DOCUMENT