TRANSITION AUDIT REPORT AND CHECKLIST FOR

ISO 9001:2015 CERTIFICATION

Organization:

Address:

Lead Auditor:

Date :

SN	Check	Clause no. of ISO 9001:2015	Evidence	Comments by LA	Comments of certification manager
1	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.? Is there a process to monitor and review information about these issues?	4.1			
2	Are interested parties (customers, end users, suppliers, distributors, regulators etc.) and their requirements identified? Are requirements reviewed?	4.2			
3	Whether Scope is maintained as **documented information** and it includes: a. Products and services covered by the QMS including non-applicability if any b. Justification for any requirement that the organization determines is not applicable to the scope of its QMS	4.3			
4	Are **Documented information** regarding Processes, their inputs, sequence & interaction,	4.4.1			

	criteria & methods, resources needed for these processes, R & A, R & O, evaluated & implemented				
5	Are the customer and Statutory & Regulatory (S & R) requirements understood	5.1.2			
6	Are Risk & Opportunity (R & O) that can affect products/services & customer satisfaction, determined and addressed in QMS	6.1			
7	Are Risk & Opportunity (R & O) determined and addressed while planning.	6.1.1			
8	Whether planning has been done to integrate and implement actions into QMS and for evaluation of the effectiveness of these actions	6.1.2			
9	Are basis used for calibration / verification **retained as documented information,** where no standards are traceable to international / national standards	7.1.5			
10	Is the Knowledge necessary for the operation of its processes and to achieve conformity of products and services determined and maintained to the extent necessary	7.1.6			
11	Has the issue of internal & external communication relevant to QMS (what, when and with whom to communicate) determined	7.4			
12	Does Organization's QMS system include documented information required by the standard ISO 9001:2015 and by the organization for effective QMS Documents to be maintained and retained are listed at Annexure A.	7.5.1			
13	Are documents identified with	7.5.2			

	description like title, date, author, reference number, approval, proper format, review, approval				
14	Are documents controlled wrt distribution, access, retrieval, update, control of change, retention, disposition	7.5.3			
15	Does D & D input include: a. Functional & performance requirements b. Standard codes of practice that the organization has committed to implement c. Internal and external resource needs d. Potential consequences of failure e. Level of control by customer and other relevant parties	8.3.3			
16	Does documented information retained on D & D outputs a) meet the input requirements; b) are adequate for the subsequent processes for the provision of products and services; c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.	8.3.5			
17	Are **documented information** regarding the criteria for evaluation, selection, results of evaluation, monitoring of performance and re-evaluation of the external providers maintained (including sub-contractor for	8.4.1			

	outsourcing) (Monitoring of performance and re-evaluation of sub-contractor has been added).				
18	Has organization defined the control & its effectiveness to ensure externally provided processes, products & services meet the requirement	8.4.2			
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 the organization used suitable means to identify status of outputs when it is necessary to ensure traceability?	8.5.2			
21	Has the organization exercised care with property belonging to customers or external providers while it is under the organization's control or being used by the organization or for use or incorporation into the products and services?	8.5.3			
22	Has the organization determined the post-delivery activities considering nature, use, life, customer requirements / feedback, and potential undesirable consequences	8.5.5			
23	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			
24	Has organization determined what needs to be measured/analysed/ evaluated, how & when it is to	9.1.1			

	be done and whether **documented information retained** as evidence of the result of monitoring, measuring, analysis and evaluation activities				
25	Has internal audit been carried out for ISO 9001:2015 and CA/PA taken for the effective closure of NCs raised?	9.2			
26	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			
27	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:

Correction/CA:

NC Status:

Recommendation of Lead Auditor:

Lead Auditor:

Comments of Certification Manager:

Certification Manager:

Annexure A:

Mandatory Documents	ISO 9001:2015 Clause
Scope of the quality management system	4.3
Quality policy	5.2
Quality objectives and plans for achieving them	6.2
Procedure for control of externally provided processes, products and services (outsourced processes)	8.4.1

Mandatory Records	ISO 9001:2015 Clause
Record of maintenance and calibration of monitoring and measuring equipment	7.1.5.1
Competence records	7.2
Product/service requirements review record	8.2.3.2
Record of new requirements for product or service	8.2.3.2
Design and development inputs record	8.3.3
Record of Design and Development Controls'	8.3.4
Design and Development Outputs Record	8.3.5
Record of Design and Development Changes	8.3.6
Record of Evaluation of External Provider (supplier)	8.4.1
Record of product/service characteristics	8.5.1
Record of Changes on Customer's Property	8.5.3
Record of Changes in Production/ Service Provision	8.5.6
Evidence of Product/ Service Conformity	8.6
Record of Nonconformity	10.2.2, 8.7.2
Monitoring Performance Information	9.1.1
Internal Audit Program and Results	9.2.2
Management Review Results	9.3
Nonconformities and Corrective Action	10.2