

ISO 9001 QUALITY MANUAL

The Atticus Advisors Report

1 June, 2021

EXECUTIVE SUMMARY

- ❑ ISO 9001 is the international standard that specify the requirement for a quality management system
- ❑ This standard is used by organizations to demonstrate their ability to provide products or services that meet regulatory requirements
- ❑ It is based on the quality management principles that includes customer centric approach, leadership, people engagement, process improvement and relationship management
- ❑ In order to implement ISO 9001, organization needs to perform gap assessment, PDCA Cycle and Internal Audit
- ❑ Various tools are used in quality management system includes flowchart, cause and effect diagram, check sheet, pareto chart, histogram, scatter diagram and control chart
- ❑ Organizations need to identify the rationale behind implementation of proper quality management tool
- ❑ In order to mitigate or eliminate risk organization need Failure Modes Effects Analysis (FMEA). It formulate strategy to mitigate risk in day to day operation of organization
- ❑ Employees should be properly trained in order to increase productivity and organizational efficiency. To prepare employees for current and future challenges, the human resources department should develop learning and skill development strategies

HOW IT CAN BENEFIT YOUR BUSINESS?

- ❑ ISO 9001 : 2015 is an Internationally recognized standard for quality management system
- ❑ It is most widely used in the whole world
- ❑ It provide framework and sensible approach to your organization



ADVANTAGE

- ❑ Improve customer satisfaction- By delivering product that meet customer requirements
- ❑ Reduce Operating Cost- By improving process and product efficiency
- ❑ Help in creating brand and reputation in both national and international market
- ❑ Tender Eligibility and Improve marketability



ISO 9001:2015 ARE BASED ON 7 QUALITY MANAGEMENT PRINCIPLES

Customer Focus

Understand the need of present and future customer

Leadership

- It establishes the organization's vision and direction, sets challenging goals, provides trust and equipment, empowers employees, and recognizes people's contributions

Engagement of people

It ensures that people's abilities are used and valued, that individual performance is evaluated, and that learning is possible

Process Approach

It manages activities as a process, measures activity capability, identifies the link between activities and priorities for improvement, and effectively deploys resources

Improvement

It improves organizational performance and capabilities, aligns improvement activities, empowers people to make improvements, and consistently measures improvement

Evidence based decision making

It ensure the accessibility of accurate and reliable data, use appropriate method to analyze data and make decision based analysis

Relationship Management

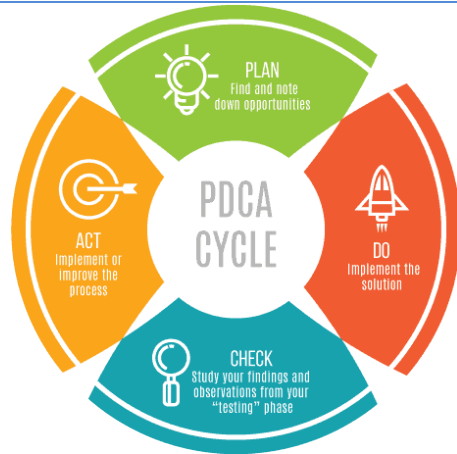
It establish relationship considering short and long term goals, sharing expertise, reviews, resources and information with the partners, it collaborate improvement and development activities and recognize supplier success



Steps To Implement ISO 9001:2015 Gap Assessment

It is a process in which you compare your company previous Quality Management System(QMS)

- Identify the correct person within the organization or hire ISO consultant
- Prepare gap assessment checklist- It contains current status, future status, gaps and action
• required to cover the gap
- Gap Assessment Questions- It contains the gap identified by the ISO 9001:2015 clauses
- Findings- Yes/No
- Implementation Plan- It contains Process owner, what is the gap, expected gap and actual gap
- Gap Assessment Summary- It contains point identified, name of the person assign to cover the gap and expected date to finish task
- Management Review Meeting



PDCA CYCLE

ISO recommends to do PDCA Cycle- Plan, Do, Check and Act

- In planning stage- Context of the organization, leadership, planning and support
- In Do section- Operation
- In Check section- Performance Evaluation
- In Act Section- Improvement

INTERNAL AUDIT

To assess the effectiveness of your organization quality management system and organization overall performance

Reasons:

- Ensure compliance with the requirements of International standard, Internal standard and Industry standard
- Determine the effectiveness of meeting quality, environmental, and financial goals
- Explore opportunity for improvements
- To meet statutory and regulatory requirement
- Provide feedback to top management

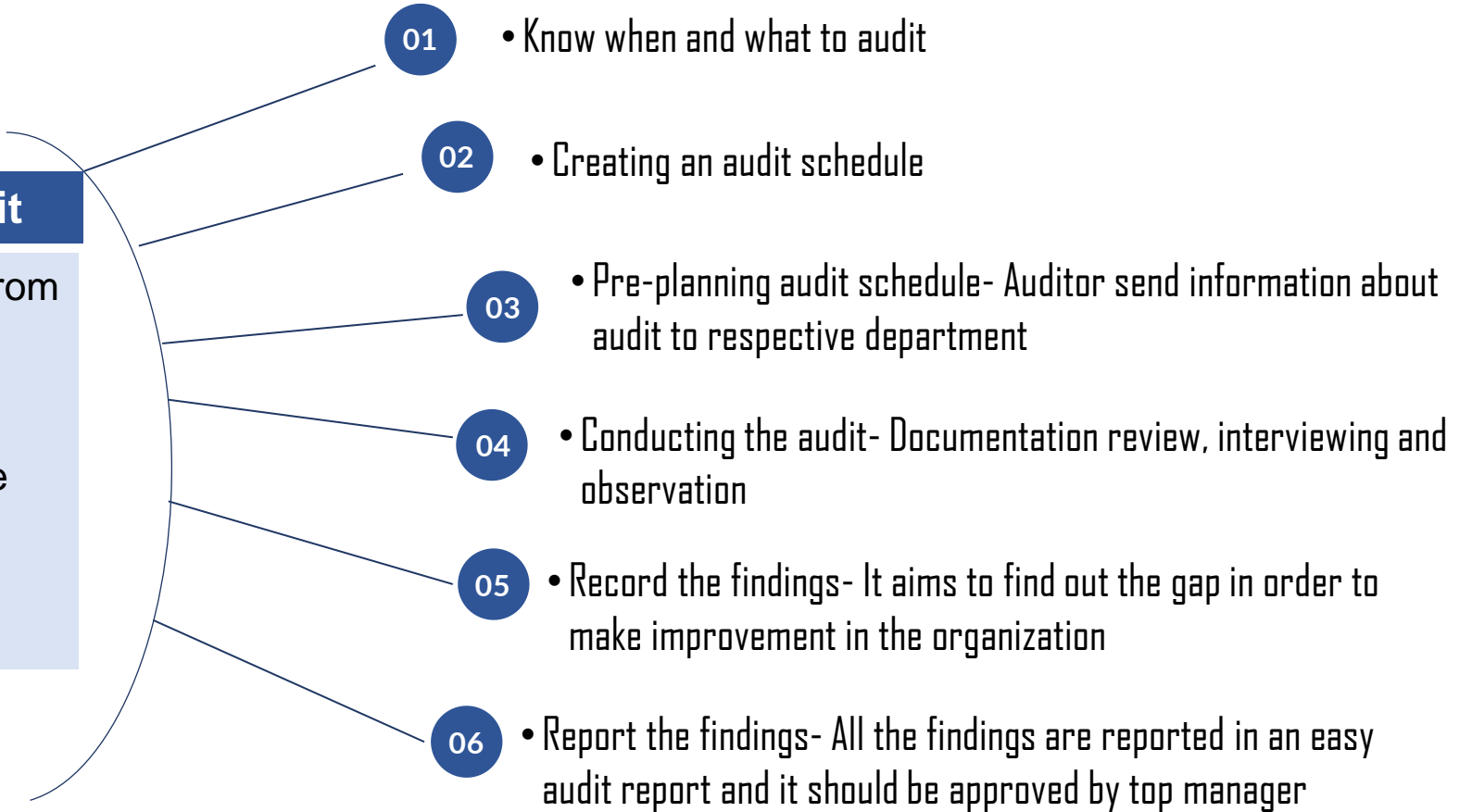




Steps To Perform Internal Audit

Requirement Of Internal Audit

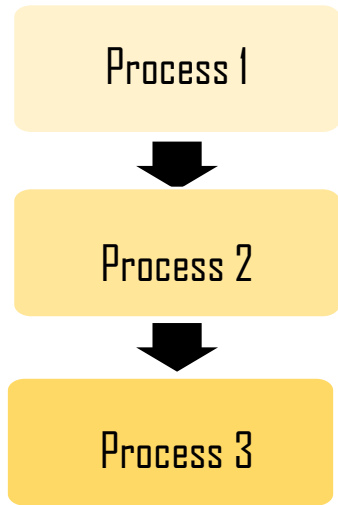
- Internal Auditor- It should not be from same department
- Audit Plan- It plan how, when and where you perform the audit
- Audit Checklist- It should be made according to ISO 9001 : 2015 clauses
- Audit Schedule





These 7 tools are used for continuous improvement within the organization **are as follows**

Flow Chart



What is the purpose of the flowchart?
It is used to describe the process, to see different activities and task during the process and to provide clear picture of what is happening

When is a flowchart used?
It can be used for any process, to identify the problem area and use to identify unnecessary loops of activity

How is the flowchart constructed?

- It has start and end point
- Each activity is identified
- Other process and records are identified

ISHIKAWA OR FISHBONE DIAGRAM

CAUSE AND EFFECT DIAGRAM ()

What is the purpose of the cause and effect diagram?

- It is used to identify all the causes which contribute to particular effect
- It is used to aid brainstorming

When is a cause and effect diagram used?

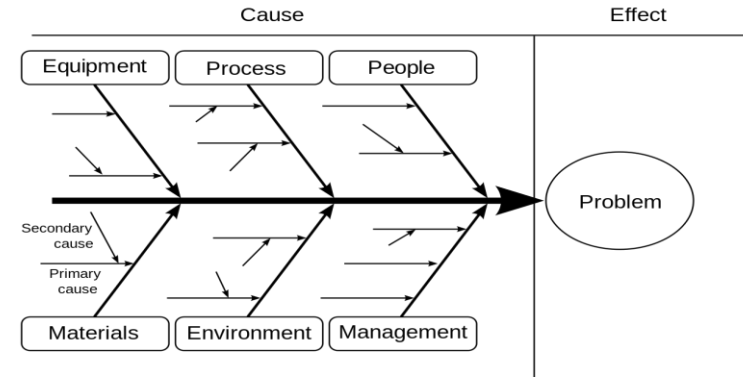
- It is used to identify the thing which combined to give a problem
- Used to look various factors that contributed to produce desired outcome

ISHIKAWA OR FISHBONE DIAGRAM

CAUSE AND EFFECT DIAGRAM

How it is constructed?

- Problem or desired outcome is placed at the head of fishbone skeleton
- Main categories of cause are identified
- Categories are brainstormed to identify specific contributory cause



CHECK SHEET

What is the purpose of check sheet ?

- It is used to collect data about activity in a way that is easy to use and analyze

When is the check sheet used?

- It is used to count number of times somethings happen

How is the check sheet constructed?

- Identify the types of fault or occurrence
- Record each time fault or occurrence is observed

Motor Assembly Check Sheet

Name of Data Recorder: Lester B. Rapp
 Location: Rochester, New York
 Data Collection Dates: 1/17 - 1/23

Defect Types/ Event Occurrence	Dates							TOTAL
	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	
Supplied parts rusted								20
Misaligned weld								5
Improper test procedure								0
Wrong part issued								3
Film on parts								0
Voids in casting								6
Incorrect dimensions								2
Adhesive failure								0
Masking insufficient								1
Spray failure								5
TOTAL		10	13	10	5	4		

PARETO CHART

What is the Pareto chart?

- It is use to assess the relative importance of the causes of the problem

When is Pareto chart used?

- Use to rank cause from most occurrence to least occurrence
- 80% of problems are result of only 20% of cause

How is the pareto chart constructed?

- Choose the comparison unit
- Record the comparison unit on vertical axis
- Place the cause on the horizontal axis from most occurrence on the left to the least occurrence on the right

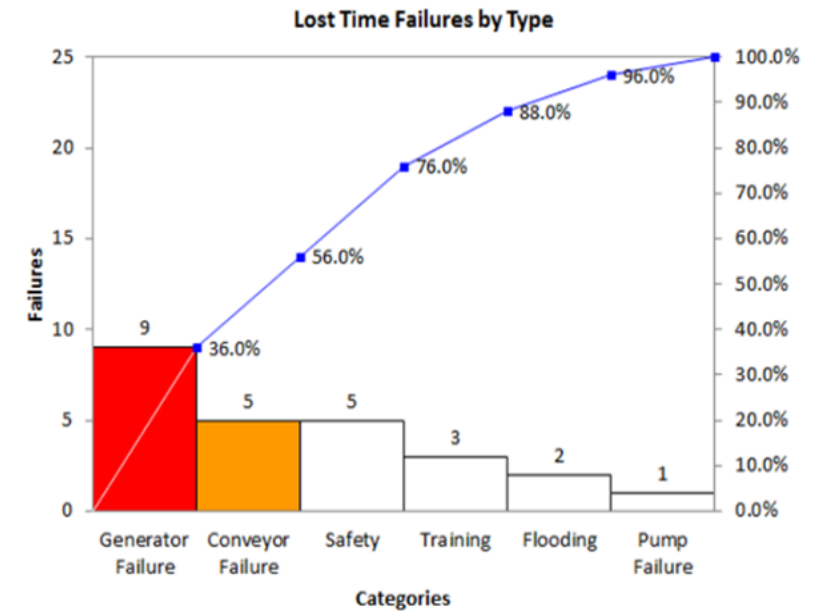
HISTOGRAM

What is the purpose of histogram ?

- Used to look at data that can be arrange in a group

When is the histogram used ?

- Use to examine large amount of data

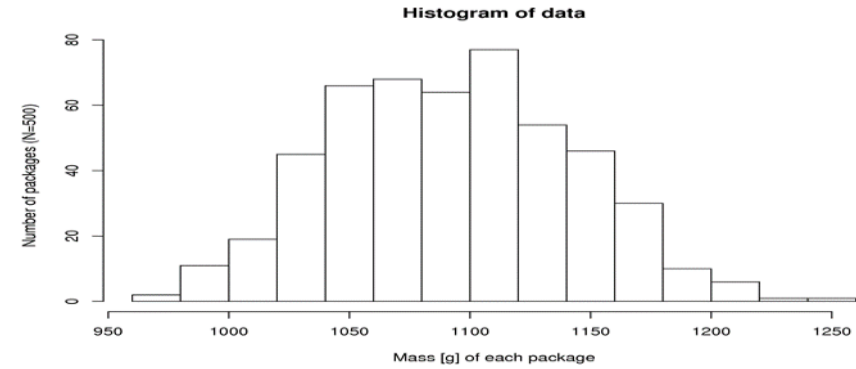




HISTOGRAM

How it is constructed?

- Choose the measurement
- Select the appropriate range
- Plot the measurement range on the horizontal axis
- Plot the number of each range on the vertical axis



SCATTER DIAGRAM

What is the purpose of scatter diagram ?

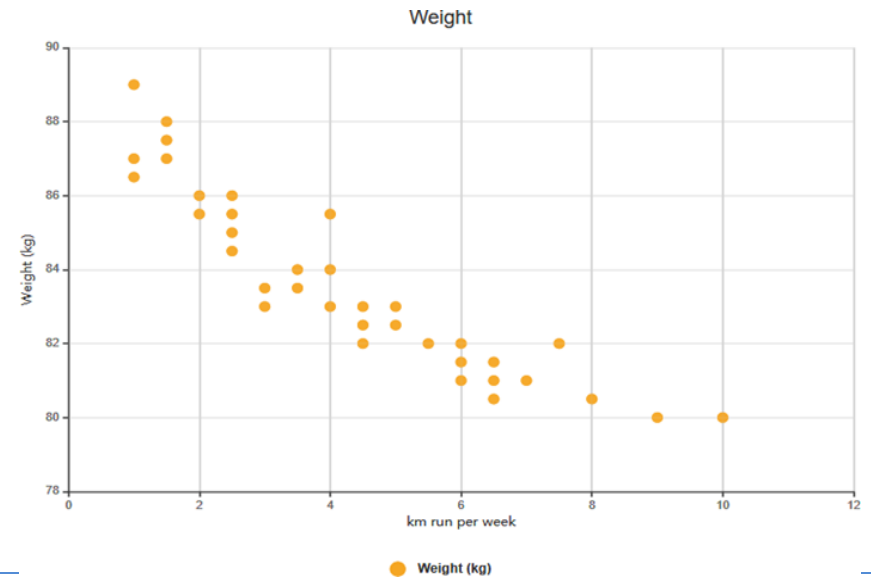
- Use to see if there is relation between two different things

When it is used?

- It is use to see when one measurement changes other one increases or decreases
- Use to see if there is relation between two measurement

How is the scatter diagram constructed?

- Choose two measurement that are related
- Plot one on vertical and other on horizontal axis





CONTROL CHART

What is the purpose of control chart?

- It is use to identify acceptable variation of a measures

When it is used?

- It is use to determine the problem within the process, if a measure is outside the limit then there is a problem with the process

How it is constructed?

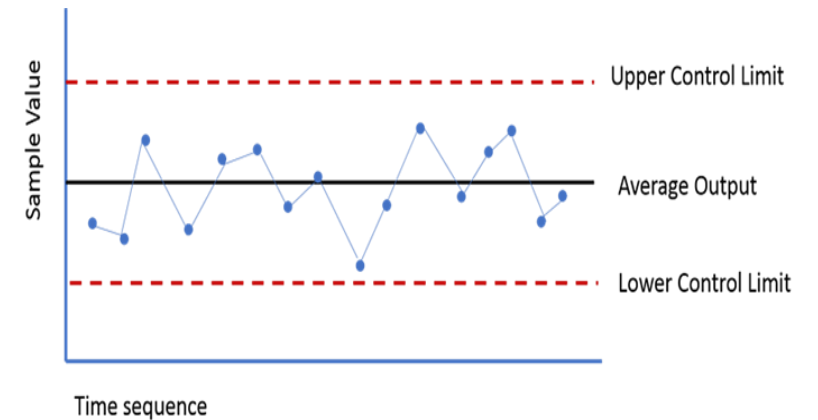
- Draw a line to represent upper limit
- Draw a line to represent lower limit

How we choose correct tool for quality management system?

In order to determine right tool for your company quality management system, you have to identify the following pointers:

- What do we want to measure
- What do we want to achieve
- What form does the data taken
- What do we want to do with the result

After analyzing all these factor you can easily identified the correct tool for the quality management system





It is used as a risk and project management tool.

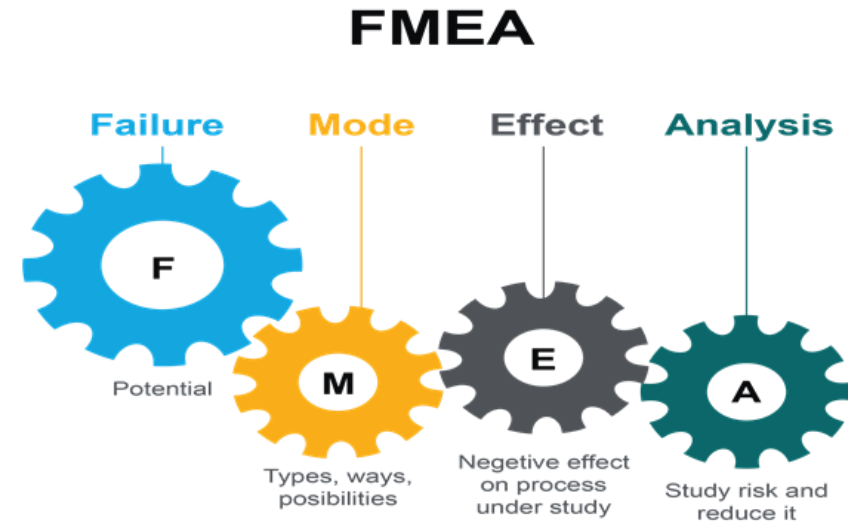
Risk Management

It is an element that is inherent in most project because most project doesn't go according to the plan. It includes following components:

- Avoid risk-Identify the alternate solution that minimizes or eliminate risk
- Transfer Risk- It involves transferring the impact of risk. For example- insurance
- Assume Risk
- Prevent or Mitigate risk- Device preventive actions using risk management tool to mitigate or prevent risk

FMEA is a risk management tool and it has two variants as follows:

- Product FMEA – More Applicable to manufacturing
- Process FMEA- More Applicable to service





How to construct FMEA Table

- **Function** - This describe function of product or processes
- **Failure Mode** -This describe the various potential failure mode
- **Effects** - This describe the effect of each potential failure mode
- **Severity Ranking** - This is the score that describe severity of failure effect
- **Causes** - This is used to identify and document the potential cause for each failure
- **Occurrence Rating** - Numeric ranking describing the probability of occurrence
- **Current Controls** - These are the controls that are used to prevent the cause of the failure
- **Detection Rating** - The assessment of the likelihood of detection of the failure
- **Critical Characteristics** - Measurement or indicators that reflect safety or compliance with government regulations and need special control
- **Risk Priority Number** - This the multiple of various number and indicator of the overall risk. It is used to priorities items for the action
- **Recommended actions and target completion date** - This ensure a fixed target date for incorporating the recommendation
- **Action Taken** - This is a follow up to the recommended action

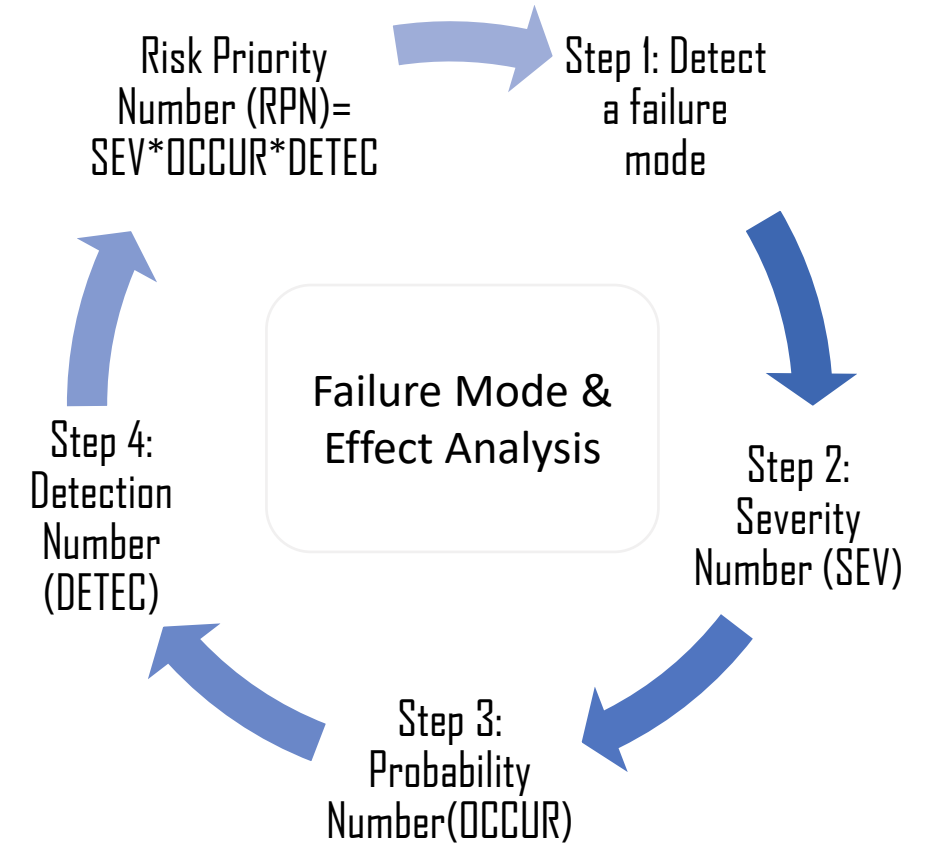
FAILURE MODE & EFFECTS ANALYSIS (FMEA)				Date: <u>1/1/2018</u>
				Revision: <u>1.3</u>
Process Name: Left Front Seat Belt Install		Process Number: SBT 445		
Failure Mode	A) Severity <small>Rate 1-10 10=Most Severe</small>	B) Probability of Occurrence <small>Rate 1-10 10=Highest Probability</small>	C) Probability of Detection <small>Rate 1-10 10=Lowest Probability</small>	Risk Preference Number (RPN) <small>AxBxC</small>
1) Select Wrong Color Seat Belt	5	4	3	60
2) Seat Belt Bolt Not Fully Tightened	9	2	8	144
3) Trim Cover Clip Misaligned	2	3	4	24



FMEA Contains

- **Potential Failure Mode** - In this you can identify how the process could fail
- **Potential Failure Effect** - Consequences on other system, part, people, noises, unstable, impaired, inoperative manner can be identified
- **Severity** - Severity of potential failure can be determined on the scale of 1 to 9
- **Potential causes of failure** - List of cause of potential failure
- **Occurrence Rating** - Occurrence of the failure on the scale of 1 to 9
- **Current Process Control** - Identify the control and preventive action
- **Detection** - Detection rate varies from 1 to 9 (1- almost certain and 9- very remote)
- **Risk Priority Number(RPN)** - It is an indicator of overall risk (RPN= Severity number x Occurrence number x Detection Number)

After calculating RPN, Highest risk will be placed on top and lowest risk on bottom, then we priorities risk from highest to the lowest and formulate mitigation plan to reduce or eliminate risk





Organization Focuses On Training And Skill Development

- To provide excellent quality product
- Understanding values and principle's policies of the organization
- Facilitate and improve job performance
- Focus on self-development
- Compliance of service standard

Every Organization Should Provide

- Induction training to new employees
- Domain specific training
- If employee need additional training to improve job performance then it should be given

Need Identification Of Training And Development

- Functional skill and behavioral requirement in case of new inductees
- New Organizational initiatives
- Annual Appraisal
- Internal and External Feedback
- New equipment, process and policies
- Few things to remember while providing training
- Prepare Training Module
- Skill Matrix
- Training Records & data
- Pre & Post evaluation post
- Prepare Skill matrix and differentiate employees into three categories:
 1. **Skilled Employees** - Perform task without any supervision
 2. **Semi-Skilled Employees** - Perform task under supervision
 3. **Un-skilled Employees** - Do not able to perform task at any cost

By adopting these strategies you can easily develop needed skills among employees to tackle current and future challenges

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