6.1 Actions to Address Risks and Opportunities

Kaizen Engineers has considered the issues referred to in Organization and its context and the requirements referred to in needs and expectation of interested parties.

Kaizen Engineers has defined the methodology to determine the risks and opportunities to give assurance that the quality management system can achieve its intended result, to enhance desirable effects, to prevent, or reduce, undesired effects and to achieve improvement.

Kaizen Engineers has planned the actions to address these risks and opportunities to integrate and implement the actions into its quality management system processes, to evaluate the effectiveness of this action. Actions taken to address risks and opportunities are proportionate to the potential impact on the conformity of products and services.

Risk is the possibility of events or activities impeding the achievement of an organization's strategic and operational objectives. It is the volatility of potential outcomes. Risk is defined by two parameters

- Severity / Impact (This is the Seriousness of the harm)
- Probability (This is the Probability that the harm will occur)
- Control (This is the control established to control occurrence)

Rating legend-

Probability (P)

1. Almost NIL
2. Low Chance
3. Medium Chance
4. High Chance
5. Almost Certain

Impact (I)

1 No/ Minor Impact

2 Low Impacts

3 Medium Impacts

4 High Impacts

5 Extremely Serious Problems

Control ©

1. Available & effective at source (No effect in Quality & Delivery)

2. Has in-built secondary control / Contingency plan available In-House (No effect in quality & delivery)

3. Control needs human Intervention / Contingency plan available / can get help from outsourced (No effect in quality & Delivery)

4. Mechanism in place but lead time to implement is more than 8 Hrs.

5. Absent or no effective control- Lead time to implement more than 2 working days- customer dissatisfied

Risk Gradation

Scale	Meaning
<20	Low
20-40	Medium
>40	High

Risk assessment is to be done individual department / process head along with their team by using the Risk Assessment & Management QMS/F21. The above matrix is used to identify the risks & opportunity and classify the risks identified as High, Medium and Low risks. **Kaizen Engineers** will initiate the actions for High risk immediately. The identified risks are addressed in individual process's procedure and necessary control methods are also defined. This method will give assurance that the quality management system can achieve its intended result, enhance desirable effects, prevent, or reduce undesired effects and achieve improvement.

6.1.2.1 Risk analysis

The organization includes in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework

6.1.2.2 Preventive action

The organization has determined and implemented action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the severity of the potential issues.
The organization has established a process to lessen the impact of negative effects of risk including the following:
a) Determining potential nonconformities and their causes;
b) Evaluating the need for action to prevent occurrence of nonconformities;
c) Determining and implementing action needed;
d) Documented information of action taken;
e) Reviewing the effectiveness of the preventive action taken;
f) Utilizing lessons learned to prevent recurrence in similar processes
Reviewing preventive action taken

6.1.2.3 Contingency plans

The organization has:
a) Identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met;
b) Define contingency plans according to risk and impact to the customer;
c) Prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures; interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; labour shortages; or infrastructure disruptions;
d) Include, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations;
e) Periodically test the contingency plans for effectiveness;
f) Conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and update as required;
g) Document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).

The contingency plan includes provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

6.2 Quality Objectives and Planning to Achieve Them

The top management has documented a set of Objectives including those needed for product realization. These objectives are not measurable and consistent with the Quality Policy.
Every year measurable KPI against each objectives are quantified and planned arrangement is made to achieve the quantified objectives decided and set by the management by setting KPI (Key Performance Indicators) for relevant function.
A plan is prepared to achieve this KPI by utilizing the analysis of data generated in past as input. Achievement and continuing suitability of this is reviewed during the management review meetings. The corrective actions, if required, are immediately taken and effectiveness is reviewed in next management review

The General Quality Objectives as applicable for the whole organization are as under –

a) Timely delivery to customer (Prod. Dept.)
b) Reduce In-House rejection. - (QA)
c) Reduce customer end rejection. (QA)
d) Improve Customer satisfaction (MKT)
e) Increase Supplier Performance Rating (Pur. Dept.)
f) Training to employees (QMSR)
g) Increase in sales (MKT/ Proprietor)
h) Increase productivity (Prod. Dept)
i) Reduce machine down time

Refer Key Performance Indicator (KPI) QMS/F/17 for department wise objectives, target & status.
The Measurable Objectives appropriate to different activities are established, and are reviewed at least once in a year

6.2.2.1 Quality objectives and planning to achieve them – supplemental

Top management ensures that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization.
The results of the organization's review regarding interested parties and their relevant requirements has been considered when the organization establishes its annual quality objectives and related performance targets**.**
Responsibility & action plan to achieve quality objective defined in Action Plan For Quality Objectives **QMS/F/19**

6.3 Planning of Changes

When the organization determined the need for the changes to the quality management system, the changes has to be carried out in a planned manner by considering:

a) The purpose of the changes and their potential consequences;
b) The integrity of the quality management system;
c) The availability of resources;

The allocation or reallocation of responsibilities and authorities

Records:

Sl.No	Record Title	Format No	Review Freq'cy	Retention period	Retention Resp.	Indexing method	Disposition
01	Risk register	QMS/F/21	1 year	Till Rev.	QMSR	File / Computer	Shred/ Delete
02	Contingency plan	PRD/F/12	1 year	03 Years	Prod. Head	File / Computer	Shred/ Delete
03	Key Performance Indicator (KPI)	QMS/F/17	1 year	Till Rev.	QMSR	File / Computer	Shred/ Delete