

ASSESSMENT CHECKLIST

1. LEADERSHIP

Opportunities for Improvement

--

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
1.1	▪ Roles & Responsibilities at all levels are clearly defined & documented			
1.2	▪ Organogram is established			
1.3	▪ Organisational Performance including regulatory compliances, quality, product & occupational safety and environmental performance is reviewed regularly for compliance and meeting the set objectives			

2. SWACHH WORKPLACE

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
2.1	▪ SOPs for cleaning & hygiene are in place addressing the nature of products, processes, customer & regulatory requirements			
2.2	▪ All equipment, tools, work spaces & areas are maintained clean, uncluttered & organized as per the SOPs & requirements			
2.3	▪ Cleanliness & hygiene is propagated & emphasized across the organisation			
2.4	▪ Mechanism for periodic audit for cleaning, hygiene & cleaning validation (wherever applicable) is in place			

3. OCCUPATIONAL (WORKPLACE) SAFETY

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
3.1	Formal safety policy is in place			
3.2	- Systems are in place to ✓ identify all safety aspects and communicate regularly to all employees and contract workers ✓ impart regular safety trainings to employees and contract workers ✓ ensure that relevant PPEs are used by the employees ✓ conduct mock drills involving employees and contract workers			
3.3	- The organisation has implemented ✓ all relevant safety systems ✓ mechanism for investigation of accidents/incidents/near-misses with Root Cause Analysis (RCA) and Corrective & Preventive Actions (CAPA) ✓ periodic mock drills involving employees and contract workers ✓ periodic safety audits			
3.4	Periodic review of safety systems & performance is conducted by the Senior Management			

4. MEASUREMENT OF TIMELY DELIVERY

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
4.1	▪ Adherence to process delivery contracts is measured and monitored			
4.2	▪ Mechanism to periodically review the delivery performance by the Senior management, is in place			

5. QUALITY MANAGEMENT

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
5.1	▪ Quality Policy is in place			
5.2	▪ Quality requirements for products and processes are established and monitored			
5.3	▪ Training is imparted to all relevant people			
5.4	▪ Periodic quality audits are in place			
5.5	▪ Root Cause Analysis (RCA), Corrective and Preventive Action (CAPA) processes are in place			
5.6	▪ Mechanism of Review of Quality Management System by Senior management is in place			

6. HUMAN RESOURCE MANAGEMENT

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
6.1	HR Processes are defined			
6.2	People development plans including induction training and employee engagement is in place for all employees			
6.3	Detailed technical skill mapping in place extending to soft skills, environmental, safety and energy conservation areas backed with training for deploying people for different tasks			
6.4	Review mechanism of people development and engagement plans/initiatives			

7. DAILY WORKS MANAGEMENT

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
7.1	Process to set & review targets for Quality, Cost & Delivery (QCD) is in place			
7.2	Daily targets on QCD are suitably displayed and all relevant employees are aware			
7.3	Status & trends on QCD are displayed and shared			
7.4	Root Cause Analysis (RCA), Corrective and Preventive Action (CAPA) processes are in place			
7.5	Mechanism to review the effectiveness of Daily Works Management is in place			

8. PLANNED MAINTENANCE & CALIBRATION

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
8.1	Preventive Maintenance and calibration plan, as applicable, is in place for all critical machines/equipment /devices			
8.2	Maintenance and calibration, as applicable, are carried out periodically, as per the plan			
8.3	Root Cause Analysis (RCA), Corrective and Preventive Action (CAPA) processes are in place			
8.4	Trends of Mean Time To Repair (MTTR) & Mean Time Between Failure (MTBF) are reviewed			

9. PROCESS CONTROL

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
9.1	Critical processes are proactively planned and established considering the process control requirements based on product, process, customer, organizational & legal requirements			
9.2	SOPs for control of all critical processes are established			
9.3	Monitoring of the critical processes is in place			
9.4	Root Cause Analysis (RCA), Corrective and Preventive Action (CAPA) processes are in place			

10. PRODUCT QUALITY & SAFETY (TESTING / CERTIFICATION)

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
10.1	All relevant product quality and safety requirements are identified			
10.2	The relevant product quality and safety requirements are fulfilled through requisite testing/certification, as applicable			
10.3	Root Cause Analysis (RCA), Corrective and Preventive Action (CAPA) processes are in place			
10.4	Mechanism of review of product quality & safety by Senior management is in place			

11. MATERIAL MANAGEMENT

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
11.1	Material management planning is done for maintaining optimal inventory			
11.2	Inventory control mechanism is in place			
11.3	SOPs/processes are established for ensuring timely availability of materials and suitable handling & management of the materials to reduce contamination, damages, losses, unintended hazards etc.			
11.4	Root Cause Analysis (RCA), Corrective and Preventive Action (CAPA) processes are in place			

12. ENERGY MANAGEMENT

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
12.1	All energy sources are identified & targets are set for energy saving			
12.2	Employees are trained in energy management			
12.3	Periodic energy audits are in place			
12.4	Root Cause Analysis (RCA) and Corrective and Preventive Action (CAPA) processes are in place			

13. ENVIRONMENT MANAGEMENT

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
13.1	- Systems are in place to identify and manage: ✓ the emissions, effluent discharge and waste management to conform to regulations/norms ✓ plant, equipment and systems required to meet the emissions/discharge norms and waste management requirements are in place			
13.2	Root Cause Analysis (RCA), Corrective and Preventive Actions (CAPA) processes are in place			
13.3	Employees are trained on Environment Management Systems			
13.4	Periodic Environmental audits are conducted			

14. MEASUREMENT & ANALYSIS

Opportunities for Improvement

S. No.	Requirement	Document/ Evidence Uploaded	Conformance (Yes/No)	Assessor Remark
14.1	■ Processes to establish targets, measure & periodically review the following, by the Senior management, are in place: ✓ Defects ✓ Rework ✓ Rejection ✓ Customer Satisfaction			
14.2	■ Root Cause Analysis (RCA), Corrective Action and Preventive Action (CAPA) processes are in place			

ASSESSMENT SUMMARY