Maintenance Practices

Maintenance Baseline Practices

The recommended Maintenance requirement for Pharma Industry to comply with cGMP in order to assure and document that quality of drug ingredients will not be compromised due to maintenance activities or lack of maintenance. It covers Maintenance Good practices

Maintenance Good Practices

Practice utilized on system that do not have direct impact. These practices include –Unique systems or component identification, PM with documentation and record keeping

Maintenance Best Practices

Practices that go beyond Maintenance Baseline practices. This includes Reliability Engineering, Enhanced controls, trending, analysis, benchmarking etc

Maintenance Program

Document prepared by Engineering and approved by Quality Assurance describing the approach for performing maintenance. The program outlines maintenance strategies, plans, documentation, training and continuous improvement

Maintenance Philosophies

Basic types of maintenance philosophies

- **Breakdown/ Emergency maintenance**
  - Breakdown maintenance, sometimes called run-to-failure maintenance.
  - Occurs when an asset completely breaks down and needs repair to resume operation.
  - Sometimes breakdown maintenance is the default maintenance strategy, relying on reactive maintenance.
- **Corrective Maintenance**
  - Maintenance is carried out following detection and aimed at restoring normal operating conditions.
  - This approach is based on the firm belief that the costs sustained for downtime and repair in case of fault are lower than the investment required for a maintenance program.
  - However, this strategy is only good until catastrophic faults occur and all savings are gone.
- **Preventive Maintenance**
  - Maintenance carried out **at predetermined intervals** or according to **prescribed criteria**.
  - Aimed at **reducing the failure risk or performance degradation** of the equipment.
  - The maintenance cycles are planned according to the need and the incidence of operating faults is reduced.

Basic Maintenance Strategy

Risk Based Maintenance

- Maintenance carried out by **integrating analysis, measurement and periodic test** activities to standard preventive maintenance.
  Data is viewed in the context of the environmental, operation and process condition of the equipment.
- Aimed to perform the asset condition and risk assessment and define the appropriate maintenance program.
  All equipment displaying abnormal values are refurbished or replaced thus extending useful life and guarantees high levels of reliability, safety and efficiency of the plant.

- **Condition Based**

  Maintenance based on the equipment **performance monitoring** and the **control of the corrective actions** taken as a result.
  on-line detection of real time parameters of equipment is measured for automatic comparison with average values and performance.
  Maintenance is carried out when certain indicators give the signal that the equipment is deteriorating and the failure probability is increasing.

  This strategy, in the long term, allows reducing drastically the costs associated with maintenance,

Performance Measurement

You can’t manage what you don’t measure

Maintenance is often organized and performed to determine the impact on the business’s success

What we need:

- consistent and reliable data
- high quality analysis
- clear presentation of the information

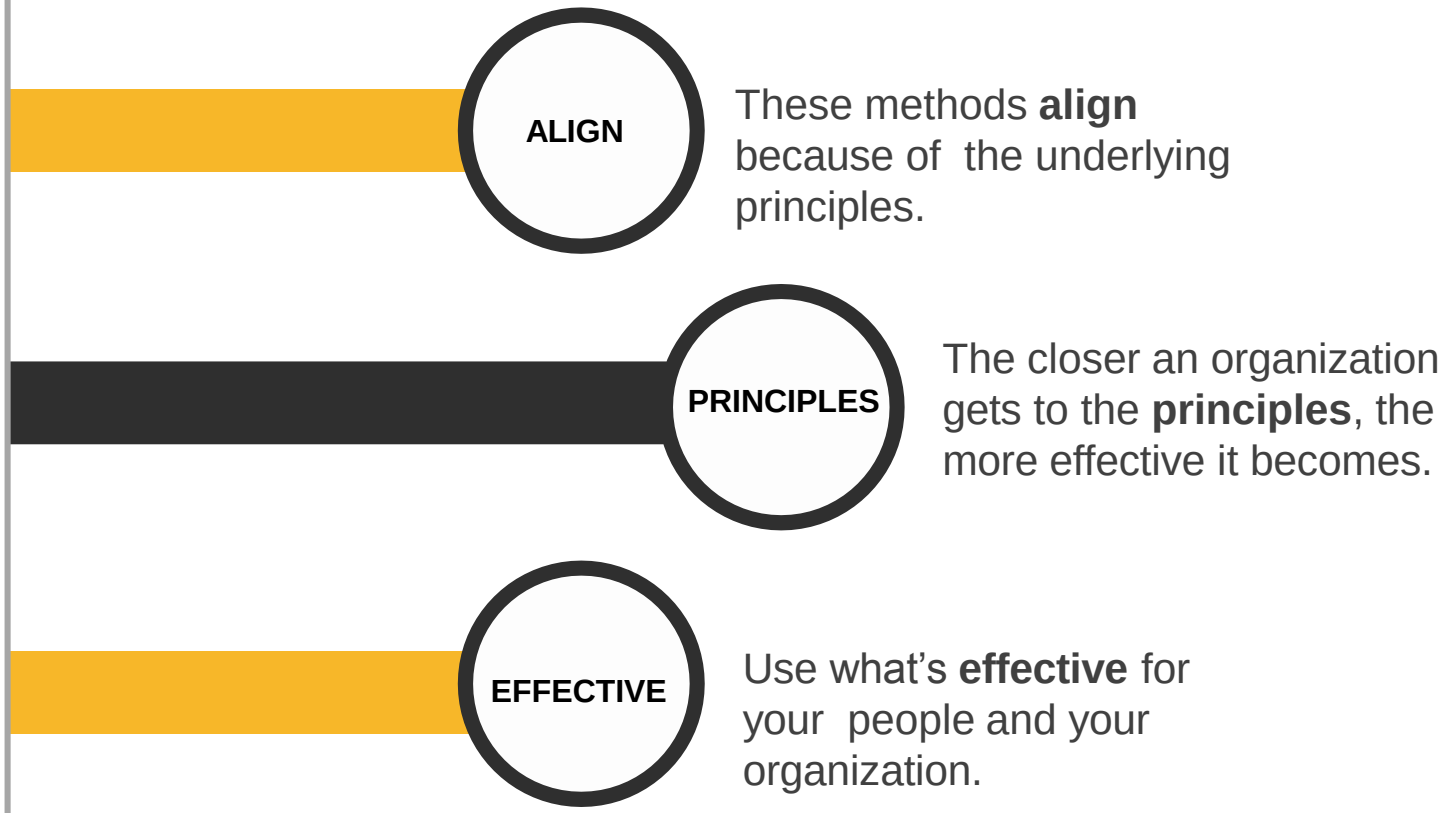
What we want to achieve,

- Reduce Breakdown
- Improve MTBF
- Reduce MTTR
- Reduce maintenance cost
- Increase utilization
- Improve setup time
- Improve maintenance skill
- Optimise spare parts inventory

Different tools for effectiveness

Focus on the Principles

- Reliability-Centered Maintenance
- Root Cause Analysis
- Six Sigma
- Total Productive Maintenance
- Kaizen
- Failure Modes Effects Analysis
- Quality
- Lean Manufacturing
- Value Streaming
- Total Quality Maintenance
- Error Proofing
- 5S



It's not about tool is applied but, ***It's HOW the method is applied.***

RCA AND RCM

Root Cause Analysis

PAST

What DID happen?

A method of investigating an incident to identify specific actions for preventing it from occurring.

(Reactive)

Reliability Centered Maintenance

FUTURE

What COULD happen?

An approach for developing a maintenance strategy to ensure equipment and process function in accordance to its inherent designed safety and reliability capabilities.

(Proactive)

Both are based on

- **Cause and Effect Principle** - Every effect has causes. Failure modes are causes.
- **Systems Thinking** - Every system breaks down into parts. The system itself dictates how the levels are broken down for the FMEA
- **Work Process** - Both focus on improving work processes with specific actions

Root Cause Analysis

Need to find root cause of the problem – fix the root cause don't just fix the symptom

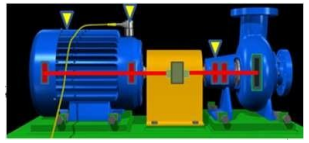
Why do we keep replacing the same bearing and seals?

50% of rotating machine damage is directly related to misalignment

Flexible couplings just transfer forces to bearings and seals

Most teams just replace bearings and seals because alignment takes too much time

Diagnose the root cause



Correct the root cause on most machines

Why are we worried about frequent loading of air compressor?

- Keeping air compressors running for important systems is critical to production
- Maintenance teams spend far too much time working and worrying about air systems
- Most teams just repair the compressors because finding leaks takes too much time
- Compressed air is expensive – largest source of energy waste in manufacturing

Scan for all leaks in the system and address those.

Common Tools and Strategies (CBM, preventive, troubleshooting etc)

Different Assets require different set of technology- Electrical, Mechanical, Thermal so on..

***Screening* tools** - thermal imagers, vibration meters, vibration sensors

Trend graphs / scan images – look for change of potential problems

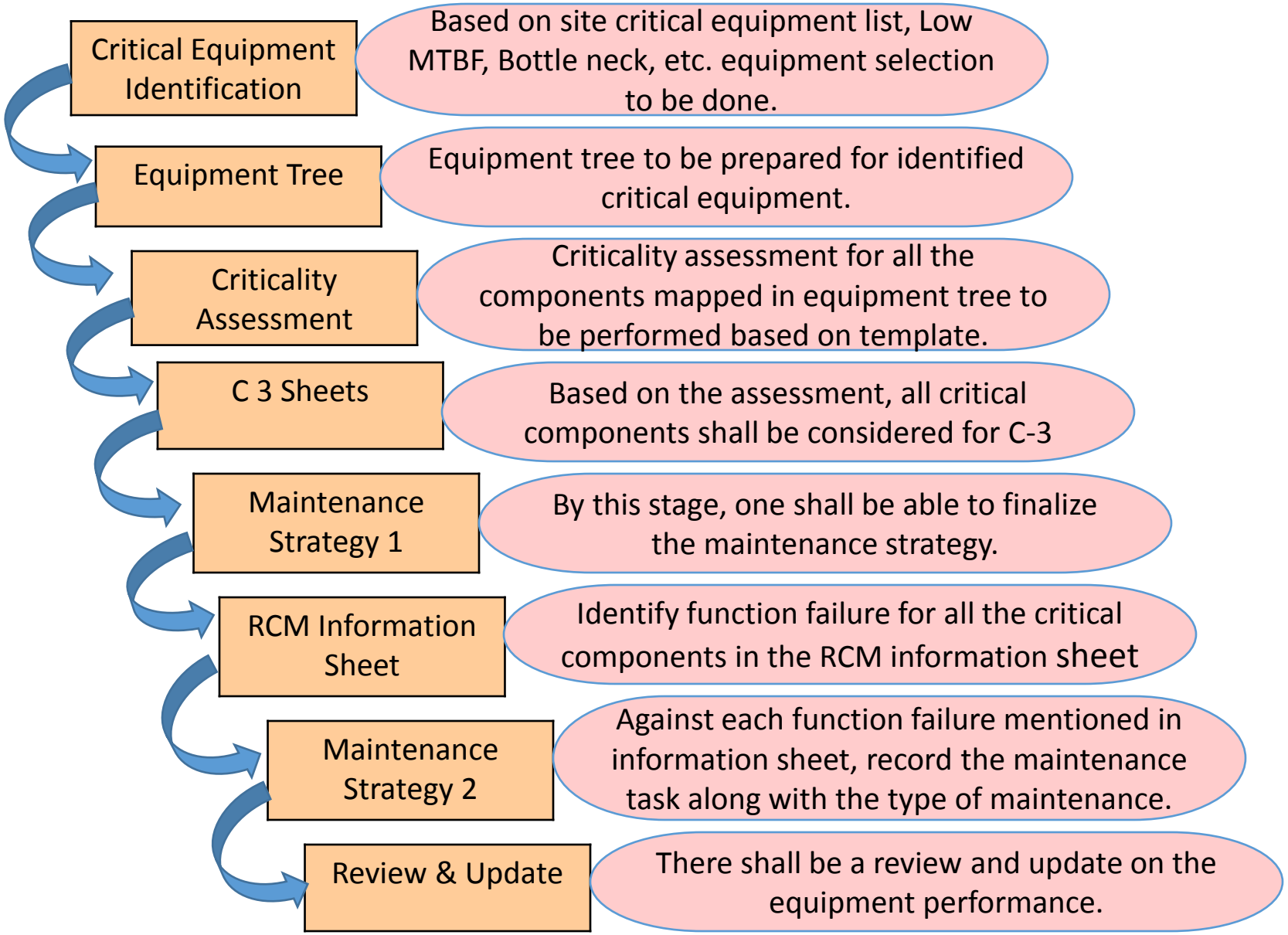
***Troubleshooting* tools** - electrical scopes, digital multi-meters, insulation testers

Analyze data – look for changes / troubleshoot of potential causes

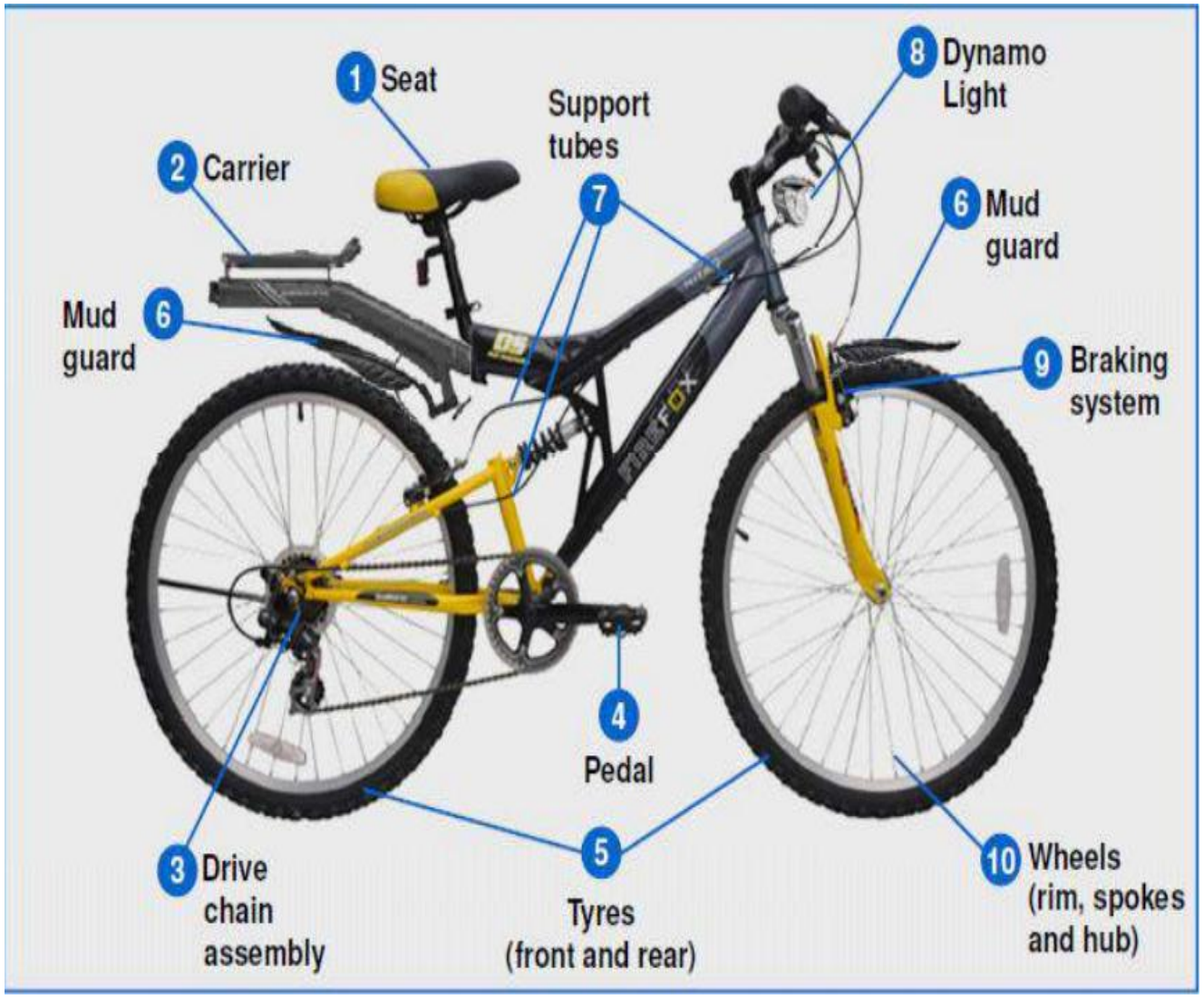
***Predictive* tools** - vibration tester, vibration analyzer, corrective tools, vibration sensors

Analyze results – evaluate faults and severity, recommend repair actions

RCM Flow


Critical Equipment Identification
Based on site critical equipment list, Low MTBF, Bottle neck, etc. equipment selection to be done.
Equipment Tree
Equipment tree to be prepared for identified critical equipment.
Criticality Assessment
Criticality assessment for all the components mapped in equipment tree to be performed based on template.
C 3 Sheets
Based on the assessment, all critical components shall be considered for C-3
Maintenance Strategy 1
By this stage, one shall be able to finalize the maintenance strategy.
RCM Information Sheet
Identify function failure for all the critical components in the RCM information sheet
Maintenance Strategy 2
Against each function failure mentioned in information sheet, record the maintenance task along with the type of maintenance.
Review & Update
There shall be a review and update on the equipment performance.

Equipment Tree

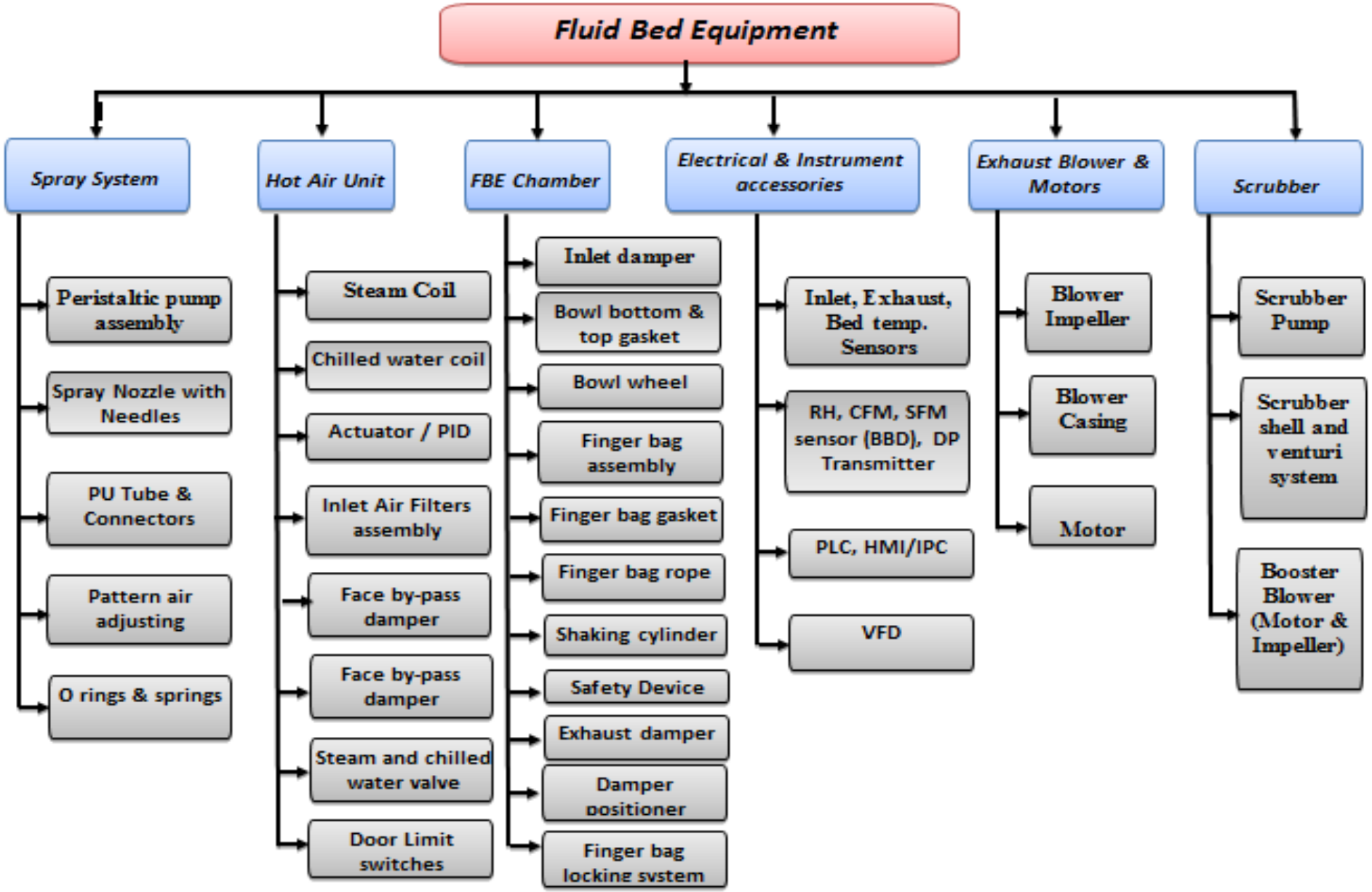


Bicycle part	Cycle run loss: Importance to keep bicycle running (High/Med/Low)	Cycle run loss: Probability/ frequency of failure (High/Med/Low)	Rating (A/B/C)	Environment rating[1] (A/B/C)	Safety rating[1] (A/B/C)
1 Seat	Low	Medium	B		
2 Carrier	Low	Low	C		
3 Drive chain assembly	High	High	A		
4 Pedal	Low	Low	C		
5 Tyres	High	Medium	A		
6 Mud Guard	Low	Low	C		
7 Support Tubes	Low	Low	C		
8 Dynamo Light	Medium	Low	B		
9 Braking System	High	High	A		
10 Wheels	High	High	A		

Top 4 critical parts

1. Drive chain
2. Tyres
3. Braking system
4. Wheels

Equipment Tree



Basic RCM Questions

1. What are the **functions** and associated performance standards of the assets in its present operating context?
2. In what ways does it **fails** to fulfil its **function**?
3. What **causes** each functional failure?
4. What **happens** when each function failure occurs?
5. In what ways does each **failure matters**?
6. What can be done to **predict or prevent each failure**?
7. What should be done if a suitable proactive **task cannot be found**?

RCM Decision Sheet

RCM TASK DECISION WORKSHEET (FBE)																
		Information Reference			Failure consequences				Proposed Tasks	Maintenance Classification (Check classification)				Initial Interval	Final Interval	Responsible
Main Component	Sub Component	F	FF	FM	H	S	E	O		PM	PDM	NSM	AM			
Spray system	PU Tube and Connector	2	A	1	Y	N	N	Y	Check the PU tube/ connector for any damage, if Found replace the same	X				3M	3M	
	Peristaltic Pump assembly	5	A	1	Y	N	N	Y	Check condition before start of load and Replace silicon tube if found damaged				X	Daily before start of load	Daily before start of load	Operator
				2	Y	N	N	Y	Replace damaged roller bearing	X				NA	NA	ENGG
				3	Y	N	N	Y	Check communication cable for any visible damage if found inform Engineering				X	Daily before start of load	Daily before start of load	Operator
				3	Y	N	N	Y	IF the cable is Damaged replace the same			X		NA	NA	ENGG
				4	Y	N	N	Y	Check proper flow of solution				X	Daily before start of load/ restart of equipment	Daily before start of load/ restart of equipment	Operator
	Inlet damper	1	A	1	Y	N	N	Y	Check the damper/ Bushes for any wear, if found replace	X				3M	3M	PMP team
	Bowl bottom gasket	2	A	1	Y	N	N	Y	Check the operating air pressure before start of equipment it should be in range 3-4 Kg.cm2. if any deviation from range observed inform Engineering				X	Daily before start of load	Daily before start of load	Operator
				2	Y	N	N	Y	Trained operators for gasket handling				X	NA	NA	PRODUCTION
				3	Y	N	N	Y	Trained operators for gasket handling and connector				X	NA	NA	PRODUCTION
				4	Y	N	N	Y	Trained operators for gasket handling and joint handling				X	NA	NA	PRODUCTION
				1	Y	N	N	Y	Check the operating air pressure before start of equipment it should be in range 3-4 Kg.cm2. if any deviation from range observed inform				X	Daily before start of load	Daily before start of load	Operator

F- Failure, FF- Functional Failure, FM-Failure Mode,
H, S, E – Impact on Health, Safety, Environment, O- Occurrence

PM – Preventive Maintenance
PDM – Predictive Maintenance
NSM – Non-Scheduled Maintenance, AM – Autonomous maintenance

Testing of Failure modes

Expected failure modes – Best Practices for each technology

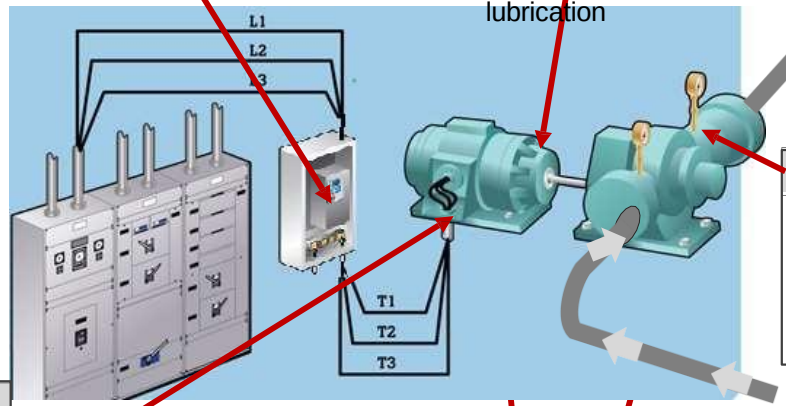
Match the best tool / technology to the expected failure mode

Think about your assets holistically - power in and work out

Combine technologies to protect each link in the chain

Thermography – high temp
- Find electrical hot spots
- Process / operations issues
- Support serious mech faults

Ultrasound – air leaks, lubrication
- Find leaks
- Valve actuator problems
- Bearings need lubrication
- Stem trap problems
- Tank tightness
- Electrical safety hazards



Oil: oil-cooled components
- Lubrication breakdown
- Component wear
- Overheating
- Wear particles

Energized:
- Current testing / MCSA /
- PF and Harmonic

Distortion De-energized:
- Motor insulation
- Megohmmeter

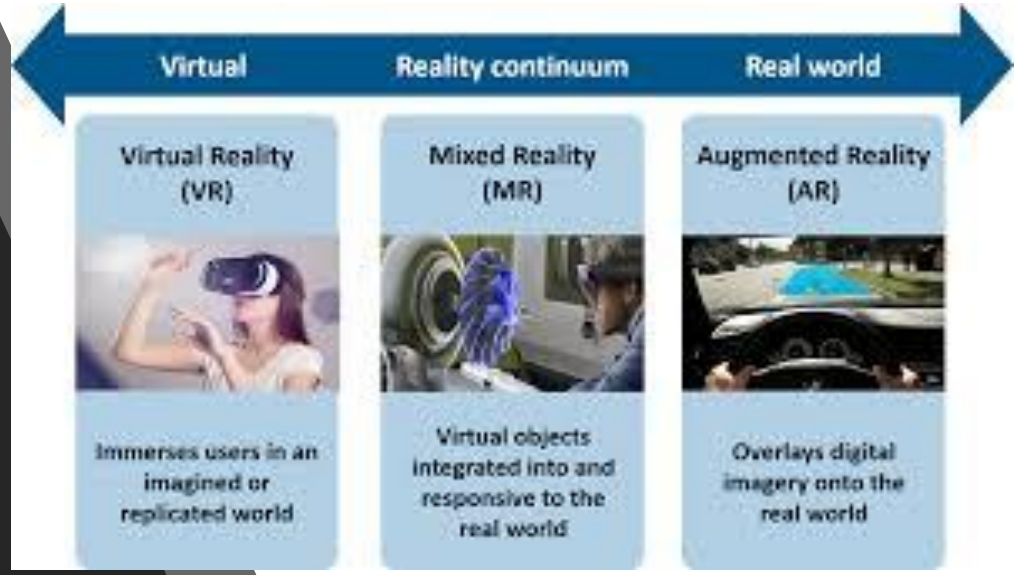
Vibration: best for mechanical faults on rotating machines
- Misalignment
- Resonance/structure Component faults
- Gear / belt faults Shaft imbalance
- Cavitation / turbulence
- Looseness
- Balancer
- Bad bearings
- Laser shaft alignment
- Laser belt alignment Speed / timing issues

Digital Enablement

- **Digitalization of what we do is current and become way of life in near future.** Some of the technologies already being explored by many,

  - **Computerized Maintenance Management System (CMMS)**
    - Reduced unplanned maintenance
    - Create Paperless environment
    - Increased visibility and Transparency
    - Increased productivity
    - Eliminate manual processes
    - Extending life of Assets
    - Spare part Management
  - **IIoT**
    - Real time Visibility on performance of equipment
    - Enhanced safety in operations
    - Increased efficiency in process
    - Online monitoring of power and other critical parameters

  - **AR,VR and MR Technology**
    - Training.
    - Enhances quality of maintenance and other operations.



THANK YOU