9.1- MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

9.1.1 General

The Top Management has determined:

a) What needs to monitor and measured;
b) The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) When the monitoring and measurement shall be performed;
d) When the results from monitoring and measurement shall be analysed and evaluated.

The organisation evaluates the performance and the effectiveness of quality management system through the use of tools like Quality Objectives, Internal Audit, Management Review, etc.

The organisation retains appropriate documented information as evidence of the results.

Documented Information

Minutes of Management Review Meeting QMS/F/10

9. 1. 1. 1 Monitoring and Measurement of Manufacturing Processes

We perform process studies on all new manufacturing processes to verify process capability and to provide additional input for process control, including those for special characteristics**.**

The Kaizen Engineers performs process studies on all new manufacturing processes to verify process capability and provide additional input for process control. (Form No. CRA/NPD/12-Process capability Report)

The Kaizen Engineers Maintains manufacturing process capability or performance as specified by the customer part approval process requirements.

Measurement techniques
Sampling Plans
Acceptance criteria
Reaction plans when acceptance criteria are not met.

The Kaizen Engineers maintains record of significant process events such as tool change or machine repair.

The Kaizen Engineers initiates the reaction plan from the control plan for the characteristics that are either not statistically capable or are unstable. These reaction plans may include containment of product and 100 % inspection as appropriate. In such cases time bound corrective action plan is prepared to assure that the process become stable and capable.

9.1.1.2 Identification of Statistical Tools

Appropriate statistical tools for each process are determined during advance quality planning and are included in control plan.

Cross Functional Team (CFT) determines the appropriate use of statistical tools. CFT verifies that appropriate statistical tools are included as part of the advanced product quality planning (or equivalent) process and included in the process risk analysis (such as PFMEA) (where applicable), and the control plan**.**

9.1.1.3 Application of Statistical Concepts

Statistical concepts, such as variation, control (stability), process capability, and the consequences of over-adjustment, has been understood and used by employees (CFT) involved in the collection, analysis, and management of statistical data

9.1.2 Customer Satisfaction

For the existence of any organization, customer satisfaction is a vital factor. Realizing the importance, Kaizen Engineers/C.R. ensures the customer satisfaction through (Form No. MKT/F/03, MKT/F/07) -

- Feedback obtained from customers at least once in a year using appropriate format for the type of product
- Customer's complaints / observations / suggestions on the product and Processes.
- Mutual interaction.

These inputs are analysed, discussed in the Management Review Meetings, and appropriate corrective and preventive actions are taken to ensure the continual improvement. CR maintains the appropriate records. Ref. Process Module for Customer Satisfaction Survey Process No. QMS/PM/18

9.1.2.1 Customer satisfaction – supplemental

Customer satisfaction with the organization has been monitored through continual evaluation of internal and external performance indicators as per criteria defined in customer perception survey form, to ensure compliance to the product and process specifications and other customer requirements.

If any of the targets is not met it is treated as customer dissatisfaction and corrective action is initiated.

9.1.3 Analysis and Evaluation

The organization analysed and evaluated appropriate data and information arising from monitoring and measurement.

The results of analysis have been used to evaluate:

a) Conformity of Product and Services;
b) The degree of customer satisfaction;
c) The performance and effectiveness of the quality management system;
d) If planning has been implemented effectively;
e) The effectiveness of action taken to address risk and opportunities;
f) The performance of external providers;
g) The need for improvements to the quality management system

Details of statistical methods to be applied are defined in Control Plans, and approved prior to release. Procedures are documented for identification of Statistical Techniques for implementation and control.

The results of all statistical analysis are properly documented and evaluated to identify levels of performance and initiate corrective or preventive action as appropriate. Ref. Process Module for Analysis of Data No. QMS/PM/22

9.1.3.1 Prioritization

Trends in quality and operational performance has been compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction

9.2 INTERNAL AUDIT

To assess the strengths and weaknesses of the QMS, the Internal Audit is an effective tool. It provides an opportunity for the independent evaluation of the efficiency and effectiveness of its processes and products. As such the audit programme of its processes and products is planned by QMS Representative taking into consideration the status and importance of the processes and areas to the audited, as well as the results of the previous audits. Some of the areas considered for internal audit are -

- Effective and efficient implementation of processes
- Opportunities for continual improvement.
- Effective and efficient use of resources.
- Adequacy and accuracy of performance measurement.
- Improvement activities
- Relationships with interested parties

The detailed operating procedure is defined in Operating Procedure for Internal audit Doc. No.: OP/QMS/05**.** The MR ensures that the appropriate actions as a result of Internal Audit are taken without undue delay to eliminate detected non – conformities and their causes.

9.2.2. 1 Internal Audit Programme

The organization has a documented internal audit process. The process includes the development and implementation of an internal audit programme that covers the entire quality management system including quality management system audits, manufacturing process audits, and product audits.
The audit programme has been prioritized based upon risk, internal and external performance trends, and criticality of the processes.
The frequency of audits has been reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints. The effectiveness of the audit programme has been reviewed as a part of management review.

9.2.2.2 Quality Management System Audit

The Organization audits its QMS to verify compliance with IATF 16949. All function of QMS audit is conducted at least once in a six month. (Form No. Audit Plan - QF/QMS/11)
The organization samples customer-specific quality management system requirements for effective implementation.

9.2.2.3 Manufacturing Process Audit

It is ensured by the organization that all manufacturing processes, which affect the product quality, are audited at least once in a year. (Form No. Process Audit QF/F/13)

9.2.2.4 Product Audit

Product at appropriate stages of production and delivery to verify conformance to all specified requirements, such as product dimensions, functionality, packaging, labelling, is audited at least once in a six month for each product. (Form No. QA/F/27)

9.3 MANAGEMENT REVIEW

The QMS representative ensures that a review meeting is held to review continuing suitability (applicability), adequacy (completeness) and effectiveness (results) of quality management system. The management review is conducted as per the Management Review procedure. It includes results of internal audits, customer feedback and customer complaints, process and product performance, status of corrective and preventive actions, action items from the previous meeting, changes that could affect the quality management system and continual improvement of the quality system.

Minutes of the management review shall be documented with action items relating to improvement of the effectiveness of the quality management system, product related to customer requirements, and necessary resources.

Ref: Procedure for Management Review (OP/QMS/06)

Records:

Sl.No	Record Title	Format No	Retention period	Retention Resp.	Indexing method	Disposition
01	Minutes of Meeting	QMS/F/10	03 Years	QMSR	File / Computer	Shred / Delete
02	SPC	QA/F/32	Till product exist + 1 Year	QA Head	File / Computer	Shred / Delete
03	Sampling Plan	--	Till Rev.	QA Head	File / Computer	Shred / Delete
04	Customer satisfaction survey	MKT/F/03, MKT/F/07	03 Years	Mkt. Head	File	Shred
05	Customer satisfaction index	MKT/F/04	03 Years	Mkt. Head	File	Shred
06	Continual Improvement/ KAIZEN	QMS/F/05	03 Years	QMSR	File / Computer	Shred / Delete
07	Quality objectives / Business Plan	QMS/F/17	Till Rev.	QMSR	File / Computer	Shred / Delete
08	Internal Audit Plan	QMS/F/11	03 Years	QMSR	File / Computer	Shred / Delete
9	Internal Audit Schedule	QMS/F/13	03 Years	QMSR	File / Computer	Shred / Delete
10	List of Internal Auditor	QMS/F/12	Till Rev.	QMSR	File / Computer	Shred / Delete

11	Internal Audit Observation Sheet	QMS/F/14	03 Years	QMSR	File / Computer	Shred / Delete
12	Internal Audit CA Report	QMS/F/15	03 Years	QMSR	File / Computer	Shred / Delete
13	Product / Process Audit Plan	QA/F/30	Till Rev.	QA Head	File / Computer	Shred / Delete
14	Product Audit Report	QA/F/14	01 Year	QA Head	File / Computer	Shred / Delete
15	Process Audit Report	QA/F/13	01 Year	Production Head	File / Computer	Shred / Delete