

**TRANSITION AUDIT REPORT AND CHECKLIST FOR
ISO 9001:2015 CERTIFICATION**

**(To be used along with surveillance or renewal audit in case of transition audit
from ISO9001:2008 to ISO9001:2015)**

Organization:

Address:

Lead Auditor:

SN	Check	Clause no. of ISO 9001:2015	Evidence	Comments by LA	Comments of certification manager
1	<p>Has the organization determined external and internal issues relevant to the purpose of achieving intended results e.g. market, competition, political, culture, knowledge of people etc.?</p> <p>Is there a process to monitor and review information about these issues?</p>	4.1			
2	<p>Are interested parties (customers, end users, suppliers, distributors, regulators etc.) and their requirements identified? Are requirements reviewed?</p>	4.2			
3	<p>Whether Scope is maintained as documented information and it includes:</p> <p>a. Products and services covered by the QMS including non-applicability if any</p> <p>b. Justification for any requirement that the organization determines is</p>	4.3			

	not applicable to the scope of its QMS				
4	Are Documented information regarding Processes, their inputs, sequence & interaction, criteria & methods, resources needed for these processes, R & A, R & O, evaluated & implemented	4.4.1			
5	Does the organization maintain documented information to support the operation of its processes and retain documented information to have confidence that the processes are being carried out as planned	4.4.2			
6	Are the Statutory & Regulatory (S & R) requirements of customer understood	5.1.2			
7	Are Risk & Opportunity (R & O) that can affect products/services & customer satisfaction, determined and addressed in QMS	5.1.2			
8	Are Risk & Opportunity (R & O) determined and addressed while planning.	6.1.1			
9	Whether planning has been done to integrate and implement actions into QMS and for evaluation of the effectiveness of these actions for actions	6.1.2			
10	Are basis used for calibration / verification retained as documented information , where no standards are traceable to international / national standards	7.1.5			
11	Is the Knowledge necessary for the operation of its processes and to achieve	7.1.6			

	conformity of products and services determined and maintained to the extent necessary				
12	Has the issue of internal & external communication relevant to QMS (what, when and with whom to communicate) determined	7.4			
13	Does Organization's QMS system include documented information required by the standard ISO 9001:2015 and by the organization for effective QMS	7.5.1			
14	Are documents identified with description like title, date, author, reference number, approval, proper format, review, approval	7.5.2			
15	Does D & D inputs include: a. Standard codes of practice that the organization has committed to implement b. Internal and external resource needs c. Potential consequences of failure d. Level of control by customer and other relevant parties	8.3.3			
16	Is documented information retained on D & D outputs	8.3.5			
17	Is the record (DI) of the results of the review of changes, personnel authorising changes and any necessary action retained Addition: personnel authorizing the change	8.5.6			
18	Are documented information regarding the criteria for evaluation, selection, results of evaluation, monitoring of performance and re-evaluation of the external providers maintained	8.4.1			

	(including sub-contractor for outsourcing) (Monitoring of performance and re-evaluation of sub-contractor has been added).				
19	Is documented information that defines the characteristics of products & services, activities to be performed, and the results to be achieved, available	8.5.1			
20	Has organization determined what needs to be measured/analysed/evaluated, how & when it is to be done and whether documented information retained as evidence of the result of monitoring, measuring, analysis and evaluation activities	9.1.1			
21	Has internal audit carried out for ISO 9001:2015 and CA/PA taken for the effective closure of NCs raised.	9.2			
22	MRM: Whether following issues were taken up in MRM 1. Effectiveness of actions taken to address risks and opportunities (new addition) 2. issues concerning external provider/relevant interested parties, (new addition)	9.3.2			
23	Is documented information retained as evidence of the results of the management reviews including actions taken	9.3.3			

Conclusion:

Follow up:

NCs raised:

CAR no. / Clause no.

Text of NC

Containment action:

RCA:

CAP

CA

NC Status:

Recommendation of Lead Auditor

Lead Auditor

Comments of Certification Manager

Certification Manager