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DESIGN OF EQUIPMENT SAFETY & RELIABILITY FOR AN ASEPTIC LIQUID FOOD PACKAGING LINE THROUGH MAINTENANCE ENGINEERING

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By

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Abstract

The organisation of maintenance, in the Aseptic Liquid Food (ALF) industry, represents an important management task that enables a company to pursue higher manufacturing effectiveness and improved market share. This research is concerned with the process to design and implement maintenance tasks. These two complementary processes (design and implementation) have been thought and designed to answer the particular needs of food industry regarding product safety and equipment reliability.

Numerous maintenance engineering researchers have focused on maintenance engineering and reliability techniques highlighting the contribution of maintenance in achieving world class manufacturing and competitive advantage. Their outcome emphasizes that maintenance is not a “necessary evil” because of costs associated, but it can be considered an “investment” that produces an added value which generates a real company profit. The existing maintenance engineering techniques pursue equipment reliability at minimum cost; but in food industry, food safety represents the most critical issue to address and solve.

The research methodology chosen is based on case studies coming from ALF industries. These show that low maintenance effectiveness could have dramatic effects on final consumers and on the company’s image and underline the need of a maintenance design and implementation process that takes into consideration all critical factors relevant to liquid food industry. The analysis of measurable indicators available, represents a tool necessary to show the status of critical performance indicators and reveals the urgency of a research necessary to address and solve the maintenance problems in food industry.

The literature review underlines the increasing regulations in place in food industry and that no literature is available to define a maintenance design and implementation process for ALF and in general for food industry. The literature review enabled also the gap existing between theory and real maintenance status, in the ALF, to be identified and the aim of the research was to explore this gap. The analysis of case studies and Key Performance Indicators (KPI’s) available highlights the problem and the literature review provides the knowledge necessary to identify the process to design and implement maintenance procedures for ALF industry.

The research findings provide a useful guide to identify the process to design maintenance tasks able to put under control food safety and equipment reliability issues.

Company’s restraining forces and cultural inertia, that work against new maintenance procedures, have been analysed and a maintenance implementation process have been designed to avoid losing the benefits produced by the design phase. The analysis of condition monitoring systems shows devices and techniques useful to improve product safety, equipment reliability, and then maintenance effectiveness.

This research aimed to fill the gap in the existing literature showing the solution to manage both food safety and production effectiveness issues in food industry. It identifies a maintenance design process able to capture all conceivable critical factors in food industry and to provide the solution to design reliable task lists. Furthermore, the maintenance implementation process shows the way to maximize the maintenance design outcome through the empowerment of equipment operators and close cooperation with maintenance and quality specialists. The new maintenance design and implementation process represents the answer to the research problem and a reliable solution that allows the food industry to improve food safety and production effectiveness.

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Glossary of terms

ALF: Aseptic Liquid Food
AM: Autonomous Maintenance
APTU: Available Production Time Utilization
BSI: British Standards Institution
CBM: Condition Based Maintenance
CCP: Critical Control Points
CIM: Computer Integrated Manufacturing
CIP: Cleaning In Place
CM: Condition Monitoring
EEC: European Economic Community
FD: Failure Determination
FDT: Failure Detection Threshold
FFA: Force Field Analysis
FFT: Fast Fourier Transform
FMEA: Failure Modes and Effects Analysis
FMECA: Failure Modes Effects and Critical Analysis
FMEHA: Failure Mode Effect and Hazard Analysis
FR: Failure Rate
FRACAS: Failure Reporting And Corrective Action System
FSSC: Food Safety System Certification
FTA: Fault Tree Analysis
GDP: Gross Domestic Product
GMP: Good Manufacturing Practices
HACCP: Hazard Analysis of Critical Control Points
HAZOP: HAZard Operability
HRM: Human Resource Management
IR: Infrared Thermography
ISO: International Standard Organization
KPI: Key Performance Indicator
LCC: Life Cycle Cost
LCL: Lower Control Limit
LCP: Life Cycle Profit
LED: Light Emitting Diodes
JIPM: Japan Institute of Plant Maintenance

JIT:	Just-in-Time
MTBF:	Mean Time Between Failure
MME:	Machine Mechanical Efficiency
MTTR:	Mean Time To Restore
MWT:	Mean Waiting Time
OEE:	Overall Equipment Effectiveness
OPE:	Overall Process Effectiveness
OPL:	One Point Lesson
PDCA:	Plan, Do, Check and Act
PDF:	Probability Density Function
PdM:	Predictive Maintenance
P&L:	Profit and Loss
PM:	Preventive Maintenance
PME:	Packaging Material Efficiency
PMU:	Packaging Material Utilization
PT&I:	Predictive Testing & Inspection
PTU:	Production Time Utilization
RCA:	Root Cause Analysis
RCM:	Reliability Centered Maintenance
RMS:	Root-Mean-Square
RPN:	Risk Priority Number
RTF:	Run-To-Failure
SPC:	Statistical Process Control
TEI:	Total Employee Involvement
Tos:	Time from onset
TQC:	Total Quality Control
TU:	Time utilization
TQMain:	Total Quality Maintenance
TPM:	Total Productive Maintenance
UCL:	Upper Control Limit
UHT:	Ultra High Temperature
WCM:	World Class Manufacturing

Statement of original authorship

I Sauro Riccetti confirm that I am the original author of this thesis and that the research needed to produce this work was undertaken solely by me.

I confirm that this work has not been published previously nor has been used towards the award of any degree or any qualification of the Brunel University or any other awarding body.

Signed: …………………………………….

Date: ……………………………………….

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1. INTRODUCTION

In this chapter, the background to the research is defined starting from an analysis of the Aseptic Liquid Food (ALF) system. Threats, coming from increasing regulations from European legislation, are discussed as the basis, which leads the liquid food-manufacturing units toward the design and implementation of maintenance procedures.

Since public health can be heavily impacted by the safety and reliability of the equipment used for aseptic packaging, the design and implementation of maintenance procedures represent a fundamental tool to reach product safety and equipment reliability.

Justification for the research is discussed through the identification of the main research problem, formulation of the research questions, and definition of aims and objectives.

This chapter answers to the following questions:

- What are the ALF criticalities?
- What are the potential problems caused by equipment failures and stops?
- What are the mandatory product safety requirements in the ALF industry?
- How to reduce uncertainties due to human factor?
- What are the aims, the objectives, and justification for this research?
- What methodology has been used to develop the research?

The first chapter provides an answer to these questions and highlights the main maintenance process requirements.

1.1 The ALF industry threat: increasing regulation on product safety

Compliance with product safety EEC directives and international standards represent a mandatory requirement for those who operate in the ALF industry. Current legislation on ALF packaging call for the producers to identify the equipment critical control points in order to put them under control during the different production phases [1]. In the ALF packaging, the following are some of the functions that can be considered as critical to satisfy product and process requirements:

- Cleaning
- Product sterilization
- Equipment sterilization

- Package forming, filling and sealing
- Package handling.

Manufacturers of food products have to comply with legal requirements. For example, EEC directive 92/46 [2] specifies composition, safety, hygiene and labelling. At the present time, rules, guidelines and regulations, covering Good Manufacturing Practices (GMP) for long-life products, are being formulated in an increasing number of countries, either on a voluntary or legislative basis. Furthermore Hazard Analysis of Critical Control Points (HACCP) is a production process control methodology introduced at the European Community level through the EEC directive 93/43 [3]. HACCP identifies and assesses specific hazards, estimates risks and establishes control measures that emphasize product safety and its control rather than reliance on end product testing and traditional inspection methods [4]. HACCP presumes that not all phases of a food production process are dangerous to man. Therefore, its attention is concentrated on analyzing only process and equipment critical control points and not the whole production process.

1.2 Background of the research: food safety problems produced by low equipment reliability

This section deals with the production process in place in the ALF industry (main process): starting from raw liquid product, UHT sterilization, aseptic packaging, up to storage and distribution. Equipment and process criticalities are defined together with potential interactions existing between equipment reliability and product safety.

1.2.1 The ALF process and criticalities

The manufacturing process for an ALF is based on three main operations:

(a) Product processing (UHT sterilization)

Product processing covers the processes from the raw product inlet tank of the Ultra High Temperature (UHT) sterilizer, to the product inlet valve of the aseptic filling equipment. The inlet product is sterilized through different technical solutions, but a commercially sterile food, as result, must be free from toxins, pathogenic micro-organisms, and micro-organisms that can grow under normal storage and distribution conditions.

(b) Aseptic packaging (aseptic filling)

Aseptic packaging covers the processes from the product filling valve (of the filling machine) to the final closure of containers. The sterile product is pumped into a sterile environment to be introduced in the packaging material normally sterilized by the aseptic filler. Package filling, forming, sealing and cutting are critical operations necessary to produce a hermetic filled package ready to be stored and distributed.

(c) Package distribution and storage

Package distribution covers the processes from the filling machine output to the storage of the packages (distribution machines such as straw applicator, tray packers, and palletizer are normally used for this purpose). Figure 1 below shows the three main blocks regarding ALF process.

Figure 1: Aseptic Liquid Food (ALF) process

An ALF process must satisfy four main requirements:

- Raw liquid product sterilization
- Aseptic packaging
- Production of hermetic sealed packages and
- Package integrity preservation during distribution and storage.

The raw product must be sterilized, packed, and kept sterile during the different phases of its shelf life. To achieve this result, the liquid product must follow an aseptic transfer throughout the whole process. After product sterilization, the liquid is pumped into a container that has been previously sterilized. The sterile product conserved in the closed package can be contaminated at any time if package integrity is lost. A small hole, of the dimension of one micrometer, produced by a scratch or due to bad package sealing, may produce product contamination. Some critical functions, such as:

- Equipment sterilization
- Package filling, forming, cutting, sealing
- Package handling

might cause product contamination if an appropriate maintenance activity is not carried out on the line equipments. Product contamination can be dangerous to public health and the production unit responsible for such problem can be forced to close down its activity.

1.2.2 The main research problem

A maintenance process, to maintain the equipment criticalities under control, represents a mandatory requisite to insure equipment reliability, to avoid negative interactions between equipment and product safety. Since a machine failure can have such a tremendous impact on the public health and on the whole manufacturing company, all the conceivable reasons of equipment failure must be identified and monitored to eliminate possible risks to human health. Lack of maintenance procedures, designed and implemented to keep the process “in control”, may also result in heavy losses and low market share due to a poor product safety and quality. In spite of these requirements and stringent health and safety regulations, many companies in liquid food processing show appalling complacency when it comes to investigating the reasons behind low process safety and reliability. This research will investigate the effects produced by the equipment failures, downtime on product safety to highlights the necessity of a maintenance process specifically designed for the ALF industry. Because no literature is available to define a maintenance design and implementation process for ALF industry, the effects of some equipment failures can represent a serious risk for the final consumer’s health resulting also in a big market share loss for the company responsible for such an event.

1.2.3 The effects of equipment stop in the ALF industry

While in mechanical industry a machine stop could have a low economical impact on production cost, in the ALF industry, equipment stop must often be followed by equipment cleaning and sterilization before a new production start. Product and package waste, together with other raw materials waste, create a strong impact on total production costs. Moreover the downtime necessary to clean, sterilize the equipment and the different criticalities to manage before a new production start, determine higher costs and product safety risks. Before a production run can start, the following two conditions need to be satisfied:

1. Equipment cleaning

Surfaces in tanks, pipes and other process equipment that come into contact with the liquid product have to be properly cleaned to avoid formation of dirt and growth of bacteria. A cleaning procedure normally involves a pre-rinsing with water, cleaning with detergents and chemical agents and post-rinsing with clean water.

2. Equipment sterilization

For UHT products, sterilization by means of heating or with chemicals is necessary to sterilize the equipment in order to render the surfaces completely free from bacteria.

The nature of the technology used means that, the average time needed to perform a cleaning program and then equipment sterilization can vary from two to four hours. Both these operations must be carried out every time that the equipment is stopped for whatever reason. Sometimes the filling machine stop involves the processing equipment stop and vice versa. In such cases, a machine fault creates a big disturbance to the whole process since all the equipment must be stopped to carry out the cleaning and sterilization programme. Therefore, while the time necessary for preventive maintenance activities can be properly reserved, an extraordinary failure will produce disturbance to the planned production and heavy losses due to the unexpected downtime.

Lack of maintenance procedures, or a maintenance approach based on reactive maintenance to equipment failure, may produce biological, chemical, and physical risks on the product packed. The process to design and implement maintenance procedures must ensure that all conceivable critical points that may result in product contamination have been identified and put under control through the implementation of reliable maintenance procedures.

1.3 Development of a process to design and implement maintenance task lists

Following the indications provided by the food safety legislations and by the GMPs, the maintenance design and implementation process must address and solve the problems linked to the product safety and equipment reliability. The process should clearly identify how to design and implement maintenance procedures, roles, and responsibilities for an effective maintenance process implementation. HACCP, GMPs and ISO directives (mandatory and voluntary) should not represent a threat, but a real opportunity for a company to develop a reliable maintenance solution to answer this important question.

The scope of this research is to define a maintenance design process able to identify the existing Critical Control Points (CCPs) in the production line equipments and the relevant maintenance procedures to put under control the product safety risks. Moreover, the research identifies an implementation process to insure an effective implementation of maintenance procedures through the integration of different company's roles.

1.4 Condition monitoring to reduce human errors and their impact on product safety

Since human errors, in monitoring and evaluating the status of equipment components, could have a dramatic effect on product safety and system reliability, the use of condition monitoring systems represent a necessary tool to reduce the risks associated with "human factor". Beyond maintenance activities, intended to maintain the intrinsic equipment safety and reliability, the use of condition monitoring devices will enable the equipment to be upgraded to a more reliable automatic control of critical parameters instead of relying on human checks. In recent years, different transducers have been developed to help equipment designers to establish automatic monitoring of critical parameters improving therefore the intrinsic equipment safety and reliability. These transducers translate various physical quantities related to fluids, solids, and gas into measurable electrical signals thus enabling automatic monitoring of critical parameters.

Such devices can be part of the equipment or be installed later on as part of a safety upgrade project intended to monitor CCPs that might have serious effects on the final product quality and safety. Furthermore, the use of some condition monitoring instruments will put under automatic control variables normally controlled by subjective checks. The integrity of a mechanical part or the heat developed by an electrical motor can be automatically controlled by instruments, which measure both vibration and temperature developed by the equipment's parts or components. The use of such tools will help to ensure that the effort spent in the design phase is not lost in the implementation phase. Thermography, vibration analysis, and tribology, with the related systems, will play an important role to reduce human errors and to improve maintenance effectiveness and equipment reliability.

1.5 Aims and objectives and their justification

The aim of this research is to establish the highest product quality and safety through the design and implementation of maintenance procedures specifically addressed to ALF industry. The process designed represents a real aim since it enables the ALF companies to put under control food criticalities, and satisfy product safety requirements mandatory in every country.

The main objective of this research is the production of the process to design and implement maintenance procedures for ALF industry. The process to design and implement maintenance procedures must acknowledge and address the following critical variables arose in the case studies:

- product safety
- equipment reliability and
- risks dependent on human factors.

All these variables have to be managed through a maintenance process to address product safety and equipment reliability together with cost demands. The research objective was the identification of CCPs in place in an ALF packaging line to design and implement a maintenance process that allows product safety and equipment reliability to be reached at a reasonable cost. Aims and objectives are justified by the literature review that showed the necessity to fill the knowledge gap, regarding lack of a maintenance process for ALF industries, to determine, as result, product safety, and equipment reliability. Maintenance processes implemented in other industrial fields, normally pursue quality, reliability, efficiency, and cost driven issues, lack of a maintenance process, able to manage food product safety critical issues, represents the research justification to produce as result the mentioned aims and objectives.

1.6 Methodology

The methodology used for this research is based on analysis of some case studies that address:

- The necessity of an ALF maintenance process specifically designed for this industrial sector
- The results (in terms of safety and reliability) produced by the implementation of the maintenance process designed for the ALF industry.

The reason that justifies the use of this methodology, based on the case studies, is the lack of a maintenance design and implementation process to address and solve the questions placed in the previous sections. The primary and secondary literature research showed that no work has been conducted by other researchers to define a maintenance process for ALF industry.

The analysis of the case studies represented the best approach to gather information on the ALF criticalities and on the need of a maintenance process to solve the problems linked to the equipment used in the ALF production lines.

The research content is defined by “two levels” of literature:

- *Level 1*: Primary literature based on company-specific material, which provided an indication of the status of maintenance within the organizations
- *Level 2*: Secondary literature that helped to define the research problem and research questions.

1.7 Conclusion

In this chapter, product safety EEC directives and standards have been examined; they represent a mandatory requirement which call the ALF industry to identify the packaging line CCPs and the relative solutions to put them under control. Examination of ALF process shown criticalities that link equipment reliability to product safety: poor equipment reliability, dependent on lack of an effective maintenance process could produce, as result, heavy consequences on product safety and then on public health. The demands placed by the legislation, compared with the complexities of the ALF industry lead to the identification of the research problem. The effects produced by lack of control, of packaging line CCPs, on product safety and on company’s costs, represent the leverage to identify the equipment criticalities together with the solutions to put them under control. Figure 2 below summarizes the different steps and questions that led to the identification of the research problem.

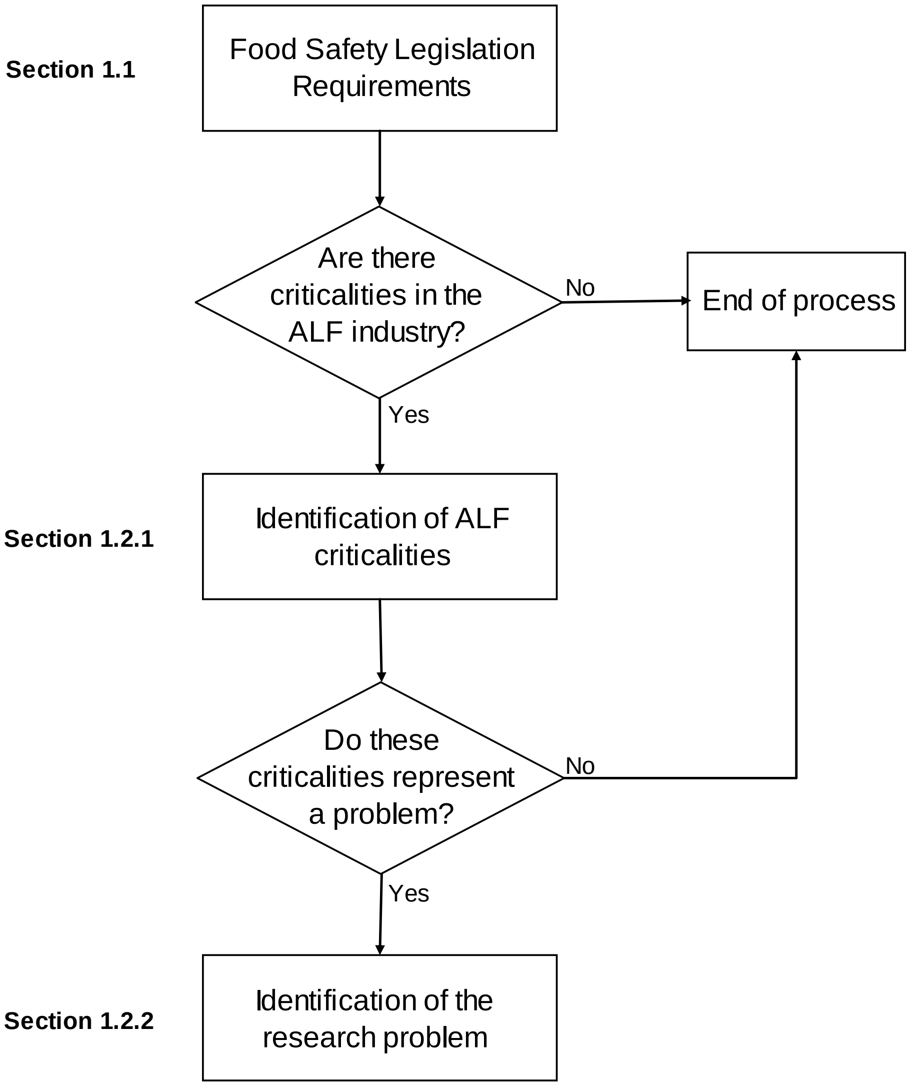


Figure 2: The process to identify the research problem

Section 1.4 showed the benefits coming from the use of condition monitoring devices in improving the inherent equipment reliability through the monitoring of CCPs and the possibility to be less dependant on the quality of subjective checks and manual control. Aims, objectives, and their justification have been identified to describe the added value of this research. The last section of this chapter identifies the methodology chosen to develop this thesis and the reasons why this methodology have been chosen.

2. ALF CRITICALITIES AND MAINTENACE NEEDS SHOWN BY THE CASE STUDIES

2.1 Introduction

The industries involved in processing and packaging aseptic liquid foods, such as milk or fruit juice, have always been conscious of the need to establish and maintain the highest standard of hygiene. In recent years, however, this requirement has assumed even greater importance due to changes in the market and technology. Market (that is consumer) expectations of quality and hygiene have been rising continually together with pressures on companies: as an effect of these trends, the organization of maintenance has an important role to play in developing competitive advantage.

The second chapter identifies:

- Problems and threats but also the opportunities in the ALF industry
- Five case studies that show the criticalities of the ALF packaging lines and the effects produced by lack of a maintenance process to design and implement maintenance tasks
- The scope and requirements of food safety certification.

This chapter describes some of the ALF market problems dealing with increased competition, cost pressures and downsizing. It presents maintenance as an important weapon to improve product quality and safety, to reduce costs, to comply with food legislation, and to improve the company’s competitive advantage. Three different case studies underlines the effects produced by lack of control of some critical points, the economical losses produced by product contamination and the need of a maintenance process to put the ALF criticalities under control.

2.2 Problems, threats and opportunities in the ALF industry

The competition in the ALF industry, mainly based on product price, leaves very little room for error for a company when estimating production costs and the influence of product safety and production effectiveness. Nowadays, cost competitiveness represents a problem to deal with for many companies, increasing competition and downsizing a real threat, but these two challenging inputs can be transformed into improvement opportunities through a new approach to maintenance with positive result on costs.

Increasing competition

The market for aseptic milk is becoming increasingly challenging because of free competition within the European Community. This competition, mainly based on consumer product price, calls for companies to reduce costs and to constantly identify possible sources of cost reduction.

Cost reduction

The constant downward pressure on prices has resulted in increasing attempts to reduce production and other costs. Activities, considered to be non-value adding, are eliminated while others, such as maintenance, have been dramatically reduced in time or frequency. Head counts are reduced progressively, affecting the ability of maintenance personnel to undertake routine tasks and sometimes to carry out corrective actions when breakdown occur. An extreme reaction to increased competition is shown by those companies that postpone investments and refuse to pursue any kind of production efficiency methodology.

Downsizing and outsourcing

Medium to large aseptic liquid food companies outsourced engineering and maintenance work as they downsized during the 1990s. Strategic alliances and partnerships with suppliers are created to retain capabilities the company once had in-house and/or to gain access to new markets and new technologies.

According to Morris [5] downsizing/restructuring has, and will continue to have both positive and negative consequences. One major effect, of course, is fewer people with more responsibilities. Most panellists who have experienced downsizing see this trend increasing in the future. Reduction of maintenance specialists represents a restriction and sets the necessity to drastically reduce equipment downtime. The technical skill necessary in the ALF requires a specific knowledge and experience over many different areas. The outsourced personnel has in most cases general electrical or mechanical competency, but lacks the experience necessary do deal with ALF problems. It has been stated that at least an experience of 3-4 years is necessary to deal with the standard level of equipment troubles.

In conclusion, downsizing creates three different problems:

- Low equipment efficiency due to the lack of experience in operating the machine

- Low supportability due to fewer specialists available to carry out corrective maintenance activities
- Low equipment reliability due to the inability of outsourced personnel to cope with all ALF requirements.

Despite the threats coming from the increasing competition, successful companies continue to implement Total Quality Management (TQM) programs, Just In Time (JIT) procedures, new technologies and new maintenance techniques to improve equipment effectiveness and product quality.

New approaches to maintenance

The external pressures on food processors, from increasing health and safety legislation and regulation and increasing competition, continue to focus attention on the maintenance function, which has to be seen not simply in terms of compliance or the avoidance of problem, but as a potential contributor to creating competitive advantage. While the state of art of the technology used today allows a reduction of critical control points that depend on human control, maintenance remains the only available tool to improve product safety, equipment reliability, and availability.

2.3 Analysis of case studies to address the need of a maintenance process for ALF industry

Under this heading, the analysis of some case studies will underline the need for a maintenance process specifically designed for ALF industry. The process for designing and implementing maintenance procedures should address and provide answers to all mandatory requirements placed by the law and by the GMPs applied to this industrial sector.

2.3.1 First case study: product contamination due to scratch in the packages

This case study comes from a company that produces pasteurized and UHT white and chocolate milk.

(a) Equipment setup

Two different sterilizers supply the aseptic product to the filler with an average capacity of 15.000 l/h. The aseptic transfer has been realized through an aseptic tank with a capacity of 25.000 litres. Four different filling machines are used to pack white milk and chocolate milk.

(b) Problem description

The company experienced an unsterility problem on one production line that caused a direct economic loss higher than 450.000 Euro.

The production manager claimed that this economic loss was only due to direct costs arising from:

- packaging material waste
- product waste and
- operator salary.

The unsterility was discovered through a product sampling scheme where four packages were drawn every 15 min. and incubated at 32° C. The evaluation done after four days, by means of product pH measurement, confirmed with plating, identified product contamination. After further investigation, carried out through a destructive testing on packages produced, some micro holes with plastic lumps were found on the longitudinal sealing of the package.

(c) Trouble shooting

To identify the potential causes behind this phenomenon a trouble shooting activity was carried out on three main areas:

- cleaning procedures
- filling machine operation
- packaging material characteristics.

During these activities, it was found that the contamination problems occurred only on one filling machine and that the type of spoilage was dominated by blown packages with a coagulated and flat sour product. The distribution of the problem was random and sporadic, but spread out over the whole production run.

After careful investigation on the filling machine, it was found that the cause of the blown packages produced was a wrong adjustment done on a package damper. The incorrect setting of this component caused a small scratch on the packages, and then an integrity loss and a steady contamination of the product packed.

(d) Conclusion

At the end of the investigation the following conclusions were drawn:

- the problem should have been detected by the filling machine operator during the package integrity checks (through the implementation of standard quality control procedures)
- preventive maintenance was not regularly executed
- the wrong damper adjustment, carried out by the filling machine operator, was an extraordinary action to solve problems depending on lack of a preventive maintenance program.

This case emphasizes the need to regularly implement the quality control checks to avoid many hours of production of contaminated product due to lack of package integrity. Package integrity is the result of correct package forming, sealing and transfer throughout the different pieces of line equipment. This experience shows the importance of maintenance in controlling the biological risk and in preventing package integrity problems that produce product contamination.

2.3.2 Second case study: product contamination due to package integrity problems

The second case study comes from a company that produces UHT milk, cream, and fruit juice.

(a) Equipment setup

One product sterilizer supplies an aseptic filler packing cream and fruit juice at a capacity of 20.000 packs/hour. The aseptic filler is well equipped with different monitoring systems to monitor critical parameters such as the filling circuit cleaning (temperature, speed, and concentration) and the sealing of packages produced.

(b) Problem description

The company claimed a product contamination, due to the sporadic presence of non hermetic transversal seals, on 200 ml packages, filled with UHT cooking cream.

Since the defect rate was not known and the failure distribution was random, the company was forced to withdraw 200.000 packs from the market and to organize a quality control inspection on the entire product produced. The economical loss produced by this event was higher than 300.000 Euro and the troubles created by the product delivery delays were underlined by different retailer claims.

(c) Trouble shooting

The trouble shooting activity started on jaw (package forming) and sealing systems to verify if mechanical and electrical operations were correctly performed. The different destructive tests, performed on a huge sample of filled packages, could identify small micro holes distributed on the package transversal sealing. Further tests have shown the presence of some micro-channels evenly distributed on top and bottom package sealing. The trouble shooting carried out on mechanical and electrical components of the forming and sealing section could identify the following anomalies:

- some pressure rubbers (used in the sealing section) were completely worn out
- some inductor profiles were out of tolerance (concave instead of straight)
- the electromechanical power transfer system (bar and slider) were mechanically worn causing voltage drop and then power loss
- one sealing transformer was damaged.

It was also discovered that, to reduce maintenance cost, the preventive maintenance program suggested by the equipment supplier was not followed and that corrective maintenance was the sole maintenance activity carried out on this equipment.

(d) Conclusion

At the end of the investigation the following conclusions were drawn:

- the problem should have been detected by the filling machine operator during the package integrity checks (through the standard quality control procedures)
- replacement of worn out inductors and pressure rubbers could be done by the machine operators following a simple daily and weekly maintenance procedures
- the wrong power transfer could be detected by the machine operator if further training had enabled him to regularly check some electrical parameters
- the company’s management understood that the tentative to save money has resulted in a wider economical loss and agreed on the necessity to implement reliable maintenance procedures.

This case shows the result of loss of control of some equipment criticalities associated to the production of hermetic sealed packages containing liquid food products. The equipment functions and parts involved in forming, filling and sealing the packages need to be put under control through maintenance procedures able to manage the biological and physical risks depending on equipment safety and reliability.

2.3.3 Third case study: product contamination due to mineral oil leakage

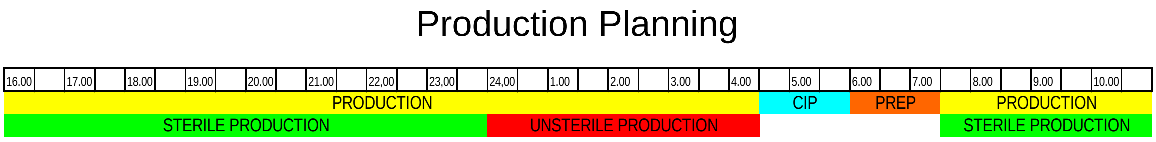
This case study concerns a company that produce UHT milk and cooking cream and that experienced a complex unsterility case.

(a) Equipment setup

Two product sterilizers supply an aseptic filler packing cooking cream with a capacity of 7500 packs/hour. The downstream equipment is quite simple and made by one cardboard packer and a final palletizer.

(b) Problem description

The company claimed a sporadic product contamination, concentrated on a specific time interval, which disappear after a final cleaning In Place (CIP) phase of the filling machine. As shown in the figure below the product unsterility started suddenly, during the standard production activity, to end with the final cleaning: no unsterility was found at the machine restart, after cleaning.



This unsterility pattern was replicated many times during the normal production activity causing heavy problems both to production planning and to product delivery.

The unsterility was detected after finding a pH variation (acidity) on a sample of packages stored at a constant temperature of 32° C, for 7 days.

The economical loss determined by this case was close to 500.000 Euro, but the disturbances produced by the filling machine stops (unplanned downtime) were really heavy since the line was often under investigation due to its inherent unreliability.

(c) Trouble shooting

The trouble shooting activity started with a huge investigation on the sterile circuit of the filler. Since no fault was detected, and the package integrity check did not show any problem, a deeper investigation was started on the packaging material fed through the whole machine (from the packaging material infeed down to the outfeed). Through a careful monitoring activity it was noticed an oil leakage coming from a hydraulic piston which is working on a cylinder that feed the packaging material throughout the filler. Since the piston tightness was lost due a progressive wear of the piston gasket, the oil dropped directly on the inner surface of the packaging material determining a source of contamination, which was not completely removed from chemical sterilization. The bacterial load, coming from mineral oil residues on the packaging material, determined a product contamination with a product pH change (acidity).

(d) Conclusion

At the end of the investigation the following conclusions were drawn:

- the problem should have been detected by the filling machine operator during the execution of final or weekly cleaning of machine
- while the preventive maintenance check lists for this machine included a regular check of the hydraulic piston in order to keep it efficient, no maintenance was carried out for about 3000 working hours
- since no HACCP analysis was applied on this filler section there was not a clear awareness about the criticality associated to the malfunction of this component
- to improve the inherent equipment safety and reliability it was suggested to replace the hydraulic piston with a motorized one.

This case shows that the filling equipment safety must primarily be managed through a design phase intended to avoid risk residues that could have important effects on product safety because of contact with chemical agents. Lack of maintenance procedures designed to put under control the equipment critical control points determined a higher risk of chemical contamination of product packed.

2.3.4 Fourth case study: unsterile packages randomly distributed over different production runs

The fourth case study regards a company that produces UHT milk, and fruit juice with two packaging lines.

(a) Equipment setup

Two different product sterilizers supply the aseptic fillers of two packaging lines with a capacity of 12.000 packs/hour each. The downstream equipment is made up by one cap applicator, one cardboard packer and a final palletizer, all installed in the same line.

(b) Problem description

This producer claimed the finding of few unsterile packages, randomly distributed, over five different production runs, produced by two different packaging lines.

Despite only one or two unsterile packages were found on each pallet produced, the company was forced to withdraw from the market the pallets containing a single pack defective. The random failure distribution, and the different types of defect found during quality control inspections, made the company eager to discover the nature of the problem as quickly as possible.

(c) Trouble shooting

Because of different type of problems found and different lines involved in producing packages with defects, it was decided to perform a quality audit on the production lines under consideration. The scope of this activity was the examination of production practices implemented during production, the analysis of daily maintenance carried out by the equipment operator, and the investigation of procedures implemented during cleaning phase. Moreover, because of diversity and complexity of problems found, special attention was placed in examining the training and skillness of people involved in operating and maintaining the equipment. The investigation done covered the following critical areas:

- pre and post-production practices
- production practices
- quality control practices during production
- cleaning procedures (pre and post production)

- preventive maintenance programme.

Here below the findings gathered according to the type of defect found:

Compliance to standards and specification

The production monitoring showed a general non-compliance versus standards and specifications as described by the equipment supplier. Practices and procedures carried out by the equipment operators were different and often customized according to people's experience.

Bad package sealing and lack of package integrity

Pressure rollers, used to realize the longitudinal sealing of the package, were not properly cleaned: product residues left on the component represented a serious risk of unsterility, and plastic residues found on its surface a risk of an uneven pressure and then a lack of a hermetic seal. The status of transversal sealing inductors and pressure rubbers were not carefully checked by the operators. Packaging material residues have been found trapped in the transversal sealing inductors (see the arrow in Figure 3 below) and this lead to their break. As result, some unsterility packages were found with a non-hermetic longitudinal and transversal sealing.

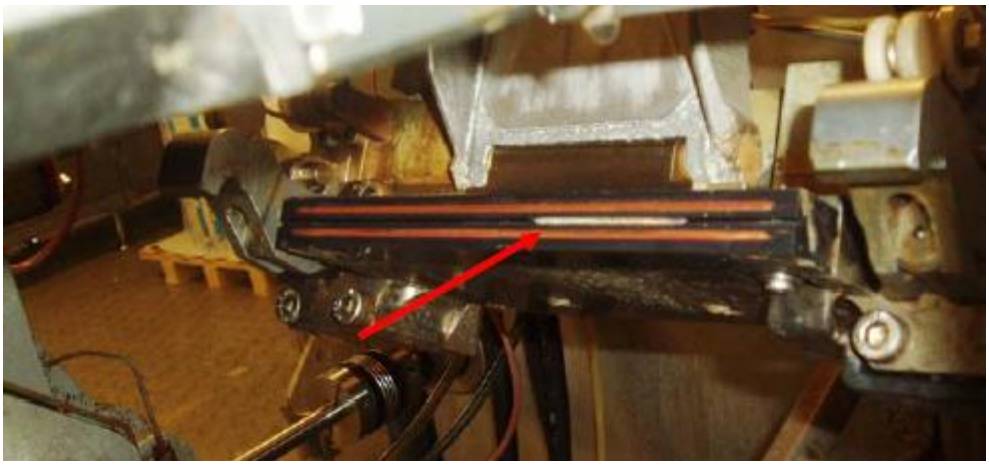


Figure 3: Transversal sealing inductor

Cleaning procedures

Cleaning of product filling pipe represents a critical operation that can produce product contamination if product residues, splashed on its surface (see Figure 4 below), are not properly removed through manual cleaning. It has been noticed a different way of cleaning this part either by using different detergents and different materials. It has been found big quantities of packaging material dust spread all over the internal sterility environment of filling machine.

Figure 4: Product residues on filling pipe

Aseptic piping: connections tightness and gasket integrity

During inspection, some residues of caramelized milk were found close to some connections of product piping, next to aseptic valves and filling pipe (see Figure 5 below). These leakages were mainly due to connections not properly tight, and to gasket completely worn. This phenomenon could be the cause of some unsterile packages found without integrity problems, but with coagulated milk inside.

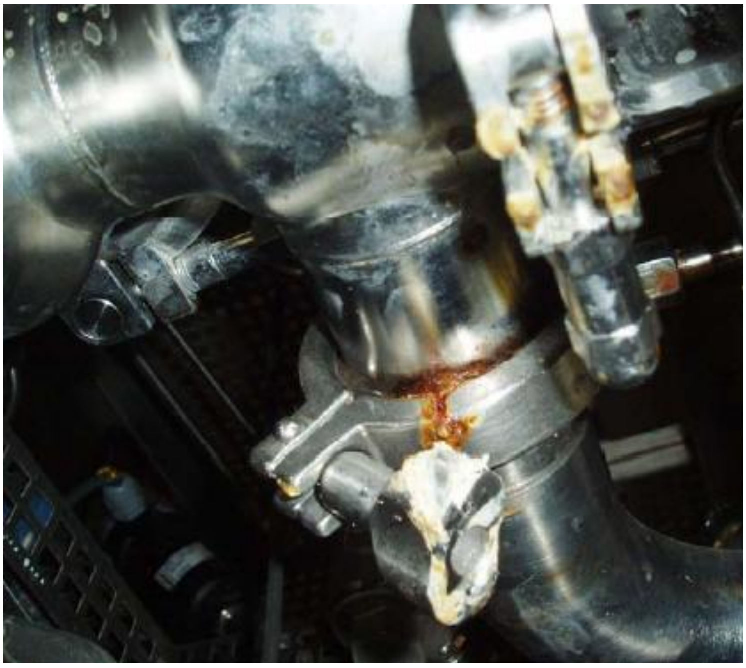


Figure 5: Milk leakages on pipe connection

Quality control of filled packages

The quality control procedures, intended to check the integrity of packages produced, were not carried out according to the standards described in the operator manual.

The interviews with equipment operators have shown deep knowledge gaps due to lack of a basic training program: it was discovered that the only training received was the one consisting in a coaching activity made by an expert colleague.

(d) Conclusion

At the end of the investigation, the following conclusions were drawn:

- the presence of unsterile packages on both lines, characterized by different problems, was a typical indicator of something not working correctly not in the equipment, but in the organizational and cultural dimension of the company.
- lack of an operator training program produced, as result a different operational way to implement production and maintenance practices. This emphasized the need to comply with the standard procedures and practices designed by the equipment supplier and to implement the mandatory quality control checks on packages produced.
- cleaning procedures and preventive maintenance was not regularly executed and this was most likely the reason of some unsterility cases.
- lack of cleaning and maintenance on longitudinal and transversal sealing inductors was the reason of some not hermetic seals found on blown packages.
- caramelized milk residues enabled to discover leakages of milk on product piping due to week connection tightness and worn gaskets.

The findings resulting from this case emphasized the need of a training program to avoid different ways to operate the equipment with relative non-conformities. Lack of standards lead to bad quality control on finished product, and to inability to detect anomalies that show preliminary signs of non-compliance to specifications. Poor implementation of cleaning and maintenance procedures caused non-hermetic longitudinal and transversal seals that produced physical and chemical transformation of product packed.

In conclusion, the analysis of this case, once more, underlined the necessity to define a maintenance design and implementation process to identify packaging line criticalities with relative solutions to avoid product safety and equipment reliability problems.

2.3.5 Peanut case shows holes in product safety net

The New York Times, on February 8, 2009, published a story regarding a ConAgra plant, based in Blakely, Georgia, USA, and producing peanut butter. Problem emerged in 2004, in the Georgia's peanut country, when was reported that the food-product giant, ConAgra Foods, had found salmonella in peanut butter at its plant in Sylvester, 75 miles from Blakely. At that time, when the plant officially declined to release their laboratory tests, the Food and Drug Administration (FDA) did not pursue the records and was unable to confirm the report of salmonella contamination. The government finally demanded the records three years later, and verified the contamination claims, after hundreds of people were sickened by salmonella-contaminated peanut butter, produced at the plant in 2007. The consequences of this huge contamination accounts for:

- half of the salmonella children illnesses traced back to the Blakely plant
- a worldwide recall that includes peanut butter shipped to schools, military bases and nursing homes
- the safety issues raised by this outbreak are drawing comparisons to those in China's contaminated milk scandal.

Robert Tauxe, a disease prevention expert, from a Center for Disease Control and Prevention said: "This outbreak is telling us we haven't been paying enough attention to food product safety prevention".

After deep investigation, it was discovered that the causes of finished product contamination were those listed below:

(a) Raw product contamination

Dispirited workers on minimum wage, supplied by temporary agencies, donned their uniforms at home, potentially dragging contaminants into the plant, which also had rodents.

(b) Failure in the equipment sterilization system

The heat treatment system, used to kill the pathogenic bacteria in the product, was not working correctly because of technical anomalies found in thermo-regulator system.

As result, the equipment sterilization system, designed to sterilize the product, was non-working at the right temperature, and no alarm or corrective action was able to switch a mandatory production stop.

(c) Product quality control
The quality control procedures, to detect potential product contaminations at source, were not implemented correctly by the operational staff involved.

In conclusion, although this case is not dealing with an aseptic liquid food process, it shows important points of discussion, to be held in great consideration, that support the ALF cases previously analyzed, and the research problem.
Here below few questions and reflections about this case:

- *Why a critical failure of the product sterilization system did not produce any equipment alarm or corrective action?*
  Beyond the possible obsolescence of the equipment used to sterilize the product, it must be said that, if a HACCP activity had been done, this important criticality would have been discovered and a reliable solution implemented. Moreover, lack of a HACCP plan, produced lack of maintenance procedures intended to put under control the critical technical parameters of thermo-regulator system.

- *Why product quality control and equipment inspection did not allow to detect the problem?*
  This case emphasize how important is the quality control of the product during the different phases of the process. If an in-line quality control system had been planned, the problem would have been discovered before product delivery. Since no equipment automation was available to detect a critical thermo regulator failure, lack of maintenance checks of critical parameters put the system completely out of control.

- *Why equipment operators were not trained and empowered to take full responsibility of process through autonomous maintenance?*
  Production of fresh, medium, and long life food products, must be done by qualified personnel, able to take full responsibility of the process and not by temporary workers.

The effects produced by this failure on public health, show the importance of a reliable maintenance design process able to identify all criticalities, together with an implementation model, which define roles, tasks for an effective implementation.

2.3.6 Analysis of case studies and lessons learned

The analysis of different case studies showed that one of the common reasons behind unsterility cases depends on lack of preventive maintenance procedures and that these can be put under control only if the different machine critical functions are properly identified and preventive maintenance actions implemented.

In the first case, integrity of packages was lost and product contaminated because of wrong maintenance activity implemented by a person not trained for such maintenance task. The analysis of this case study showed a lack of regular maintenance inspection of this critical device (package dumper) and the reason was due to the unavailability of a HACCP plan intended to identify CCPs and relative countermeasures to put critical variables under control. The HACCP analysis should have identified this CCP and asked for a maintenance task to avoid biological risk produced by lack of package integrity. The economical loss produced by this event was high, but reduction of market share, resulting from damages on company's image was not quantifiable.

The second case study showed that, due to economic pressures, maintenance approach chosen was corrective only and that, as consequence, a loss of control of different critical points, regarding package integrity and forming, was experienced. In this case, an analysis based on product safety and equipment reliability risks should have revealed lack of maintenance procedures necessary to put under control safety and reliability critical issues.

The third case emphasized the necessity to carry out a deeper HACCP analysis intended to examine primary and secondary sources of potential product contamination. An oil leakage from a hydraulic piston produced packaging material and then product contamination because no one identified this CCP and, once again, no HACCP plan was implemented. This case showed that safety and reliability investigations might produce the necessity of mandatory equipment modifications to upgrade the inherent equipment safety and reliability.

The fourth case summarized the different drawbacks found in the other cases and underline how important maintenance is in determining a whole control over the different critical process elements that produce, as result, product quality, and safety.

The fifth case showed the dramatic effects of a food process out of control: lack of a HACCP plan, of a reliable quality control and maintenance process, produced heavy problems for public health.

At the end of this section some common conclusions can be drawn:

a) The process to design maintenance procedures must be able to identify all conceivable equipment critical control points that might affect product safety and equipment reliability
b) The design and the implementation process must ensure that all equipment critical functions have been examined and that maintenance tasks designed and implemented are effective to determine product safety and equipment reliability.
c) The equipment operator plays a key role in managing the equipment criticalities through operational and maintenance activities able to prevent equipment downtime and product safety contaminations.
d) An effective maintenance design process enables the identification of equipment reliability weakness areas where improvements can be achieved through condition monitoring systems, structural modifications or through reliable maintenance procedures.

2.4 Food safety system certification (FSSC)

Food safety is a global concern, not only because of the importance for public health, but also because of its impact on international trade. Globalization of food production and procurement makes food chains longer and more complex and increases the risk of food safety incidents. Food safety certification represents a mandatory step for an ALF manufacturing plant, which ensures that all conceivable risks arising from the whole production process are under control, and that corrective actions have been established to avoid product safety hazard [6]. Effective and harmonized food safety systems shall manage and ensure the safety and suitability of food in each link of the supply chain. For this reason, ISO (International Standard Organization) developed the standard for food safety management systems ISO 22000, which applies to all organizations in the food chain and thus ensures integrity of the chain. FSSC 22000 is specifically developed to audit and certify food safety systems of food manufacturers that process or manufacture products with long shelf life at ambient temperature. The FSSC 22000 certification scheme sets out the requirements for certification bodies to develop, implement, and operate a certification scheme and to guarantee its impartiality and competence. FSSC 22000 sets out the requirements to assess the food safety system of food manufacturing organizations and to issue a certificate. The added value for an organization with a certified food safety system lies in the efforts made by the organization to maintain that system and its commitment to continuously improve its performance.

In the requirements, food safety is defined as the concept that the food will not harm the consumer. Organizations in the chain are therefore required to take into account the food safety hazards of their operation for the final product in the chain when establishing prerequisite and HACCP programs (reference: ISO 22000, clauses 3.1 and 3.3, note 4).

As is stated in chapter 2 of ISO/TS 22004, ISO 22000 promotes the adoption of a food chain approach when developing, implementing, and improving the effectiveness and efficiency of a food safety management system. In this regard, the organization is required to consider the effects of the food chain prior and subsequent to its operations when developing and implementing its food safety management system.

About specifications for services, the food manufacturing organization shall ensure that all services (including utilities, transport, and maintenance) which are provided and may have an impact on food safety:

- shall have specified requirements,
- shall be described in documents to the extend needed to conduct hazard analysis.
- shall be managed in conformance with the requirements of BSI-PAS 220, clause 9, (Reference: ISO 22000, clauses 7.2.3.f and 7.3.3. and BSI-PAS 220, clause 9).

Moreover, the organization shall ensure the effective supervision of the personnel in the correct application of the food safety principles and practices commensurate with their activity (Reference: ISO 22000, clause 6.2.2). In the requirements and regulations for providing certification (appendix II B) important technical issues are taken under consideration:

- **Layout of premises workspace**

- Location of equipment
- Laboratory facilities
- Storage of food, packaging materials, ingredients, and non food chemicals.

- **Utilities: air, water, energy**

- Water supply
- Boiler chemicals
- Compressed air and other gases
- Lighting.

- **Equipment suitability, cleaning and maintenance**

- Hygienic design
- Product contact surfaces
- Temperature control and monitoring equipment
- Equipment cleaning
- Preventive and corrective maintenance.

- **Measures for prevention of cross contamination**

- Microbiological cross contamination

- Physical contamination.

- **Cleaning and sanitizing**

- Cleaning and sanitizing agents and tools
- Cleaning and sanitizing programs
- Cleaning in place (CIP) systems
- Monitoring sanitation effectiveness.

2.5 Conclusion

In this chapter the ALF criticalities have been considered regarding to problems placed by the threats coming from mandatory legislations, from higher competition, due to globalization, and from cost reduction which often produce downsizing and outsourcing.

Some of the effects produced by these threats involve reduction of economical and human resources for maintenance, and a general tendency to move from preventive maintenance to corrective maintenance only. The case studies examined showed that lack of a HACCP plan intended to identify the equipment CCPs and relative countermeasures, to put critical variables under control, may produce biological risks due to lack of package integrity. The case studies highlighted that the process to design maintenance procedures must be able to identify all conceivable equipment critical control points that might affect product safety and equipment reliability and the relative maintenance tasks to manage such criticalities. The case studies showed that the economical loss produced by the unsterility cases was high, but reduction of market share, resulting from damages on company’s image was definitely higher and difficult to quantify. At the end of the chapter, a short description of food safety certification, required by ISO, allows to identify a useful tool to “certify” the compliance to standards of layouts, services, utilities, and maintenance to produce food hygiene and safety.

3. CRITICAL STUDY OF MAINTENANCE ENGINEERING TECHNIQUES AVAILABLE IN THE LITERATURE

3.1 Introduction

To be able to answer the main research questions regarding product safety and equipment reliability, an extensive literature search has been carried out to identify the key maintenance engineering techniques to be used to develop the maintenance design and implementation process. The scope of this chapter is to present a short highlight of some of the reliability principles and maintenance engineering techniques chosen to support the maintenance design and implementation process. The questions to answer at this point of the research are:

- Why literature review is necessary for this research?
- What type of literature has to be searched?
- What criteria should be used to select maintenance principles and techniques?
- How the selected literature can contribute to the maintenance design and implementation process?

This chapter will not only answer these questions, but it displays the main characteristics of the safety, reliability, and maintenance engineering techniques used in the maintenance design and implementation process. The extensive literature review shows a picture of the status of art of the safety and maintenance techniques available today and the advantages coming from their application in the process to design and implement maintenance procedures.

3.2 Equipment availability through reliability, maintainability, and supportability

The equipment availability represents one of the most important factors to be used to measure production and maintenance effectiveness: the line equipments must be available to allow the manufacturing company to produce the right amount of product, at the right time, and with the right quality. Equipment availability, itself, depends on equipment reliability, maintainability, and supportability, and the scope of this section is to identify the key topics that will be part of the process to design and implement maintenance procedures for the ALF industry.

Availability

The British Standards (BS) define availability as "the ability of an item (under combined aspects of its reliability, maintainability and maintenance support) to perform its required function at a stated instant of time or over a stated period of time" (BS4778). In other words, availability is a measure of how big a part of total production time the machine is available for production [7]. Availability is then depending upon reliability, maintainability, and supportability. Availability can be calculated using the formula:

$$Availability = \frac{MTBF}{MTBF + MTTR}$$

Where MTBF stands for "Mean Time Between Failure" and MTTR for "Mean Time To Restore". In order to keep availability high, the MTTR must be as short as possible. According to Figure 6, given a machine with a good standard of design and reliability, with high maintainability, much depends upon the skill of the operator and service engineer in effecting a rapid return to operation. However, there are other factors that can reduce MTTR concerned with the diagnostic instruments necessary to find out faults, spare parts availability and maintenance policy adopted.

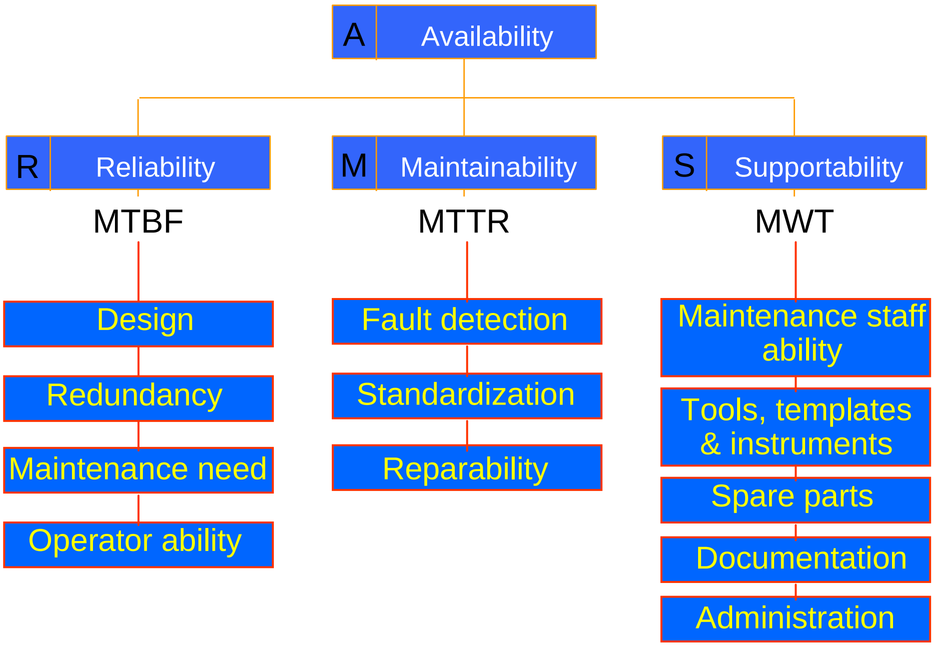


Figure 6: Line Availability

Reliability

The definition of reliability given by the British Standards, BS 4200, part two, is: “Reliability is the ability of an item to perform a required function (without failure) under stated conditions for a stated period of time”. Here an item means a component, instrument, or system. For example, the reliability of one machine might be quoted as 0.99 for 1000 hours operating time under well defined operating conditions. This means that the probability of satisfactory operation, without any failure, is 99% during a period of 1000 hours. According to BS 5760 failure is “the termination of the ability of an item to perform a required function”.

Reliability maintenance techniques & failure curves

Each maintenance task need to be designed to cope with different failure modes found for each machine component. For the different component failure modes, the specific reliability maintenance techniques, listed in Figure 7, will be applied.

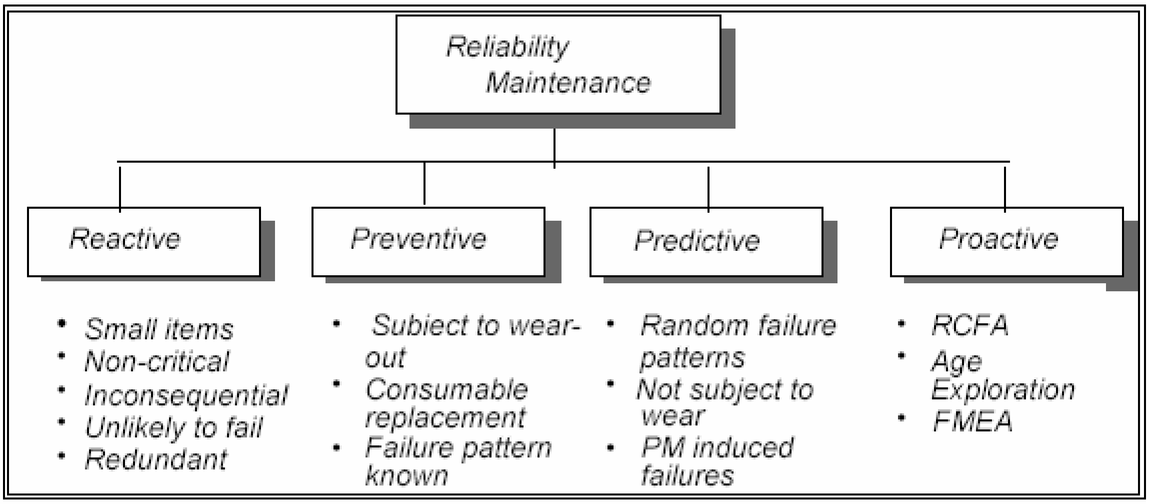


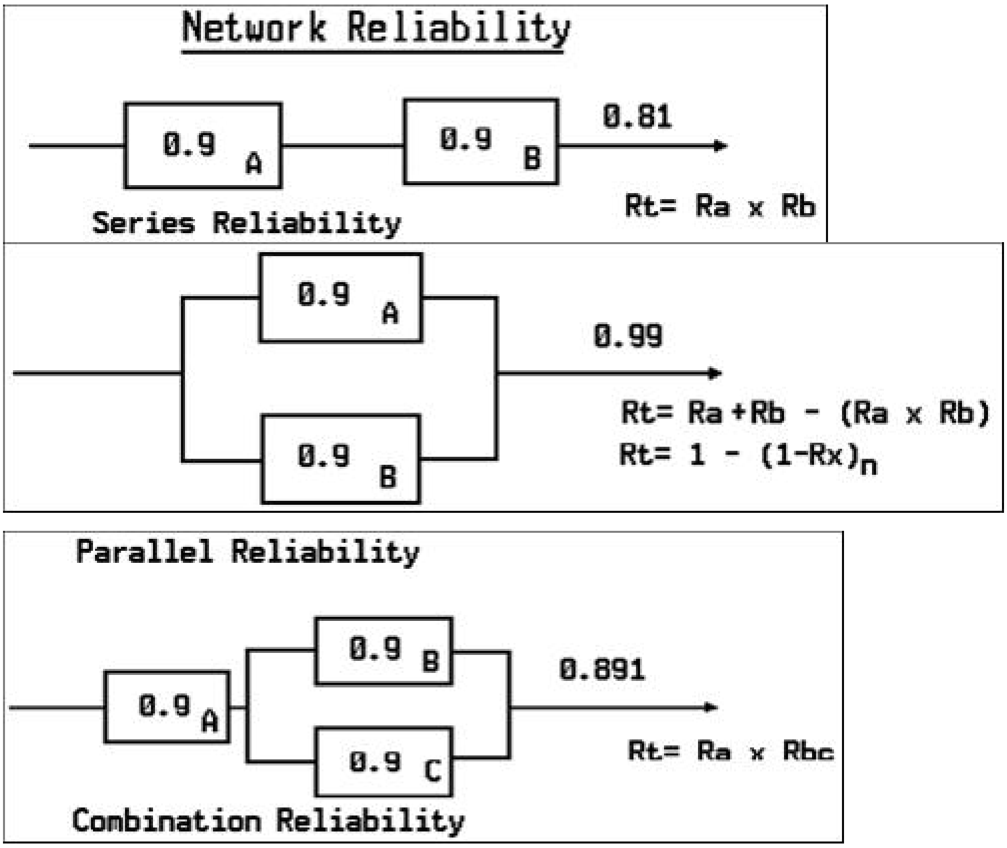
Figure 7: Reliability maintenance techniques [8]

Product law of reliability

For units (machines) in series, such that failure of one machine determines the failure of whole system (production line) reliability of the system is:

Rs = R1 x R2 x R3 x Rn

Here below some possible circuit configurations [8]:



Where product quality issues are involved, redundancy of critical components represents a real equipment investment, to gain higher reliability and product safety.

Factors which affect reliability

The cost of ownership of a product, such as a filling machine is made up of the:

- capital cost (the purchase price)
- operation cost and
- maintenance cost.

At the same time, the above factors have a direct impact on machine and process reliability. As the machine design is improved, because of components redundancy, the use of high quality devices and materials which result in a higher safety, the machine reliability is still improved. In purchasing a machinery the attempt to safe money just looking at the machine price, without considering the machine quality design, might produce a saving in the short term, but heavy losses in the medium-long term.

Maintainability

Maintainability is defined as the probability that a system, that has failed, will be restored to a full working condition within a given time period. Maintainability or Mean Time To Repair/Restore (MTTR) expresses the average time that it takes to correct a fault. The mean time to repair or to restore and the repair rate (μ) are measures of maintainability:

$$\mu = \frac{1}{MTTR}$$

and maintainability $M(t) = 1 - e^{-\mu t} = 1 - e^{-t/MTTR}$ where t is the time allowed for the maintenance action. Appendix A shows an example of how maintainability and MTTR can be calculated.

Factors which affect maintainability

The machine designer can aim for a low value of MTTR by paying for example close attention to the accessibility of components and to their standardization. In the liquid food industries, because of use of perishable product, particular effort is to be spent in reducing MTTR as much as possible. A fault on the sealing section of an aseptic filling equipment, for example, may be quickly solved, without machine reset to zero position, if the time necessary to repair is shorter than the time allowed for the machine to be in stand by position.

Supportability

The effectiveness of support system, around the machine, is measured by the Mean Waiting Time (MWT). This can be defined as the time, which elapses from occurrence of a fault until the repair is started. The support system within an aseptic liquid food company is made up of the following factors:

(a) Maintenance staff ability

Development of the necessary abilities, for maintenance technicians and machine operators, to carry out maintenance activities, represents a real opportunity to reduce MTTR and to improve the company’s competitive advantage. Development of skillness, in the area of corrective maintenance, requires a good understanding of system fault location methods, in addition to an understanding of overall system and circuit operation. The equipment operator empowerment, through different types of training, represents one of the best investments to improve the effectiveness of company’s support system.

(b) Equipment needed

Different diagnostic tools are often necessary to carry out maintenance activities, they are:

- templates for mechanical measurements
- temperature measurement instruments
- oscilloscope and electronic multimeter
- notebook computer with diagnostic software.

Furthermore, microbiological lab with all necessary test instrumentation is necessary to carry out product analysis in case of product contamination.

(c) Parts supply

To reduce MWT, the company must ensure that spare parts, more frequently needed to solve machine faults, are available to repair the equipment. Lack of necessary spare parts might produce waste of time for maintenance staff, just for waiting the parts, and unavailability of machinery for production activity.

(d) Technical data

In order to benefit of a good support system, around the production equipment, the provision of a comprehensive service manual is vital. This must contain easy-to-read circuit and layout diagrams; spare parts lists with possible equivalents; technical specifications and test instructions; fault location guides and dismantling instructions.

(e) Administration

Administration refers to the activities concerning management of figures and data available from production activity. Statistical figures about faults, divided into categories, records of preventive maintenance activities, feedback information on equipment availability, reliability and so on, enable management to better understand the equipment needs.

3.3 Product safety techniques

Product safety techniques, through maintenance, play a very important role in managing the critical factors that could produce non-conformities to product quality and safety. The maintenance design process for ALF industry will make use of the techniques described in this section, but the effectiveness of this process cannot be ascribed to these techniques only, but to the ability to integrate both safety and reliability techniques.

3.3.1 Product safety through the application of HACCP methodology

Hazard Analysis of Critical Control Points (HACCP) is a production process control methodology introduced at the European Community level through the ECC directive 93/43. HACCP identifies and assess specific hazards, estimates risks and establishes control measures that emphasize product safety, though problem prevention and control, rather than reliance on end-product testing and traditional inspection methods. HACCP presumes that not all phases of a liquid food machine operation are dangerous to man. Therefore, its attention is concentrated on analyzing only the Critical Control Points (CCPs) and not the whole line process [9]. Machine parts or components, whose fault may produce biological, chemical, or physical hazard, are examined to devise critical control limits and preventive maintenance countermeasures. The use of HACCP methodology leads to the identification of Critical Control Points (CCPs) of the process, and to the design of new maintenance tasks to establish process, product safety, and reliability. Machine parts or components, whose fault may produce biological, chemical, or physical hazard, are examined to devise critical control limits and preventive maintenance countermeasures. Application of HACCP will first enable identification of the following issues:

- hazards, directly connected to the machine/system/component functions
- Critical Control Points (CCPs)
- critical limits for each CCP
- preventive measures, to carry out at every maintenance interval
- monitoring procedures to detect loss of control at the CCP.

The development of HACCP plan requires seven principal activities whose implementation can ensure the goal of safer food [9]. These principal activities have to be applied to the process equipment to identify CCPs and to establish adequate maintenance procedures. The following seven principal activities form the basis for the application of HACCP system:

ACTIVITY 1: conduct hazard analysis, identify hazards (biological, chemical and physical) and specify control measures
ACTIVITY 2: identify critical control points
ACTIVITY 3: establish critical limits at each CCP
ACTIVITY 4: establish monitoring procedures
ACTIVITY 5: establish corrective action procedures
ACTIVITY 6: establish verification procedures
ACTIVITY 7: establish documentation procedures as appropriate.

ACTIVITY 1: Listing all hazards and considerations of any control measures to eliminate or minimize hazards

As first step, a list of all hazards that may be expected to occur in the production line under consideration are identified. The hazards considered are the following:

- Biological hazards

regard toxigenic agents that could contaminate the product. This can, in many cases, be due to lack of package integrity.

- Chemical hazards

include, among the others, cleaning compounds and sterilisation agents.

Chemicals, normally used to clean equipment and pipe surfaces, and to sterilise packaging materials, could come in contact with the product if predictive and preventive maintenance activities are not regularly implemented.

- Physical hazards

include objects, such as metal fragments, glass… that can be found in the package together with the product, and that may cut the mouth, break teeth or perforate the package.

This activity can be effectively performed by a team of experts involved in different areas such as quality, production, and maintenance.

ACTIVITY 2: Establishment of Critical Control Points

After all hazards have been identified, a CCP decision tree is used to identify the existing CCPs for each specific hazard. The hazards which may be reasonably expected to occur, or be introduced at each step, should be considered. If a hazard has been identified for which no control measure exists, the machine part or component should be modified so that hazard is eliminated or reduced to acceptable or minimal levels. The module shown in Figure 8 below is a HACCP decision tree used for establishing CCPs.

ACTIVITY 3: Establishment of critical limits for each CCP

Critical limits must be identified for each control measure, at each CCP.

In some cases, more than one critical limit can be specified at a particular CCP. In some cases, quantity variations may require the use of target levels to ensure that critical limits are met. Historical and statistical information can represent a reliable tool to identify limits and thresholds.

ACTIVITY 4: Establishment of monitoring system for each CCP

Monitoring is the periodic measurement or observation at a CCP to determine whether a critical limit or target level has been met. The monitoring procedure can be performed by an automatic system or by human control and must be able to detect loss of control at the CCP.

ACTIVITY 5: Establishment of corrective actions

Corrective actions are those actions to be taken either when monitoring results show that a CCP has deviated from its specific critical limit or target level or, preferably, when monitoring results indicate a trend toward loss of control. Different limits or thresholds can be established regarding critical areas of variable hazard.

ACTIVITY 6: Establishment of verification procedures

Procedures for verification must be established to ensure that HACCP system is working correctly. Monitoring and auditing methods, procedures and tests, including random inspection and analysis, can be used for this purpose.

ACTIVITY 7: Establishment of record-keeping and documentation

Adequate, accurate record-keeping and documentation are essential to the application of the HACCP system. Examples of records are: HACCP plan; CCP monitoring records; deviations file; preventive maintenance procedures, included in the check lists and check lists review.

HACCP methodology will be used in the design process, as a mandatory tool to identify all CCPs that may have a relevant impact on product safety hazards. After CCPs identification, a deeper reliability analysis of critical components and parts will be necessary to design maintenance task lists that enable a reliable maintenance control of each critical point.

Diagram 1

Logical Sequence for Application of HACCP

1 Assemble the HACCP team

2 Describe the Product

3 Identify Intended Use

4 Construct Flow Diagram

5 On-site Confirmation of Flow Diagram

6 List All Potential Hazards
Conduct a Hazard Analysis
Determine Control Measures

7 Determine CCCPs See Diagram 2

8 Establish Critical Limit for each CCP

9 Establish a Monitoring System for each CCP

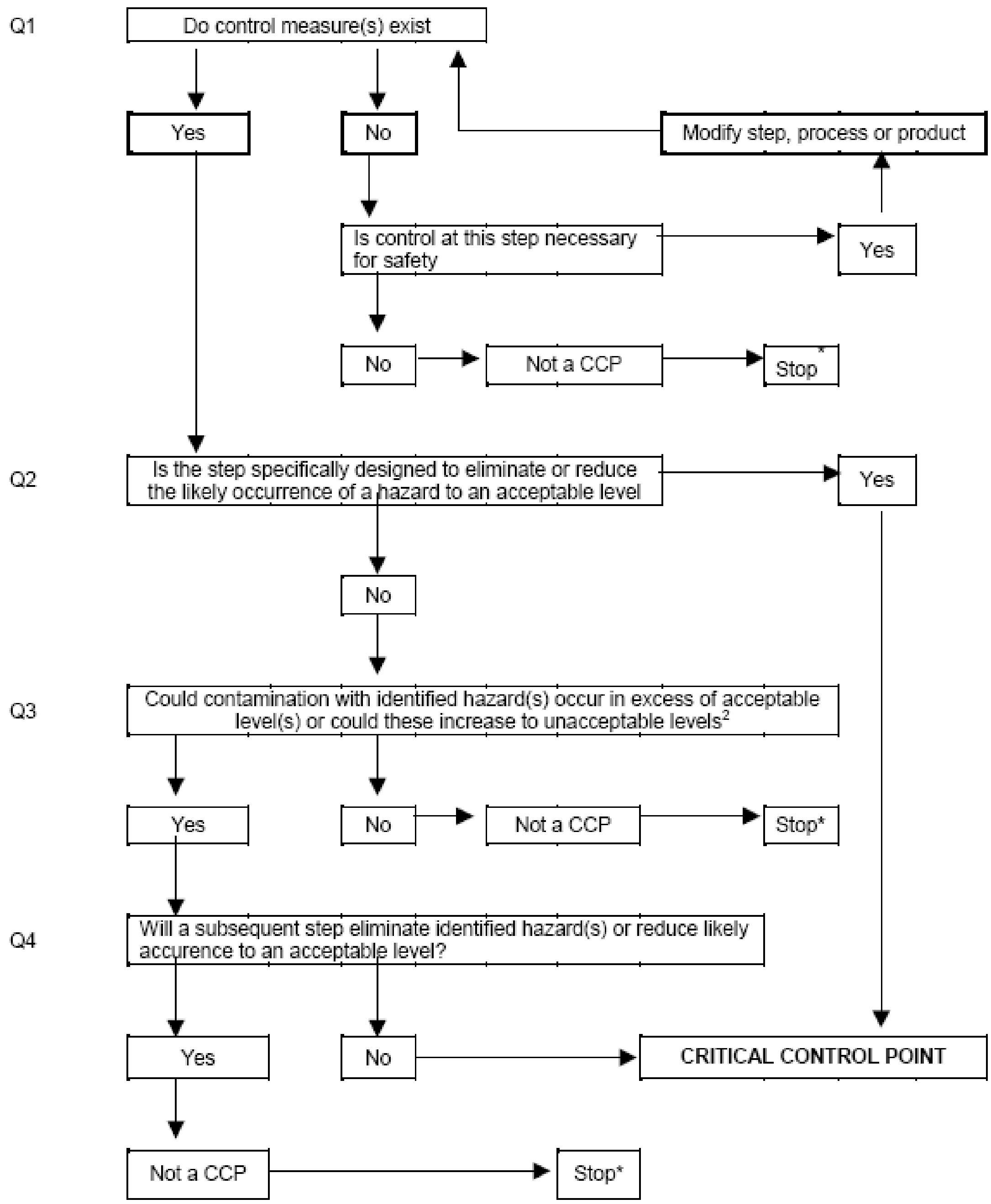
10 Establish Corrective Action for Deviation that May Occur

11 Establish Verification Procedures

12 Establish Documentation and Record Keeping

Diagram 2

Example of Decision Tree to Identify CCPs
(answer questions in sequence)



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[*] Proceed to next identified hazard in the described process
[2] Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of the HACCP plan.

Figure 8: HACCP decision tree to identify CCPs [9]

3.3.2 Application of HAZOP (HAZard OPerability)

HAZOP reviews have been arising from the chemical industry in Britain during the 1960’s. Imperial Chemical Industries developed a standardized method of analyzing processing hazards based on the basic operation conditions and then changed individual parameters one at a time to see the subsequent consequences [10]. This evolved into a standard practice within their company and soon found its way into the general chemical industry (although it was not universally or consistently applied). This technique has been selected because it can be applied to the ALF process to monitor the critical factors depending on both product and human behaviour.

The HAZOP general overview

Most hazards that arise in a system are thought to be due primarily to defects in design, material, workmanship, or human error. There are many methods of safety analysis reviews that are available and can be applied to a facility or project design to overcome human errors and the various failures of the process system. The methods may be either qualitative or quantitative in nature. HAZOP can be considered a qualitative method.

The HAZOP process is based on the principle that a team approach to hazard analysis will identify more problems than when individuals working separately combine results. The HAZOP team is made up of individuals with varying backgrounds and expertise. The expertise is brought together during HAZOP sessions and through a collective brainstorming effort that stimulates creativity and new ideas, a thorough review of the process under consideration is made.

The HAZOP process

The HAZOP team focuses on specific portions of the process called “nodes”. A process parameter is identified, say pressure, and an intention is created for the node under consideration. Then a series of guidewords is combined with the parameter “pressure” to create a deviation. For example, the guideword “no” is combined with the parameter pressure to give the deviation “no pressure”. The team then focuses on listing all the credible causes of a “no pressure” deviation beginning with the cause that can result in the worst possible consequence the team can think of at the time [10]. Once the causes are recorded the team lists the consequences, safeguards and any recommendations deemed appropriate. The process is repeated for the next deviation and so on until completion of the node. The team moves on to the next node and repeats the process.

The primary objective of HAZOP is to assure that catastrophic incidents will be avoided during the lifetime of the facility from the processes under review. The reviews objectives are to be thorough, impartial, and adequate. Safety reviews are ultimately, primarily looking for the possibilities of where human error may occur. Human error is commonly thought of as mainly occurring during the operational phase of the facility or system, but human error can also be the cause of defects in the design, material, or workmanship. Human error is considered when one of the following events occur (which may be applied equally to design or operation of a production line):

1. An individual fails to perform a task or some portion of a task.
2. The task (or portion) is performed incorrectly.
3. Some step(s) is/are introduced into the sequence, which should not have been included.
4. A step is conducted out of sequence.
5. The task is not completed within an allocated time period.

Human errors may be accidentally performed by all personnel: designers, engineers, operators, and managers. Some theories attribute up to 90% of all accidents to human errors.

The concept of Point Of Reference (POR)

When defining nodes and performing a HAZOP on a particular node, it is useful to use the concept of point of reference (POR) when evaluating deviations. As an illustration of this idea, suppose in the example of the flash drum, the node consists of the flash drum and liquid product piping up to the flange on a product storage tank. If the deviation "no flow" is proposed then a dilemma becomes apparent when you start talking about the causes of no flow [10]. If a cause of no flow is pipe rupture and the pipe ruptures at the flange connection on the flash drum. The term "no flow" is ambiguous since there is flow out of the flash drum but not through the piping to the storage tank. Therefore, a POR should be clearly established at the time the node is defined. It is recommended to always establish the POR at the downstream terminus of the node.

3.4 Maintenance engineering techniques

The maintenance engineering techniques will play a very important role in the maintenance design process, and this section shows the main features of some well-known techniques widely used in industry. Quantitative and qualitative analysis of failures allows to gain a deeper knowledge on each failure type, and on the effects produced on the equipment; the analysis guide to the identification of maintenance activities to be designed for each failure type.

3.4.1 Reliability centered maintenance (RCM) technique

In 1976, the "Reliability Centered Maintenance", a landmark 495 page report by Stanley Nowlan and Howard Heap, described the RCM methodology developed for the Boeing 747, Douglas DC-10 and Lockheed 1011 [11].

The key to RCM was abandoning the philosophy of "preserve-equipment" in favour of "preserve-function". Equipment became the means to an end, not the end in itself. In addition, Nowlan and Heap concluded that a maintenance policy based on operating age would have little, if any, impact on failure rates. Thus, applying time-based maintenance on equipment which has no "wear-out" pattern was futile. This forced a change in philosophy from, "It wasn't broke, but we fixed it anyway" to "If it isn't broke, don't fix it". Nowlan and Heap [12] also concluded that:

- Time-based maintenance works only for a small percentage of components, and then only when there is solid information on their "wear-out" characteristics.
- Condition Based Maintenance (CBM) is the most-preferred option. That means monitoring, observing and taking non-intrusive actions, such as lubricating and cleaning, until a condition signals that corrective action is necessary.
- Run-To-Failure (RTF) is a viable tactic in situations when there is no safety and little economic impact.
- In a significant number of situations, the very act of maintenance itself causes subsequent failure of the equipment.
- Non-intrusive maintenance tasks should be used instead of intrusive maintenance whenever possible. In other words, do not do any maintenance,

except monitoring and non-intrusive sustaining actions, until condition directs intrusive corrective action.

Four statistically significant studies have confirmed the validity of RCM.

When we come to the understanding of maintenance and the role of Reliability Centered Maintenance, the airlines are far ahead of industrial manufacturers. After all, RCM was invented by the airline industry, but also, in the airline business, the maintenance mission is quite clear, it begins with an understanding of equipment functions and the failure modes that result in functional failures and ends with a very specific maintenance strategy designed to mitigate the consequences of each failure mode. As a result, maintenance is viewed as a reliability function instead of a repair function [11].

In viewing maintenance as a reliability function, the airline industry simply charges maintenance with the following mission: To keep airplanes airborne, full of passengers, and safe. Safety and reliability are also the main goals to be pursued for the equipment and product packed in the ALF industry. This mission leads to a very tight set of maintenance guidelines, procedures, and controls. On the other hand, inside the typical manufacturing plant where maintenance is viewed as a repair, the maintenance mission is not that clear [13]. For example, if a packaging line goes down for a couple of hours, that may not be such a big deal, but when you are talking about a plane with hundreds of people on board, that is a totally different story. The fundamental difference between RCM and all previous approaches to maintenance is based on the emphasis on two things: safety and reliability. RCM is a systematic, decision-logic approach that analyses:

- failure modes
- critical data,

to establish a cost-effective maintenance strategy. In this strategy, scheduled replacement, preventive maintenance based on condition, periodic rework (overhaul), and scheduled inspections are combined to minimize the cost of maintenance without increasing the risk of failure [14]. Based on the results of this process, optimized maintenance task lists (task schedules) can be defined to address:

- inspection or monitoring/measurement for parts more susceptible to failure

- rework or rebuild to “like-new” condition
- removal/replacement with new parts/assemblies, or
- inspection for undetected failures.

Development of such a program depends on a determination of how a component/system can fail, the consequences of failure, and classification of failure distributions (infant mortality, random failures, or wear out). RCM is designed to minimize costs without increasing the probability of failure through a logical analysis of preventive maintenance needs and can be used as a design tool. The benefits of RCM are that it concentrates only on doing what needs to be done. People often focus on doing preventive maintenance tasks that really do not have much effect and this produces waste of time and money [15]. RCM is a logical discipline for developing a scheduled maintenance program that will realize inherent reliability levels of complex equipment at a minimal cost. RCM is based upon the premise that maintenance cannot improve the safety or reliability inherent in the design of the hardware. Good maintenance can only preserve those characteristics.

When phasing in an RCM program, it is strongly recommended by all experts that is done one system at a time. It is also important to choose a single system and take it all the way through each step of the RCM process before moving on the next. The classic approach includes:

1. System selection
2. Boundary definition & Operational mode summary
3. Functional and potential failure determination
4. failure modes and effects analysis (FMEA)
5. maintenance history and technical documentation review
6. task selection and frequency determination.

3.4.2 Failure reporting and corrective action system (FRACAS)

FRACAS is a continuous improvement system utilizing a closed-loop feedback path in which the maintainer and operator work together to collect and record data relating to failures of assets. This data is then reviewed and analyzed by a reliability engineer, considering such factors as Failure Rate, MTBF, MTTR, Availability, Cost, etc. The resulting analysis identifies corrective actions that should be implemented and verified to prevent future failures from recurring. FRACAS is particularly useful to analyse historical data regarding equipment failures to identify potential and functional failures together with their impact on product safety and company's costs.

The FRACAS process may also be referred to as DRACAS (Data Reporting, Analysis, and Corrective Action System), or PRACA (Problem Reporting, Analysis, and Corrective Action System), as well as CA (Corrective Action) systems, and other acronyms. At its core, FRACAS is a comprehensive closed-loop corrective action system which can collect, quantify, and control a wide range of incoming incident reports, such as test data, field data, or repair data. A Failure Reporting, Analysis and Corrective Action System (FRACAS) is a system, sometimes supported by a software, that provides a process for reporting, classifying, and analyzing failures, and planning corrective actions in response to those failures [16]. The method calls for a systematic failure data collection, management, analysis, and corrective action implementation. FRACAS process is a disciplined closed loop failure reporting, analysis and corrective action system and is a useful tool in the achievement of product reliability and safety. FRACAS promotes reliability improvement throughout the life cycle of the asset. Considering a standard asset life cycle from cradle to grave, the phases described in Figure 9 occur:

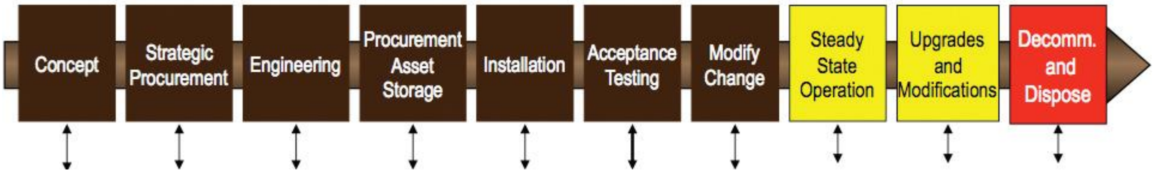


Figure 9: FRACAS phases [16]

Corrective actions and the impact to total cost of ownership are small during the conceptual design phase and then have greater impact as the asset gets farther along in its life cycle. The earlier the failure cause is identified and positive corrective action implemented, the greater the asset utilization and the lower the total cost of ownership.

3.4.3 Quantitative failure measures through statistical analysis

Quantitative analysis is to be used to "weight" a failure in order to gain a knowledge about its importance and how it is distributed over the time. Potential and functional failures must be measured through statistical tools to assess their impact on the production activity. The development and use of statistical theories about distributions and how they vary has become the corner stone of process improvement [17]. Statistical Process Control (SPC) allows the user to continuously monitor, analyze, and control the process. SPC is based on the understanding of variation and how it affects the output of any process. Variation is the amount of deviation from a design nominal value. If we consider a failure (Y) as a function of different variables ($X_{1,2,n}$) then it can be represented in this way: Y = F(X). If we know the variations caused by the X's, then, through SPC, it is possible to monitor the X's first. Using SPC we are attempting to control the critical X's in order to control the failure Y. To get an effective result we should be able to find the "vital few" X's, to put them under control through SPC to achieve a desired result on Y.

Y can be defined as:

- Dependent
- Output
- Effect
- Symptom
- Monitor.

$X_1, \ldots X_n$ can be defined as:

- Independent
- Input
- Cause
- Problem
- Control.

Statistical Process Control involves the use of statistical techniques, to interpret data, to control the variation in processes. SPC is primarily used to act on "out of control" processes, but it is also used to monitor the consistency of processes producing products and services. A primary SPC tool is the Control Chart, a graphical representation for specific quantitative measurements of a process input or output. In the Control Chart, these quantitative measurements are compared to decision rules calculated based on probabilities from the actual measurement of process performance. The comparison between the decision rules and the performance data detects any unusual variation in the process, variation that could indicate a problem with the process. Several different descriptive statistics can be used in Control Charts.

Control Charts, are Time Series Charts of all the data points with one extra addition. The Standard Deviation for the data is calculated for the data and two additional lines are added to the chart. As shown in Figure 10, these lines are placed +/- 3 Standard Deviations away from the Mean and are called the Upper Control Limit (UCL) and the Lower Control Limit (LCL).

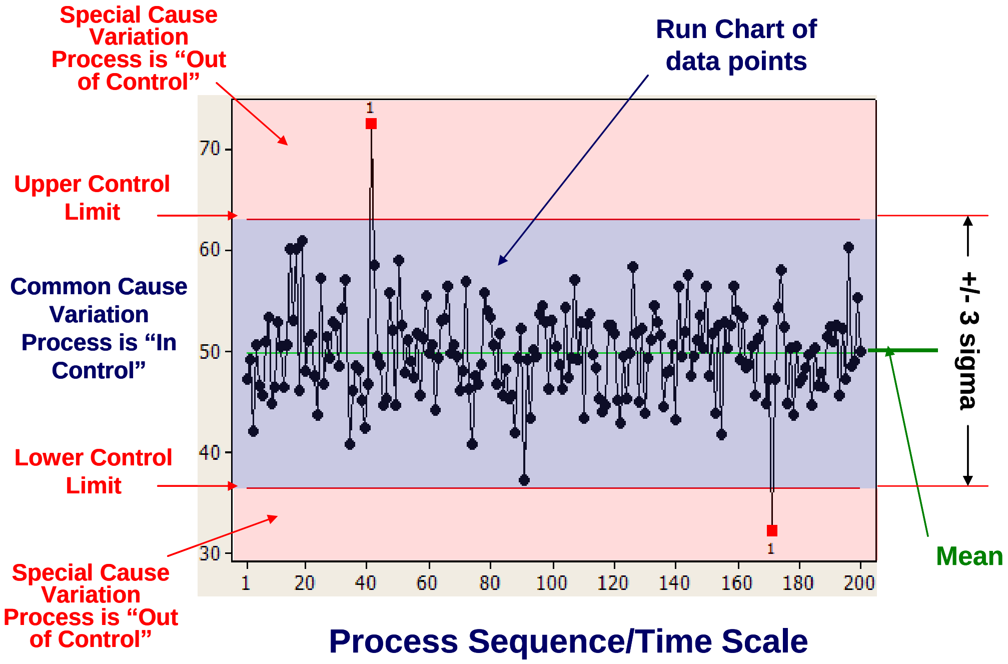


Figure 10: SPC control chart

Now the chart has three zones:

(1) The zone between the UCL and the LCL which called the zone of common variation,

(2) The zone above the UCL which a zone of Special Cause variation and

(3) another zone of Special Cause variation below the LCL.

Application of SPC to potential and functional failures

Not every equipment stop can be due to a potential failure deviation or to a functional failure, that is why we need to establish tolerances on the nominal values to judge whether an equipment stop is to be considered as failure or not. Control charts are one SPC tool that enables us to monitor and control process variation. During the equipment operation we can experience both potential and functional failures:

- Potential failure

Potential failures can be considered as *variables* depending on condition monitoring, hence a measurement such as a dimension, weight, and its unit of measurement can be specified. When this is the case, such a measurement can form the basis of SPC using variables.

- Functional failures

Alternatively, a functional failure expresses the non conformity or lack of availability of the equipment for production activity. In this case SPC uses *attributes* that are usually applicable to judgment of overall quality. In short, *variables* are measured while *attributes* are counted.

Every variation of the process must be weighted through condition monitoring in order to get the distribution of variations that is the distribution of weight for different failure categories. Sample information obtained through automatic monitoring and operational feedback, on potential and functional failures, show the lifetime of population of mechanical components, such as bearings, seals, gear… and the variation of the units of measure associated to these failures. Normal distribution (Gaussian) of failures show a tendency for the variables to take a central mean time value with positive and negative deviations equally distributed all around the mean. Other failure probability distributions, used to show material strength or time-to-failure of electronic and mechanical components, are normally represented by the different shapes of Weibull distribution.

Failure Distribution

Using reliability data to predict the performance of the machine generally involves assuming that the historical performance will reflect the current performance. The latter is best measured by strategic use of equipment monitoring techniques. Therefore, the best way to utilize this information to predict failures is by intelligent use of predetermined alarm limits. From analysis of numerous failure data on the mechanical groups, a general failure pattern becomes apparent which takes the form shown in Figure 11.

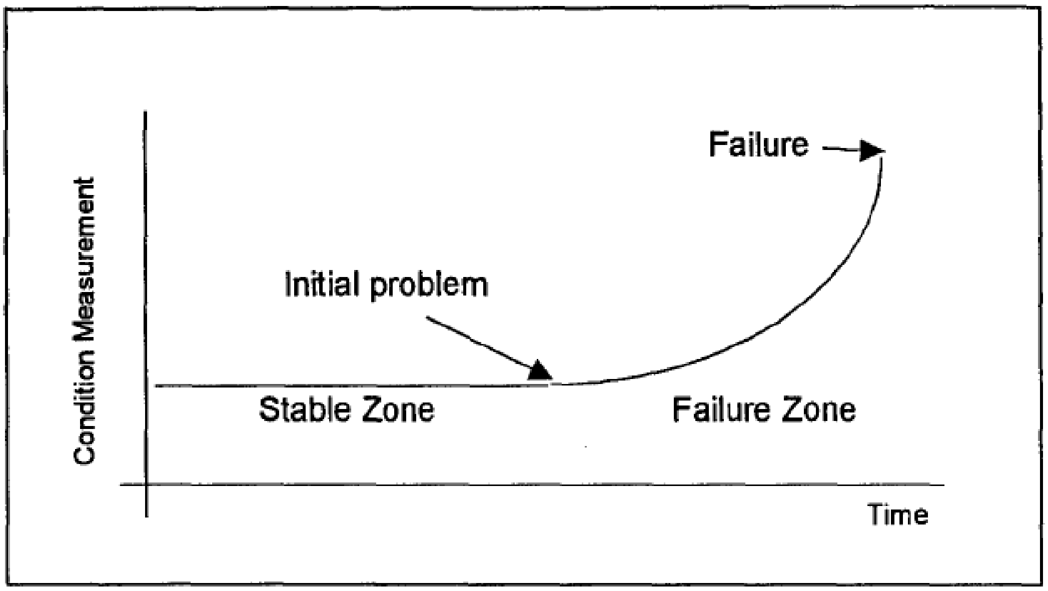


Figure 11: General mechanical failure pattern [15]

In the “stable zone”, measurements are simply varying about an average value. The variance may be due to process changes between successive measurements and/or measurement error. When the measurements start to deviate from these values, it becomes apparent that a problem exists and the equipment may have entered the “failure zone”. The setting of realistic alarm limits is achieved using SPC theory, such that when the condition monitoring measurements move outside the limits imposed, normally set at three standard deviations about the average, the condition is registered as being “unstable” and the operation has entered the designated failure zone. Each zone is defined in terms of whether the condition monitoring measurement is inside or outside the alarm limits. On this basis, it is evident that the condition data acts as switch or go/not go signal. However, in order to make further use of the condition data, a model of the failure zone pattern is also introduced. This is depicted in Figure 12 below.

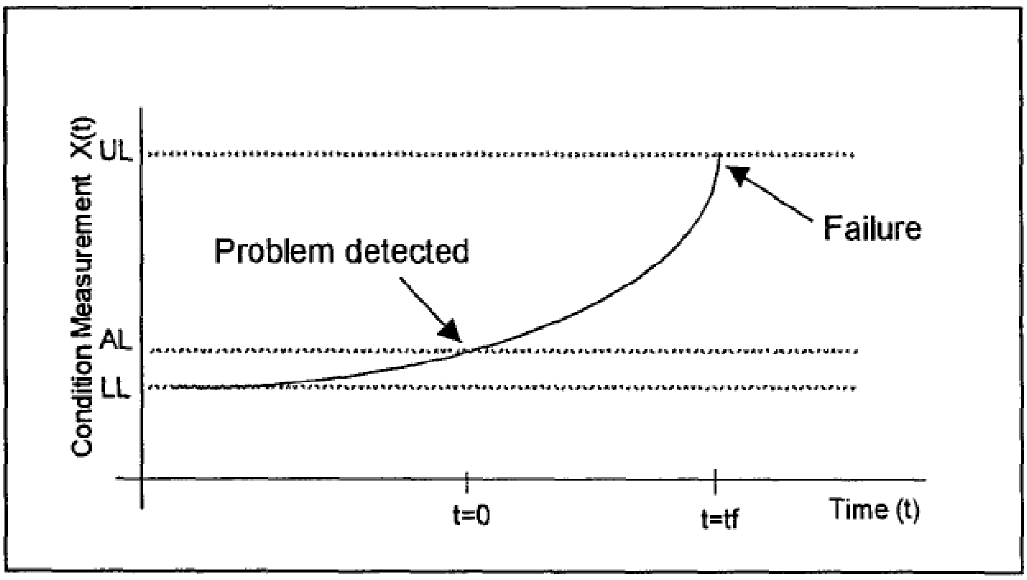
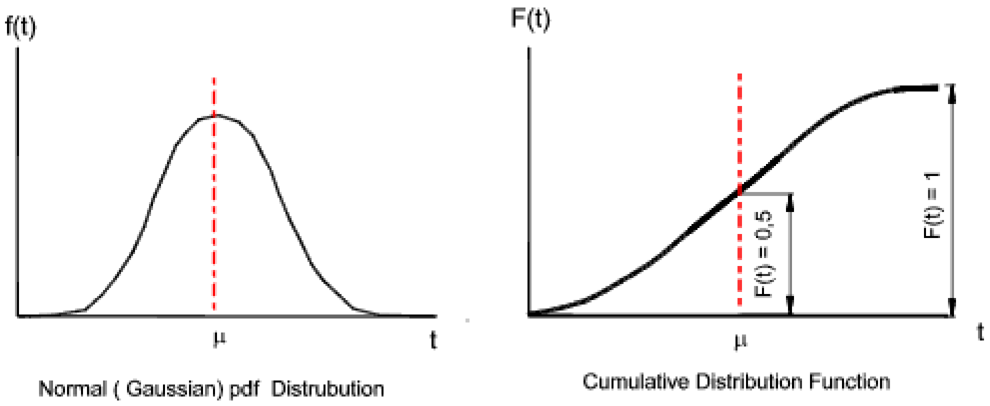


Figure 12: Failure Zone Model [15]

The failure condition commences at the lower limit (LL), which is the averaged conditional value within the stable zone. The condition measurement X(t) increases until it is detected passing through the alarm limit (AL). Subsequently, at some time, t = tf, the upper limit is reached (UL) and the machine needs to be inspected or withdrawn from production. Inspection of actual failure case histories revealed that the failure pattern could be approximated to an exponential curve [18]. While this behaviour cannot be said to apply to every situation, it nevertheless serves as an initial starting point for developing the prediction model. Values for LL and AL are obtained from the SPC modelling of the stable zone. The estimate of UL is more problematical since it is the maximum possible level the machine is permitted to reach before actual failure occurs. UL must, therefore, be estimated using information available from either within the company, or from other sources, such as equipment suppliers, or by reference to universal standards. The time “tf” is obtained by reference to reliability analysis of previous failures.

Distribution of variations

Every variation must be weighted and distribution of variations is the distribution of the weights. The curve is what we would expect if the distribution is a “Normal” distribution. Normal distribution (Bell curve) is represented by a pattern which repeats itself endlessly regarding manufactured products and in nature. Normal distributions are the most common type of distribution found in nature, but they are not the only type of distribution. In determining the lifetime reliability of a population of components (bearings, seals, gears etc.) sample information is obtained from automatic monitoring and operational feedback on the failure history of components. From the information obtained it is possible to produce a graph of the probability density function (pdf) f(t). This is a plot of the frequency at which components fail as a function of time divided by the whole population. As shown in Figure 13, the pdf curve can take many forms: one curve representing purely random events is the normal (Gaussian) curve. This is shown below with the associated Cumulative Density Function (CDF).



Normal (Gaussian) pdf Distrubution

Cumulative Distribution Function

Figure 13: Normal and cumulative distribution [18]

Normal Distributions are appropriate in the following conditions:

- there is a strong tendency for the variable to take a central value,
- positive and negative deviations from this central value are equally likely,
- the frequency of deviations falls off rapidly as the deviations become larger.

The equation for the normal distribution is:

$$f(t) = \frac{1}{\sigma\sqrt{2\,.\pi}}\ e^{-\frac{1}{2}\left(\frac{t-\mu}{\sigma}\right)}$$

Where “μ” is the mean (MTTF, MTBF) and “σ” is the Standard Deviation.

The Weibull distribution is a general-purpose reliability distribution used to model material strength, times-to-failure of electronic and mechanical components, equipment, or systems [18].

These probability distributions are related to distribution of failures, where the failure rate is proportional to a power of time. Shapes represented by different colours indicate different failure rate that, for instance, decrease, due to infant mortality following installation of new equipment or increase due to an aging process. Stan Nowlan and Howard Heap (1978) studied aircraft failures looking for correlations between those failures and the maintenance that was being performed [19]. They recognized that maintenance was a contributing factor to many of the failures but in some other cases maintenance was able to improve the situation. They looked for patterns and found them. As shown in Figure 14, there were actually six patterns of Conditional Probability of Failure.

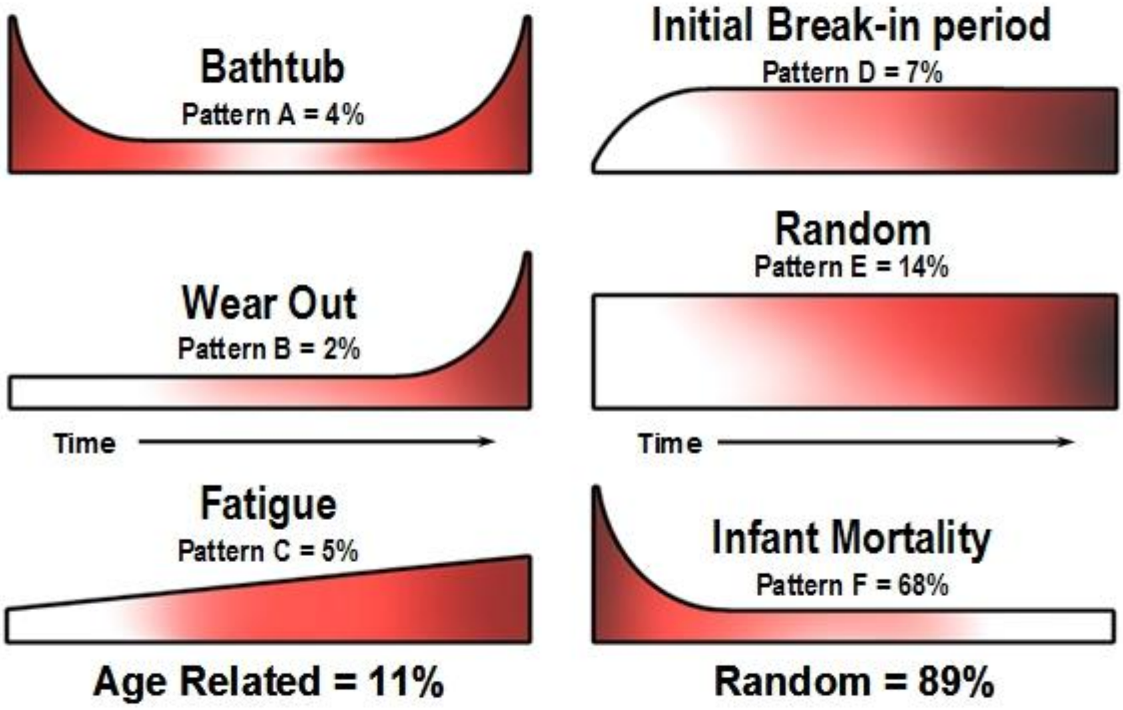


Figure 14: Failure shapes [25]

- Pattern A is the well-known bathtub curve. It begins with a high incidence of failure (known as in infant mortality) followed by a constant or gradually increasing conditional probability of failure, then a wear-out zone. This pattern appears in biological systems (like human) and in simple systems that have only a few dominant failure modes.
- Pattern B is classic wear out: shows constant or slowly increasing conditional probability of failure, ending in a wear-out zone. Prior to the Nowlan and

Heap study, this was the dominant view of equipment failure. It occurs in assets that are in contact with product, process fluids and slurry's and drives components.

- Pattern C with gradual aging, shows slowly increasing conditional probability of failure, but there is no identifiable wear-out age. This occurs where there is erosion, corrosion or fatigue.
- Pattern D is best new, shows low conditional probability of failure when the item is new or just out of the shop, then a rapid increase to a constant level. This occurs in systems, usually complex, that are maintained and put into service by highly qualified technicians before being turned over to less qualified operators. Examples are hydraulic, fluid power and pneumatic systems.
- Pattern E is totally random, shows a constant conditional probability of failure at all ages. This pattern appears in many systems or components that are, on their own, not typically subject to maintenance work. Rolling element bearings and incandescent light bulbs are examples of this type of failure.
- Pattern F starts with high infant mortality, dropping to a constant or slowly decreasing conditional probability of failure. This is common in complex systems that are subject to start up and shut down cycles, frequent overhaul type maintenance work and product cycle fluctuations.

Nowlan and Heap's study on civil aircraft showed that 4% of the items conformed to pattern A, 2% to B, 5% to C, 7% to D, 14% to E and no fewer than 68% to pattern F. The number of times these patterns occur in aircraft is not necessarily the same as in industry. There is no doubt that as assets become more complex, we see more and more of patterns E and F. Later studies (Broberg, in 1973, also studied aircraft and two studies were performed on submarine failures, MSP in 1982 and SUBMEPP in 2001) have shown the same patterns with somewhat different, but similar, distributions [20].

3.4.4 Qualitative analysis through Ishikawa, cause mapping and root cause analysis

Once quantitative analysis has provided the necessary information about the weight of potential and functional failures, qualitative analysis is necessary to identify the potential causes behind each failure and the relationships existing among these causes. The scope of this analysis is to gain a real understanding about the nature of the failure through the use of the quality tools described here below. In 1950s Japan, Kaurou Ishikawa became one of the first to visually lay out the causes of a problem. His fishbone, or “Ishikawa Fishbone,” helped visually capture a problem’s possible causes and, ultimately, has become a standard in corporate-quality and Six-Sigma programs [21]. It begins with a problem, and then identifies possible causes by separate categories that branch off like the bones of a fish. Its categories, as shown in Figure 15, typically including materials, methods, machines, measurement, environment, and people can be modified to better match a particular issue.

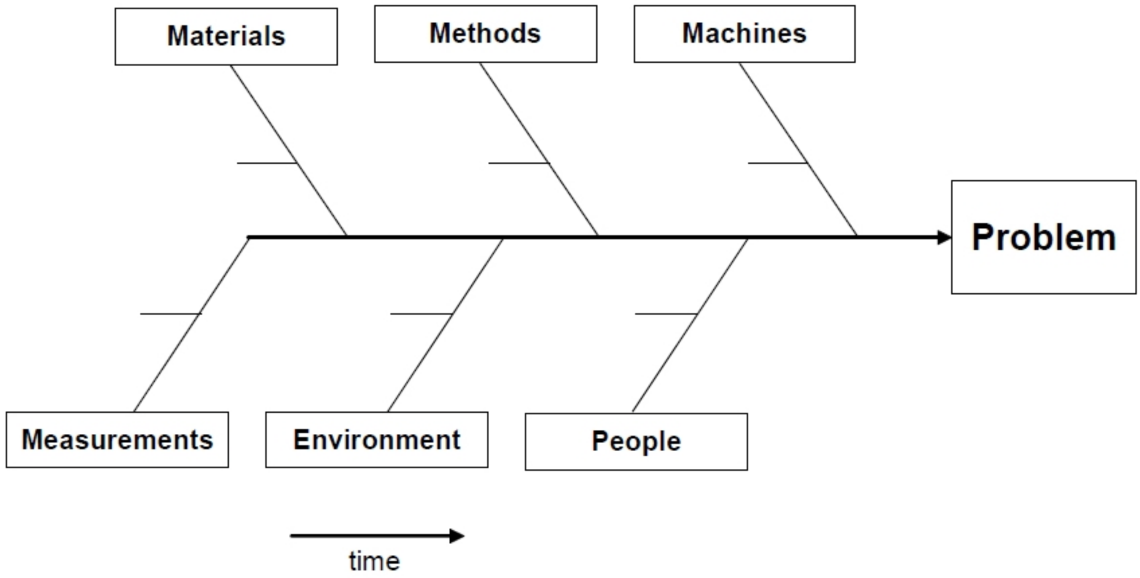


Figure 15: Ishikawa or fishbone diagram [21]

As an enhanced tool that captures problems and solutions visually, Cause Mapping expands on some of the basic ideas of the fishbone diagram for a clearer, more accurate and more specific cause-and-effect analysis. Cause Mapping uses a systems-thinking approach to root-cause analysis and incident investigation that improves the way people analyze, document, communicate and solve problems. The following five points, below, show five features that distinguish Cause Mapping from the standard fishbone diagram, and each helps make the Cause Mapping investigation process and solutions more effective.

1. Cause Maps (read left to right)

Since the traditional Japanese language reads right to left across a page, the fishbone starts with a problem on the right and builds across the page moving left. A Cause map starts on the left and reads right. At every point in both on the fishbone and Cause Map, investigators ask “why” questions that move backward through time, studying effects and finding their causes [21]. This distinguishes the Cause Map from the process map, which moves forward through time with arrows pointing left to right (the process involves performing step one, then step two, etc.)

2. Root Cause Analysis & Cause Maps tie problems to an organization’s overall goals

Root cause analysis is an approach for identifying the underlying causes of why an incident occurred so that the most effective solutions can be identified and implemented. It is typically used when something goes badly, but can also be used when something goes well [22]. Within an organization, problem solving, incident investigation and root cause analysis are all fundamentally connected by three basic questions: What's the problem? Why did it happen? and What will be done to prevent it? The picture in Figure 16 below highlight the basic principles, linking the result (symptom of the problem) to the underlying causes.

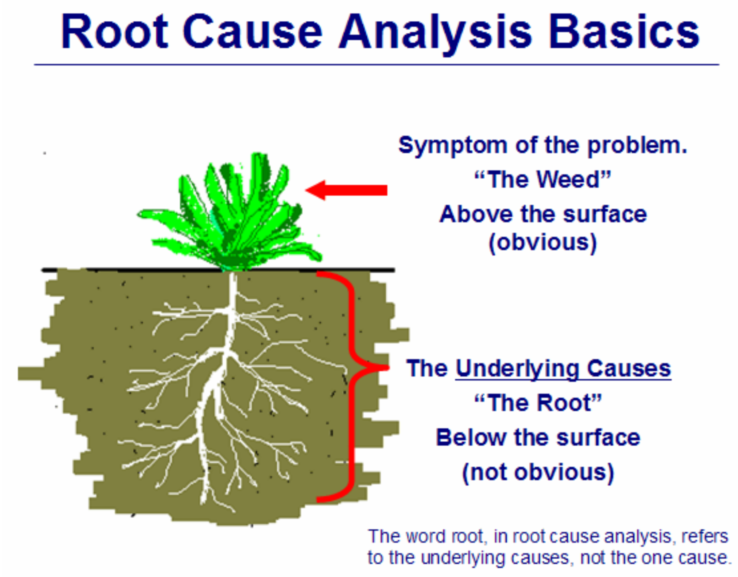


Figure 16: Basic principles of Root Cause Analysis [22]

The fishbone defines one problem and finds causes. The Cause Mapping solution, however, recognizes that problems are not always that simple. As shown in Figure 17, first, just try defining one problem by asking: "What's the problem?". That question can create significant disagreement in any organization, with answers varying widely depending on a person's perspective. What some see as a problem, others may see as just a symptom of a larger, more significant issue. Starting an investigation with a single problem does not necessarily reflect the nature of an incident or failure.

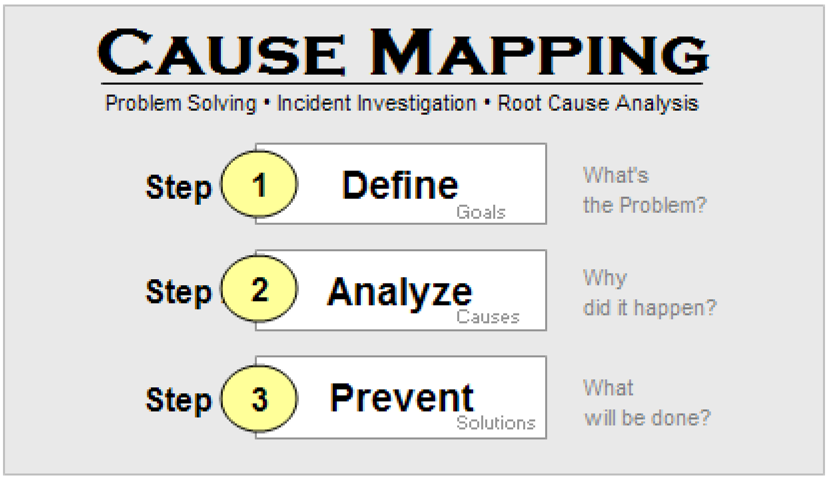


Figure 17: Cause Mapping process [21]

3. Cause Maps focus on cause-and-effect, not categories

As shown in Figure 18, an analysis breaks something down into its parts; analyzing an incident involves breaking it down into specific cause-and-effect relationships.

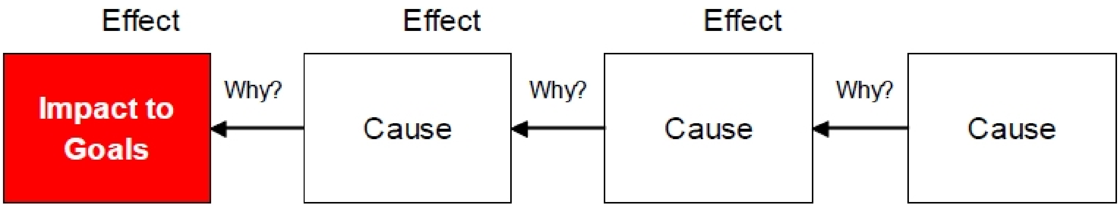


Figure 18: Cause mapping cause and effect boxes [21]

Fishbone diagrams group similar causes into categories: method, machine, material, man, etc. Categorization, however, creates generalizations and represents a polar opposite of analysis. Grouping an incident's possible causes by category does not show the cause and effect relationships. In effect, a fishbone's categories simply create a "Yellow Pages" directory of causes not a map that details how causes and effects relate. For instance, a training issue grouped under "people" can cause a person to make an error that results in an equipment failure, grouped under "machinery" [21].

4. Cause Mapping focuses on evidence-based causes

The fishbone method regularly identifies possible causes, which encourages speculation. Cause Mapping, on the other hand, focuses its analysis on causes supported by evidence. Causes produce effects; anything required to produce an effect is, by definition, a cause of that effect. Heat, fuel and oxygen, all interacting, "cause" fire. Causes are supported by evidence while possible causes lack that evidence. During analysis of a past event, investigators may develop possible causes, identifying them throughout the Cause Map. But they are identified and treated as such, clearly distinguishable from the Cause Map's principal focus: causes supported by evidence. This makes sense, since any past incident only has actual causes, not possible ones.

5. Cause Maps focus on systems thinking

Which part of a car is required for the car to function: the engine, the transmission, the battery, the driver, the steering wheel, the tires, the brakes, or the fuel? They all are, of course, because all of these elements work as a system; remove one element, and the system does not operate the way it should. Considering how these systems relate to causes and effects requires systems thinking [21]. It does not look for one answer, or the cause, but analyzes how elements and systems work together to create an incident. It also helps explain why there are so many disagreements when people try to identify "the cause" of an incident. In fact, most organizations only focus on a single cause and fail to see the incident as a system.

6. Conclusion

The Cause Mapping approach builds upon and refines some of the fishbone diagram's original concepts. The concepts, examples, and exercises involved with Cause Mapping improve the way people analyze, document, communicate, and solve problems. The purpose of an investigation is to find the best solutions to prevent an incident from occurring, and a Cause Map helps reach this ideal by efficiently laying out-on one map- the organization's goals, problems and the systems of evidence-supported causes [21].

3.4.5 Other qualitative failure analysis tools

Failure Determination (FD) and Fault Tree Analysis (FTA) are currently used in industries to determine potential failures of products. In order to eliminate or reduce the possibility of failure, designers need to be aware of all of the potential significant failure modes in the systems being designed. An essential and crucial part of these methods is a required function-failure knowledge base of previous products. A systems failure analysis is an investigation to determine the underlying reasons for the non-conformance to system requirements. A systems failure analysis is performed to identify non-conformance root causes and to recommend appropriate corrective actions. Systems failure analysis begins with a clear understanding of the failure (i.e. a definition of the problem) [23].

- Fault Tree Analysis (FTA): identifying all potential failure causes

When confronted with a systems failure, there is often a natural tendency to begin disassembling hardware to search for the cause. This is a poor approach. Failed hardware can reveal valuable information and safeguards are necessary to prevent losing that information from careless teardown procedures. Fault tree analysis is a graphical technique that identifies all potential failure causes. The fault tree starts with a top undesired event, which is the system failure mode for which one is attempting to identify all potential causes [23]. The analysis then continues to sequentially develop all potential causes. In FTA, there are two categories of symbols: events and gates. Fault tree events are linked by gates to show the relationships between the events [24]. As shown in Figure 19, there are two types of gates: "and" gates and "or" gates. The "and" gate signifies that all events must occur simultaneously to result in the event above it. The "or" gate means that if any of the events occur, the event above it will result.

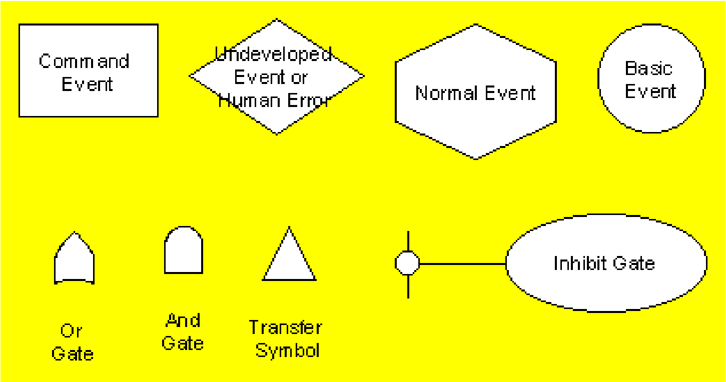


Figure 19: Fault Tree Symbology represented by logic gates [24]

Figure 20, shows the problem of a light bulb that does not illuminate. This becomes the top undesired event, and top undesired events are always shown in a command event symbol, as they will be commanded to occur by events in the tree below.

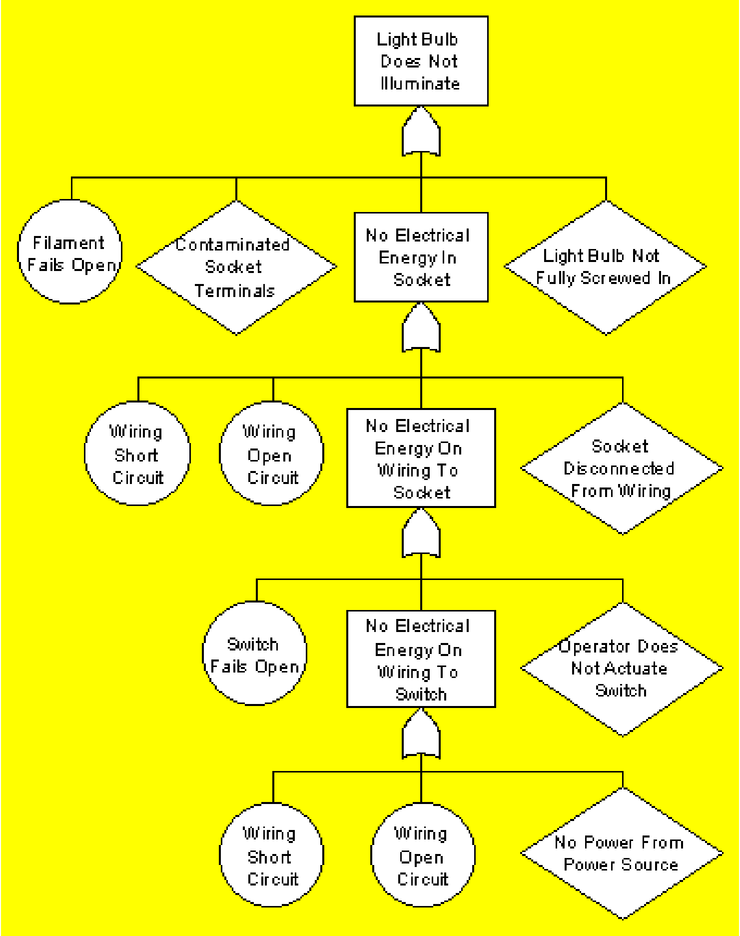


Figure 20: Fault Tree applied to a light that does not illuminate [3]

This simple fault tree develops potential causes for an indicator light system failing to illuminate. A common shortcoming is to jump around in the system, and start listing things like a power loss in the building, a failed switch, and perhaps other events, but the fault tree requires discipline [24].

- The Failure Mode Assessment and Assignment Matrix

After completing the fault tree, the next step is to prepare the failure mode assessment and assignment matrix (the FMA&A). As shown in Table 1, the FMA&A is a four column matrix that identifies the fault tree event number, the fault tree event description, an assessment of the likelihood of each event, and what needs to be done to evaluate each event. The FMA&A shown in Table 1 shows what actions are required for evaluating each indicator light potential failure cause, and it provides a means of keeping track of the status of these actions.

Event	*Description*	*Assessment*	*Assignment*
1	Filament Open	Unknown	Examine bulb for open filament. Hughes; 16 March 2007
2	Contaminated Socket Terminals	Unknown	Examine socket for contaminants. Perform FTIR analysis on any contaminants observed in socket. Hughes; 16 March 2007
3	Light Bulb Not Fully Screwed In	Unknown	Inspect bulb in socket to determine if properly installed. Smith; 14 March 2007
4	Socket Disconnected From Wiring	Unknown	Examine wiring and perform continuity test. Smith; 16 March 2007
5	Wiring Short Circuit	Unknown	Examine wiring and perform continuity test. Smith; 16 March 2007
6	Wiring Open Circuit	Unknown	Examine wiring and perform continuity test. Smith; 16 March 2007
7	Operator Does Not Activate Switch	Unknown	Interview operator and check switch function. Hughes; 16 March 2007
8	Switch Fails Open	Unknown	Check switch function. Hughes; 16 March 2007
9	Wiring Short Circuit	Unknown	Examine wiring and perform continuity test. Smith; 16 March 2007
10	Wiring Open Circuit	Unknown	Examine wiring and perform continuity test. Smith; 16 March 2007
11	No Power From Power Source	Unknown	Check power supply with multimeter. Smith; 14 March 2007

Table 1: The Failure Mode Assessment and Assignment Matrix [24]

3.5 Maintenance engineering techniques for the implementation process

In this section, different maintenance engineering techniques have been selected to carry out a critical study of features that can give their contribution to the design of the maintenance implementation process. These techniques show characteristics that link the design and implementation phases through a reliable management and control of critical factors.

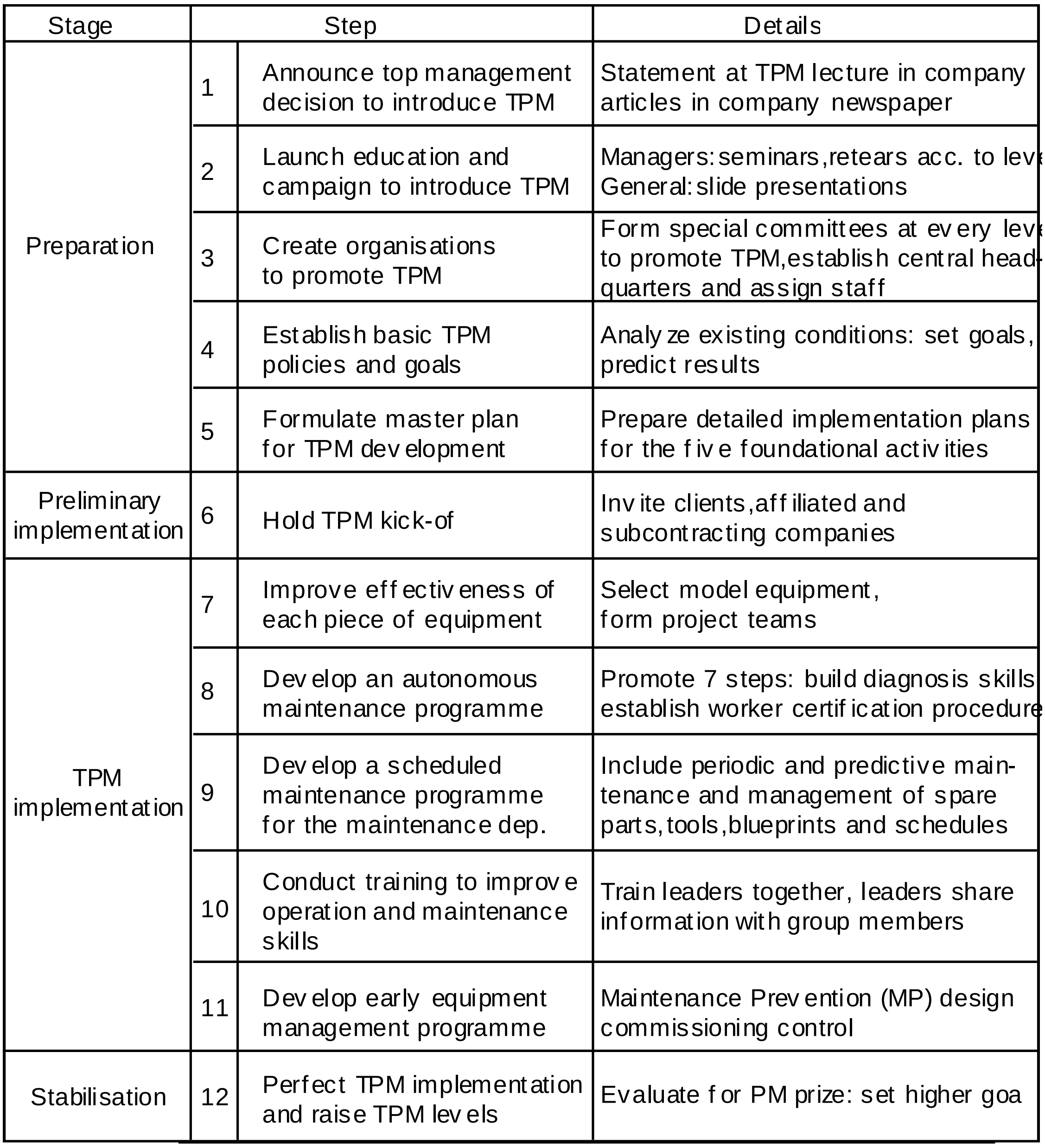
3.5.1 Total Productive Maintenance (TPM) technique

Seiichi Nakajima, vice president of Japan Institute of Plant Maintenance (JIPM) introduced the TPM methodology in Japan since the beginning of 1971. The TPM is a new approach to maintenance which pursues the equipment efficiency optimization, cutting down faults through the Autonomous Maintenance (AM) activities, carried out by the machine operators, integrated with preventive maintenance activities done by the maintenance specialists. TPM pursues the elimination of six fundamental causes of production losses:

- *Loss of time*
    1. Equipment failure due to faults
    2. Set-up and adjustment due to changes in production runs.
- *Equipment speed reduction*
    3. Downtime because of machine stops due to wrong settings and anomalies of devices
    4. Reduction of equipment speed due to the gap existing between the original and real speed.
- *Equipment failure*
    5. Machine faults due to the process which involve waste of product or repair activities to restore the product quality
    6. Reduced yield in the equipment start up phase [25].

Table 2 below, lists the twelve steps, suggested by Nakajima, and needed to develop and implement a TPM program. The twelve steps are combined into four main stages:

1. Preparation
2. Preliminary Implementation
3. TPM Implementation
4. Stabilization.



Stage	Step		Details
Preparation	1	Announce top management decision to introduce TPM	Statement at TPM lecture in company articles in company newspaper
	2	Launch education and campaign to introduce TPM	Managers: seminars, retears acc. to lev General: slide presentations
	3	Create organisations to promote TPM	Form special committees at every lev to promote TPM, establish central headquarters and assign staff
	4	Establish basic TPM policies and goals	Analyze existing conditions: set goals, predict results
	5	Formulate master plan for TPM development	Prepare detailed implementation plans for the five foundational activities
Preliminary implementation	6	Hold TPM kick-of	Invite clients, affiliated and subcontracting companies
TPM implementation	7	Improve effectiveness of each piece of equipment	Select model equipment, form project teams
	8	Develop an autonomous maintenance programme	Promote 7 steps: build diagnosis skills establish worker certification procedure
	9	Develop a scheduled maintenance programme for the maintenance dep.	Include periodic and predictive maintenance and management of spare parts, tools, blueprints and schedules
	10	Conduct training to improve operation and maintenance skills	Train leaders together, leaders share information with group members
	11	Develop early equipment management programme	Maintenance Prevention (MP) design commissioning control
Stabilisation	12	Perfect TPM implementation and raise TPM levels	Evaluate for PM prize: set higher goa

Table 2: The twelve steps of TPM development [26]

TPM success is measured through the Overall Equipment Effectiveness (OEE) which measures:

- Availability

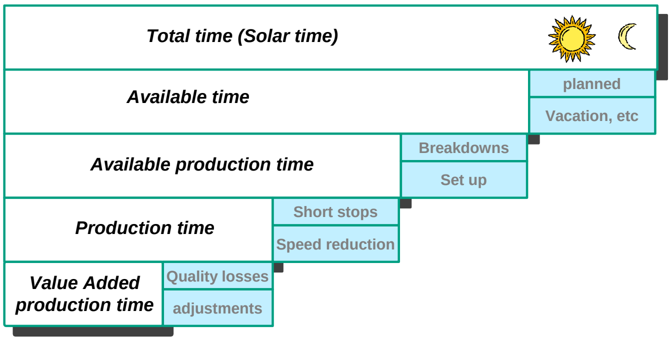
  Downtime used for preventive and corrective maintenance
- Equipment speed

Actual production speed compared to the theoretical production capacity

- Quality

  Proportion of defective products (packages waste).

Then the formula used reflect not only the equipment faults, but all the losses regarding breakdowns, set-up and registrations, short stops, speed reductions, time spend for quality defects and rework. The OEE is the index measuring the line/machine productive effectiveness in the scheduled time. Figure 21, shows the time domain taken into consideration and the formula used to measure OEE.



$$\text{OEE} = \frac{\text{Value Added production time}}{\text{Available time}}$$

Figure 21: Production time domain with OEE formula [27]

Total productive maintenance (TPM) principles implementation

Equipment operator empowerment, and its integration with maintenance specialist, is a mandatory activity to reach efficiency, reliability targets and cost improvement results. Implementation of TPM goes through the following steps:

- *Define machine operator role in operating & maintaining the machine*

One of the most important characteristics of TPM philosophy is Autonomous Maintenance (AM) carried out by those who operate the equipment. AM requires the operator to clean, lubricate, check and inspect his or her equipment in the name of order, clearness and efficiency. The seven steps implemented to initiate autonomous maintenance are:

1. Initial clean up: this is a useful activity for discovering faults
2. Eliminate causes of contamination and make cleaning easier
3. Cleaning and lubrication rules

4. Improve inspection and technical skills (training)
5. Develop autonomous inspection activities
6. Standardize procedures and work place rules
7. Complete Autonomous Maintenance (AM).

To enable a successful AM implementation, machine operators have to be empowered through the improvement of their competencies. The following four abilities must be developed:

(a) ability to discover anomalies
(b) ability to fix the anomalies and set the normal operating conditions
(c) ability to define the normal operating conditions and the standard valuation
(d) ability to manage and maintain the equipment.

- *Integration between machine operator and maintenance specialist*

Figure 22 shows a picture that helps maintenance and operator personnel to understand and learn, that, based on partnership between operations and maintenance, TPM enables operators and maintenance specialists to become multi-skilled.

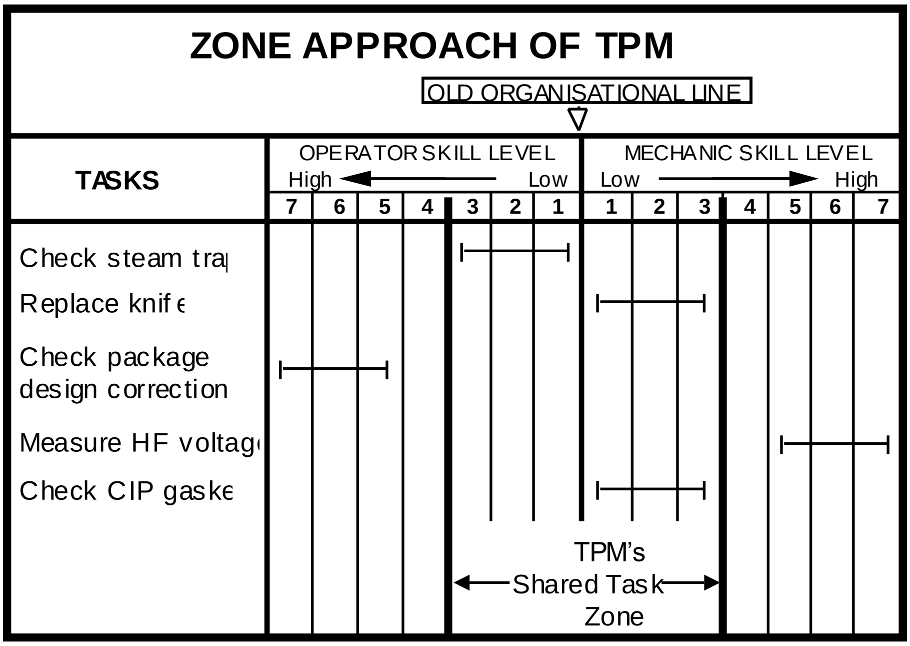


Figure 22: TPM's shared task zone [28]

- *Maintenance specialists and operators are trained to safely perform tasks listed in the shared task zone*

> In the example made above, since a replacement of knife is in the task zone, the operator who observes the need for replacing this component, he can simply do it, without losing time to communicate with maintenance and operation supervisors, and then waiting for maintenance specialist.

Condition-Based Maintenance and specialistic PM activities, which required good electrical and mechanical skill, are performed by maintenance specialists.

Operator empowerment through co-operation with maintenance specialists

TPM is, by definition, an effective maintenance management system supported by the Autonomous Maintenance where each production equipment operator becomes "proprietor" of his/her machine and takes care of all details that will preserve that machine in the best possible condition.

TPM's goals are accomplished through one or more of the following concepts:

1. Operators doing routine maintenance
2. Operators assisting maintenance specialists when equipment is down
3. Maintenance specialists assisting the operators with shutdown and start-ups
4. Transfer of tasks not requiring craft-workers
5. Team approach to computerized calibration
6. Transfer of tasks between operating groups
7. Multi-skilling of craft-workers [28].

1. Empowering operators to perform specified routine maintenance tasks on their equipment

Operators assuming ownership of their equipment helps to eliminate potential causes of failure. Once autonomous maintenance is implemented, the recurrence to the maintenance department is minimized. Gradually, the operator becomes qualified to determine the status of different components and groups and can make small adjustments and repairs. When maintenance is needed, the operator already knows the procedure and is a great help. In many cases, the procedure has been simplified and the operator is a key element in these improvements that increase the maintainability of the equipment. A great deal of this improved effectiveness comes from the motivation given to the employees through adequate training and education. Operators are given the proper training and tools to perform the "CLAIR" tasks: Clean, Lube, Adjust, Inspect, and Repair [28].

C = Clean
L = Lubricate
A = Adjust
I = Inspect
R = Repair.

2. Empowering operators to assist and support maintenance specialists in the repair of equipment when it is down

As the operators become more expert with their equipment, the TPM coordinator, supported by the maintenance technicians, will be giving more instruction to the operators and giving directions on pertinent safety measures so they keep advancing in their capacity to intervene in the equipment. When a complex equipment failure is experienced the operator is committed to understand the reason of failure and to assist the maintenance specialist while he is carrying out the trouble shooting activity. In this case, the maintenance force is enlarged; the operators do not loose their central role due to lack of work and ultimately the failed equipment is returned to service more quickly.

3. Empowering maintenance technicians to assist operators in the shutdown and start-up of equipment

Cooperation between maintenance technicians and equipment operators enables us to save time in shutting down and starting up equipment. Once the maintenance specialist finish the repairs, they assist the operators in returning the equipment to service by correcting leaks and other mechanical or electrical problems as they occur. Maintenance specialists can also be trained to perform some of the operation tasks without the assistance of the operators.

4. Empowering lower-skilled personnel to perform jobs not requiring skilled craft-workers

There are many routine tasks that can be done by just about anyone who has been given proper tools and training. Under the TPM program, these tasks are identified. If it is not feasible for skilled operators or maintenance specialists to do the job, lower bracket people are used. As the maintenance personnel spend less time on routine work, they can concentrate more on improving equipment reliability and doing the work for which they have been specially trained.

5. Use computerized technology to enable operators to calibrate selected instruments

The use of Statistical Process Control (SPC) charts to control operations is based on process feedback that is as accurate as possible. As part of TPM program, instrument calibration test units can be used to ensure the proper function of the instrumentation normally used to carry out preventive maintenance.

6. Transfer of tasks between operating groups

In many cases, unnecessary waiting time and equipment downtime are the attendant results. Identifying these non-productive interfaces and restructuring job responsibilities can remove such inefficiencies.

7. Multi-Skilling of craft-workers

The focus of this concept is training mechanics, electricians, and other craft-workers to use the zone approach in analyzing their job interfaces. Frequently if an electrician learns some mechanical skills and a mechanic learns some electrical skills, further reduction can be made in equipment downtime. Multi-skilling reduces the number of times an operator hears: “it is not a mechanical problem, but an electrical problem, then you need to get an electrician” or “it is not an electrical problem, then you need to get a mechanic”. Multi-skilled craft-workers become stewards of the problem and lose the “that’s not my job” attitude.

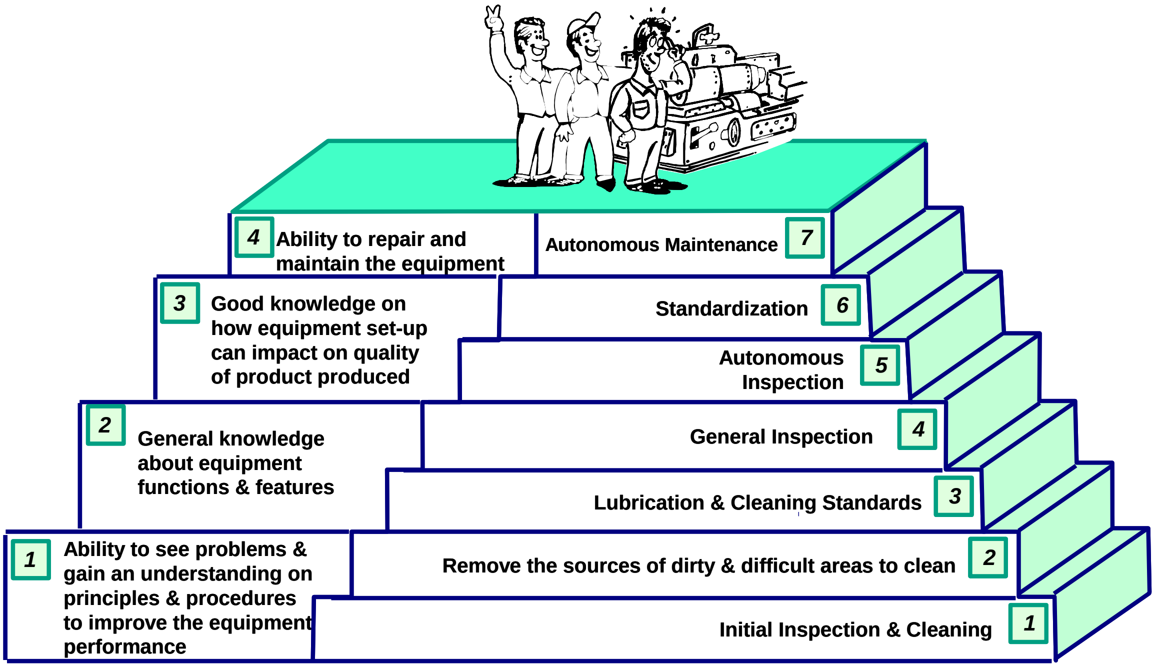


Figure 23: The different steps to become an operator able to carry out AM [29]

The new TPM management concept consists of a more effective and realistic delegation of responsibilities (empowerment), the different activities, shown in Figure 23 above, enable the operators to know their equipment better than anyone else. The “collective participation” gives the operators a greater satisfaction. Kaizen is a Japanese term that means continuous improvement [30], when carrying out this process, constant success is obtained and the participants look for new opportunities. The habit is to constantly look for more opportunities to improve the process, the workplace, the quality of the product, etc. These people enjoy contributing their spontaneous creativity to the solution of a problem. They are capable of developing and communicating a creative and friendly environment.

3.5.2 World Class Manufacturing (WCM)

A manufacturing firm achieves world-class status when it has successfully developed manufacturing capabilities to support the entire company in gaining a sustained competitive advantage over its competitors in such areas as cost, quality, delivery, flexibility, and innovation. World-Class Manufacturing (WCM) is defined as a manufacturing philosophy or ideology that is used to achieve world-class manufacturer status. The essence of WCM philosophy is continuous improvement involving everyone in the organization. Organizations that adopt this philosophy constantly seek opportunities for improvement in such key competitive areas as quality, cost, delivery, flexibility, and innovation. Such improvements are essential to survival and profitability. Companies that are pursuing world-class status may take different paths that, in turn, require different precepts.

Figure 24 below, identifies the main steps to be implemented on a manufacturing company, starting from the first WCM step, which can assess the actual status of the equipments and production practices, up to the final step which pursues a consolidation of zero defects philosophy.

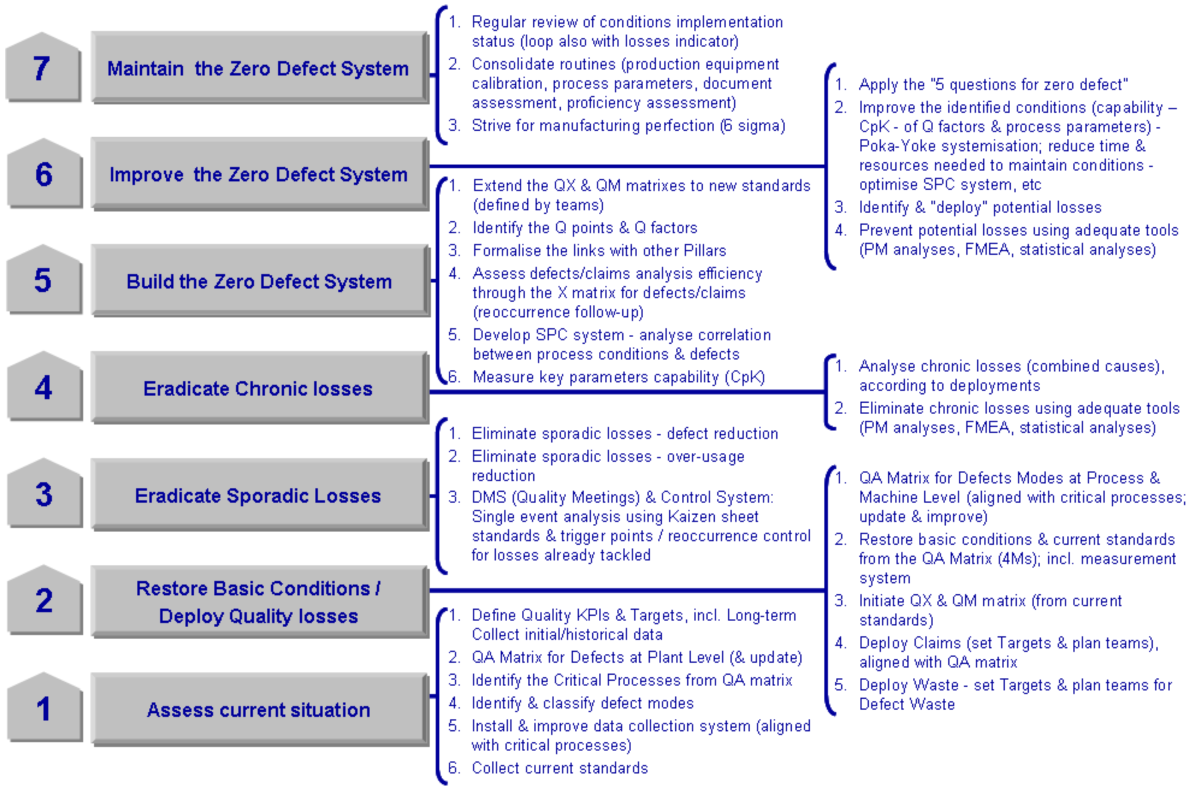


Figure 24: Main WCM steps [29]

The main steps of WCM methodology are described here below.

First step: assess current situation

In the first step, it is necessary to define the quality KPIs & targets, including long-term collection of initial and historical data. Normally targets will be defined on three years base covering KPIs regarding losses and processes. The Quality Assurance Matrix for defects at plant level identifies and scores the existing defects and the critical processes.

Second step: restore basic conditions / deploy quality losses

Using the QA matrix for defect mode, at process & machine level, restore the basic condition & current standards through the implementation of qualitative techniques. Deploy claims, aligned with QA matrix and set target & dedicated teams. Deploy the different waste categories, set target & establish teams to eradicate defects and waste.

Third step: eradicate sporadic losses

Eliminate sporadic losses and pursue defect reduction is the scope of the third step.

Equipment is normally stopped due to a combination of sporadic and chronic problems. Fault Tree & Root Cause Analysis can be carried out to identify the causes of sporadic and chronic hidden problems.

Fourth step: eradicate chronic losses

Analyse chronic losses (with combined causes) according to the deployment carried out through PM analysis, FTA, RCA, FMEA, and Statistical analysis. The use of these tools can eliminate chronic losses. To gain a better understanding of inherent problems it is necessary to have a good knowledge of the system and the phenomenon produced.

Fifth step: build the zero defect system

The established teams identify the quality factors to be implemented in order to pursue the zero defect objectives. Quality results can be achieved thorough a close link with other pillars. Assessment of defects, claims analysis and equipment efficiency to gain a holistic view of the production reality. Development of SPC system is necessary to analyse the existing correlation between process condition and defects.

Sixth step: improve the zero defect system

Apply the “5 questions for zero defects”:

- Is the condition clear?
- Is it easy to set conditions?
- Is the value variable?
- Is the variance visible?
- Is it easy to restore?

Improve the identified conditions defining priorities and implementing the necessary countermeasures. Identify & deploy potential losses and prevent those using adequate tools.

Seventh step: maintain the zero defect system

In the last step, regular review of conditions, about implementation status with monitoring of losses indicators, is the never ended activity necessary to consolidate the gains obtained. Quality activities are regularly carried out striving for higher manufacturing effectiveness that makes use of six-sigma methodology.

3.5.3 Total quality maintenance (TQMain) technique

This model, developed by Dr.Basim Al-Najjar (1996) is mainly based on the Deming cycle: Plan-Do-Check-Act (PDCA), which is the foundation of TQMain, and can be used for the improvement of any technical or managerial system. Al-Najjar’s research focus is on Condition Monitoring (CM) by vibration analysis, and it is therefore natural that his model for maintenance should specifically include inspection and monitoring. As TPM, maintenance should be integrated with production activity and scheduled with it. Condition Based Maintenance (CBM) is based on:

- Subjective CBM,
  which means that the status of component is checked by listening, looking, feeling etc.
- Objective CBM,
  which means that the status of a component is checked through measurement of physical parameters such as vibration, pressure, temperature…

Modern machines are normally equipped with on-line measuring devices that are used where critical component breakdown can produce serious effects on process reliability and product safety. Success in TQMain is measured by a modified version of Overall Equipment Effectiveness (OEE) measure of Total Productive Maintenance (TPM), which he calls Overall Process Effectiveness (OPE). The OEE measure combines the six big losses of TPM under three headings, Availability (including preventive down time), Speed (actual production rate / theoretical production rate), and Quality (1-proportion defective).

$OEE = A.\eta.(1 - p_d)$ where:

A: is the time loss due to equipment downtime
η*: is the time loss due to speed reduction*
p_d*: is the time loss to produce defective products.*

TQMain expands this measure to show how its constituent factors are calculated, but it also calculates over a whole process rather than a single machine, and recognizes that the same machinery may have different OPE’s for different processes. The formula used is:

$OPE = \{1 - N_s / \mu T\}.\{1 - (n_m / \mu_m + t_r) / t_o\}.\{1 - (n_f + n_c + n_s) / n\}$ where:

OPE = {1- No Stoppages/Repair rate x Loading time} x {1- (No Minor stoppages/Minor repair rate + Time lost to reduced speed operation) / Operating time} x {1- (defectives made just after stoppages + defectives made when process was in control + defectives due to assignable QC causes) / Total No made}.

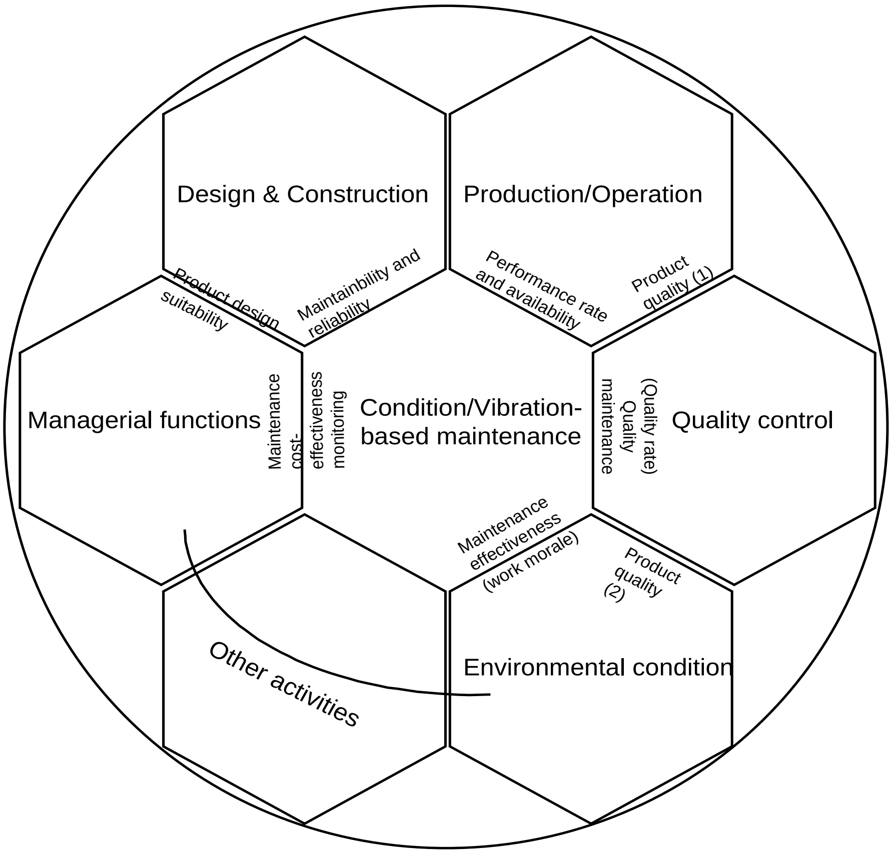


Figure 25: The TQMain Football [23]

TQMain also recognises that the relative importance of the various factors to be considered in maintenance policy-making varies between projects and with the viewpoint of the manager [23]. To illustrate this, Al-Najjar devised the TQMain Football as shown in Figure 25 above.

3.5.4 Terotechnology principles

The terotechnology model comes from the work done by the British government, and develops feedback criteria coming from quality gurus. Figure 26 below, shows the basic idea that expands, upon the data collection, analysis and schedule optimisation that should occur during the operation phase, and emphasise the needs for Failure

Modes Effect and Critical Analysis (FMECA) and testing of new designs and training operators and maintainers. The originators of terotechnology, led by Dennis Parker (1970) did not specifically mention optimization as such, but did advise the revision of schedules as result of experience. Since sensitivity of the cost rate to PM interval are very difficult to judge without data and calculation, feedback loops are very important to enable PM optimization and equipment design improvements.

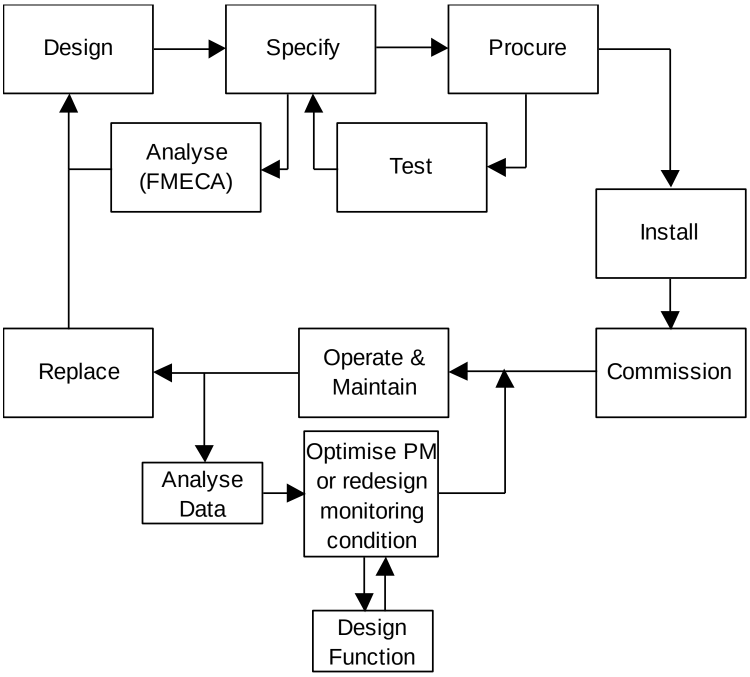


Figure 26: Terotechnology maintenance model [31]

Terotechnology, moving from Life Cycle Cost (LCC) to Life Cycle Profit (LCP), allows maintenance function to be seen as contributing to profits rather than just spending money. To accommodate the profit aspects, effects of maintenance on product quality and prompt delivery, which in turn affect market share, overall profit margins and pricing, should be measured and acknowledged. LCP will perhaps remain a real worthy objective, and the company's IT system should be sufficiently integrated to cope with the demands for instant, to supply detailed and unambiguous information to feed the mathematical models and other decision-guiding calculations.

Figure 27 below, shows the different economical indicators, such as loss of revenues, due to machine stops, the costs of direct and indirect maintenance throughout the entire equipment lifetime, and their projection against OEE and the amount of money involved for each indicator.

- Direct maintenance costs

Direct maintenance costs are those related to manpower (salaries), spare parts, templates and technical documentation.

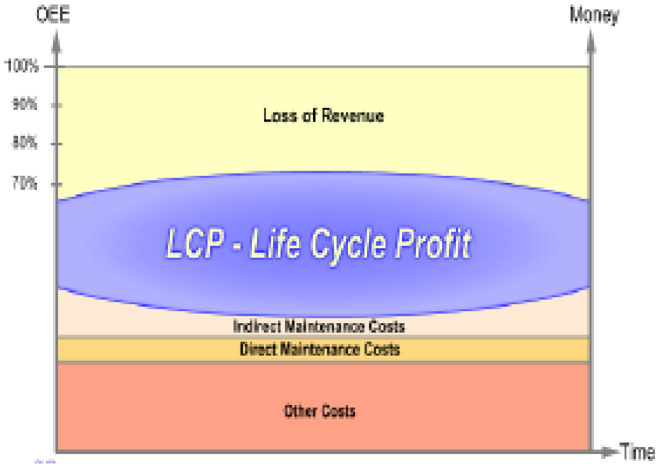


Figure 27: Life Cycle Profit (LCP) [27]

- Indirect maintenance costs

Indirect maintenance costs are all the costs generated by insufficient or lack of maintenance (losses, wastes…). Lack of maintenance affected not only maintenance costs, but also operational and capital costs.

- Loss of revenue

Every hour of standstill or rejection of products should be interpreted as a loss of revenue. The graph shown in Figure 28, identifies the area where an optimum costs balance can be found.

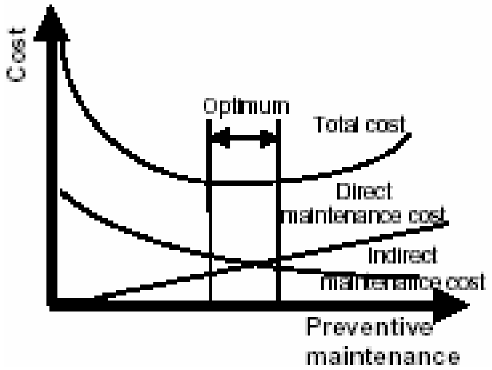


Figure 28: Maintenance costs [32]

The operational cost for thousand packages produced can be calculated as shown in Figure 29 below.

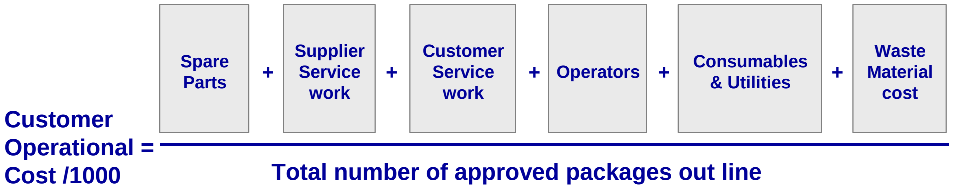


Figure 29: Producer operational cost per thousand packages produced [33]

3.6 Conclusion

In this chapter, a critical study of some reliability principles, product safety, and maintenance engineering techniques have been examined to underline their value and contribution in defining the maintenance design process. The extensive literature review could highlight the main features of techniques and methodologies to shape a maintenance design process intended to design maintenance tasks for ALF equipments. Safety, reliability, and engineering techniques have shown their potential to identify equipment CCPs and in providing tools and criteria to be used to design maintenance tasks necessary to determine product safety and equipment reliability. Statistical and engineering tools have been examined to carry out quantitative and qualitative analysis of failures to discover the real nature of a failure and its impact on production runs. Other maintenance engineering techniques, such as TPM, WCM, TQMain, and Terotechnology, have been analyzed to identify the principles to be used in the maintenance implementation process for ALF industry. Some of the factors that could partially or totally prevent the effective implementation of maintenance procedures have been examined to guide toward the model that enables implementation effectiveness for ALF environment. Beyond reliability principles, different implementation methodologies have been investigated to select useful ideas to design an implementation process able to address and solve human, cultural, and organizational complexities.

4. CRITICAL REVIEW OF CONDITION MONITORING (CM) TECHNIQUES

4.1 Introduction

Monitoring the condition of critical machine elements enables component degradation to be identified before it causes a failure. Equipment functions and components can be monitored using different type of sensors to detect when wear, damage, or a critical signal is starting to occur. By detecting deterioration of critical signals early, unplanned stoppages and further damage can be avoided. Condition monitoring can therefore be thought as a cost-effective insurance policy for critical ALF parameters or components [34]. Although very few machine builders incorporate condition monitoring as standard, the equipment used for the ALF, or food industry in general, should automatically incorporate monitoring systems of critical parameters such as those linked with machine sterilization or package integrity. The different type of sensors available, make a vital contribution to the reliability improvement of products and processes. The automated production lines, in the food and beverage industry, normally benefit from the use of different kind of sensors to monitor critical parameters both online or on request.

The scope of this chapter is to investigate this field to identify:

- the benefits of online monitoring systems
- the condition monitoring systems available in the market
- the added value provided by different applications
- how each application can give its contribution to improve safety and reliability of ALF production lines.

4.2 Online monitoring systems

An on-line monitoring system makes use of a device which constantly monitors a specific magnitude or movement to convert one type of energy or physical attribute to another with the purpose of measuring and monitoring its function.

A primary consideration for an online monitoring system is to determine which machine part or function warrant surveillance monitoring as compared to what can be accomplished with a portable or protection monitoring systems. Figure 30 below provides a good representation of where surveillance monitoring traditionally lies in a vibration measurement condition-monitoring program.

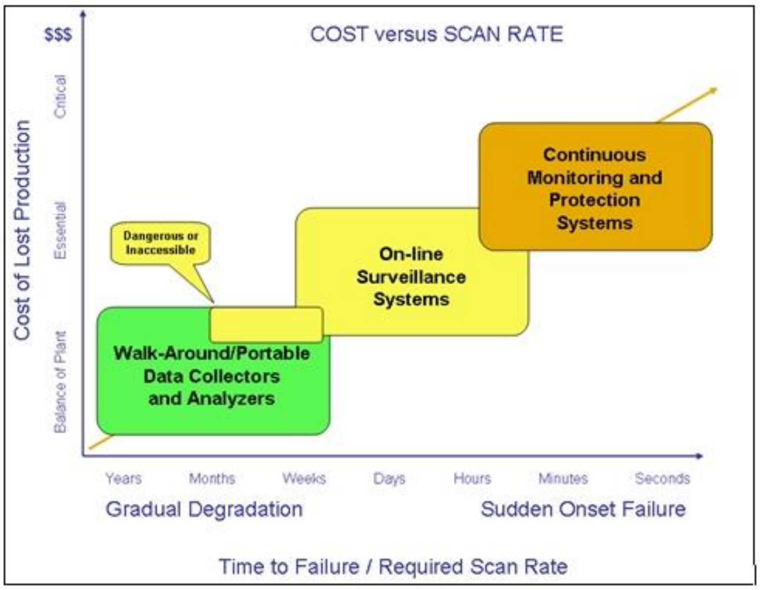


Figure 30: Cost versus scan rate in the surveillance monitoring [35]

As this graph indicates, on-line surveillance systems are most commonly employed on equipments that are costly to maintain and those that negatively influence production efficiency when out of service. Another key consideration is the anticipated time from the first indication of a developing problem to the actual onset of failure. For instance, if the equipment is likely to fail in days or weeks, then an on-line surveillance system is the most cost effective approach. Surveillance systems have found widespread use for dangerous and inaccessible locations or for critical machine functions.

Continuous condition monitoring and remote diagnosis

A PC condition monitoring is a powerful driven hardware interface for monitoring system status in critical environments. The system directly accesses the condition of the electronic boards and systems, and delivers that data to equipment operators or to service technicians as user-defined text messages (GSM SMS), e-mails, or on-site visual signals. The potentiality of the continuous remote monitoring is such that can replaces some preventive maintenance by “repair on demand”, greatly reducing the costs of on-site troubleshooting service calls. Required hardware maintenance can frequently be diagnosed early and carried out during planned shutdown times. In addition, system availability increases, since most failures of monitored components can be detected in advance and thus prevented [36]. Some examples of measurable condition parameters are time, temperature, concentration of fluids, monitoring of processors, but also supply voltages and other physical parameters.

4.3 Condition monitoring systems to increase maintenance effectiveness

Traditionally, condition monitoring was a field requiring expert knowledge to interpret complex signals produced by machines to determine when mechanical failure will occur. Today, a sensor monitors machine condition, and the sensor itself analyses the data, removing the need for interpretation periodically by an expert technician. Vibration sensor can recognize a problem with a bearing right down to which rolling element is causing the problem, and is able to ignore any background noise that is occurring. Infrared Thermography is a diagnostic technique in which an infrared camera is used to measure temperature variations on the surface of the body, producing images that reveal sites of abnormal tissue growth. Tribology is the science and technology of interacting surfaces in relative motion. It includes the study and application of the principles of friction, lubrication, and wear. Any product where one material slides or rubs over another is affected by complex tribological interactions, whether lubricated or unlubricated as in high temperature sliding wear in which conventional lubricants cannot be used. Here below a list of condition monitoring techniques applied to different equipment components and functions:

MECHANICAL COMPONENTS

1. Infrared Thermography
2. Oil Analysis (Tribology)
3. Airborne and Structure-borne Ultrasonic
4. Vibration Analysis
5. On-line Motor Circuit Analysis

ELECTRICAL COMPONENTS

1. Infrared Thermography
2. Oil Analysis
3. Airborne and Structure-borne Ultrasonic

4. Vibration Analysis
5. Off-line Motor Circuit Analysis

STATIONARY ASSET
1. Infrared Thermography
2. Airborne and Structure-borne Ultrasonic
3. Pulse Echo Ultrasound
4. Magnetic Particle Testing
5. Penetrant Testing
6. Visual Inspection
7. Radiographic Testing
8. Eddy Current Testing.

Infrared thermography, vibration analysis, and tribology are now shortly examined to highlight the main features and benefits, and limitations from their use in predictive and preventive maintenance.

4.3.1 Infrared thermography (IR)

Infrared Thermography, thermal imaging, thermographic imaging, or thermal video, is a type of infrared imaging science. Thermographic cameras detect radiation in the infrared range of the electromagnetic spectrum (roughly 900–14.000 nanometres or 0,9–14 µm) and produce images of that radiation. Since infrared radiation is emitted by all objects based on their temperatures, according to the black body radiation law, thermography makes it possible to “see” one’s environment with or without visible illumination. The amount of radiation emitted by an object increases with temperature; therefore thermography allows one to see variations in temperature. When viewed by thermographic camera, warm objects stand out well against cooler backgrounds; humans and other warm-blooded animals become easily visible against the environment, day or night [37].

Electrical inspections can reveal some potential problems that usually go undetected until a serious breakdown occurs. At the same time, electricity leaks or not properly balanced loads increase electricity peak loads and, thus, may result to unnecessary charges. An IR inspection on electrical components can detect various problems in the electrical cabinet, like poor connections, short-circuits, overloads, load imbalances, as shown in Figure 31.

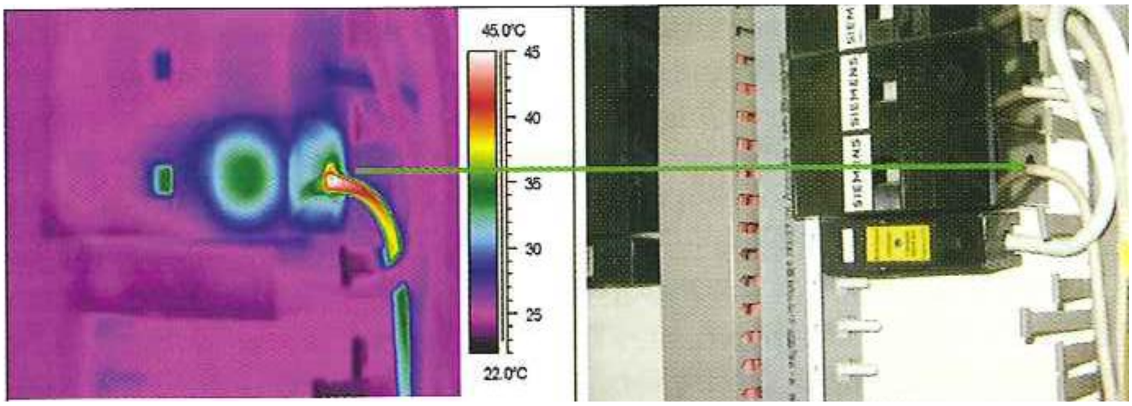


Figure 31: IR inspection shown high temperature on an electrical connection [37]

The figure shows a high-temperature difference on two main phase fuses (about 20°C above the left fuse). This is a result from an overload that has caused frequent failures. One of the main advantages of electrical inspections is that they are performed under full-load and real operating conditions. The inspection of even large electrical installations can be performed in a short amount of time, without interrupting service. Identifying the potential source of a problem can minimize workload and prevent costly failures. Focusing on specific components will significantly cut down the time required for a short building audit. Various issues on the definition of critical equipment parts are available, but can be found through HACCP and FMECA application. This system can also be used to set up an effective Electrical Preventive Maintenance (EPM) program.

Problems and limitations of infrared thermography

In general, the interpretation of IR thermographs from electrical inspections need to take into account that the problem identification involves by default some errors since the accuracy of the temperature measurement is not sufficiently high in order to determine the microscopic area of high resistance where the heat is generated. Consequently, the temperature at some specific locations may even reach the melting point. However, at a distance of even a few centimetres this may appear within the expected ranges. In addition, the evolution of the phenomena may alter the problem. For example, it is possible that a previous undetected problem may have caused local damages, which are not visible any more (i.e. possible melting may have caused rejoining of the contacts). This may result to a temporary temperature drop. The magnitude of the problem may be a more serious one that it appears when the operating conditions at the time of the inspection are not at full-load. Transformers are usually one of the most dependable elements of an electrical installation. However, they are vulnerable to heat related failures. Operating temperature rises over ambient of 65°C for oil filled and 150°C for air-cooled transformers are common. Above these temperatures, the internal insulation begins to fail very rapidly due to a breakdown in the insulation on the windings causing an electrical short.

The IR mechanical inspections can concentrate to critical equipment and components, and to rotating equipment. For example, to inspect pipes and ducts, to locate leaks from distribution networks (i.e. air ducts, pipes, boiler flue gas leaks), to check operating status of air supply inlets and outlets located at hard to reach places, and to verify proper operating conditions of rotating equipment. Pipe inspection can identify internally damaged sections, as a result of erosion that locally reduces wall thickness (i.e. especially in pipe elbows). Using IR thermography, it is possible to detect subsurface defects, with measurements under transient conditions. For example, to inspect a network of chilled or hot water pipes, the measurements are made when the main system starts its operation, that is when a thermal transient is generated inside the pipe as the water temperature is changing. Local pipe surface corrosion under insulation is another hidden problem that can be revealed with an IR inspection, before it grows to become a serious one. Corrosion is most severe in steel pipes at about 90°C (common conditions for most hot water heating systems in ALF industry). The problem is caused by the entrance of water (i.e. from water leakage, condensation) into the insulation that traps the water in contact with the metal surface. In this case, it is first necessary to inspect sections with damaged or deteriorated insulation. Although the inspector cannot see through the insulation material, the IR inspection can detect a temperature difference between dry and wet insulation and, thus, it is possible that there is corrosion under the wet insulation area.

4.3.2 Vibration analysis

Vibration refers to mechanical oscillations about an equilibrium point. The oscillations may be periodic such as the motion of a pendulum or random such as the movement of a tire on a gravel road. Vibration is occasionally “desirable”. More

often, vibration is undesirable, wasting energy and creating unwanted sound and noise. For example, the vibrational motions of engines, electric motors, or any mechanical device, like ball bearing, in operation, are typically unwanted. Such vibrations can be caused by imbalances in the rotating parts, uneven friction, the meshing of gear teeth, etc. Vibration is considered the best operating parameter to judge dynamic conditions such as balance (overall vibration), bearing defects (enveloping) and stress applied to components. Many machinery problems show themselves as excessive vibration. Rotor imbalance, misalignment, mechanical looseness, structural resonance, soft foundation, and gear mesh defects are some of the defects that can be measured by vibration. Measuring the “overall” vibration of a machine, a rotor in relation to a machine or the structure of a machine, and comparing the measurement to its normal value indicates the current health of the machine [38].
Different type of sensors are used to measures the vibration of a machine while it is operating. To know how to best monitor a machine’s condition requires one to know: which measurements to take, where and how to take them.

Types of defects detected by vibration analysis

The presence of a defect causes a significant increase in the vibration level. Bearing defects may be categorized as “distributed” or “local”. Distributed defects include surface roughness, waviness, misaligned races, and off-size rolling elements. The surface features are considered in terms of their wavelength compared with the Hertzian contact width of the rolling element raceway contacts. Surface features of wavelength of the order of the contact width or less are termed “roughness”, whereas longer-wavelength features are termed “waviness” [39]. Distributed defects are caused by manufacturing error, improper installation, or abrasive wear. The variation in contact force between rolling elements and raceways due to distributed defects results in an increased vibration level. The study of vibration response due to this category of defect is, therefore, important for quality inspection as well as condition monitoring. Localized defects include cracks, pits, and spalls on the rolling surfaces. The dominant mode of failure of rolling element bearings is spalling of the races or the rolling elements, caused when a fatigue crack begins below the surface of the metal and propagates towards the surface until a piece of metal breaks away to leave a small pit or spall.

Techniques used to measure vibration

Several techniques have been applied to measure and analyze the vibration response of bearings with localized defects. These techniques are not totally independent; rather, in many cases, they are complementary to one another.

Time-domain approach

The simplest approach in the time domain is to measure the overall root-mean-square (RMS) level and crest factor, i.e., the ratio of peak value to RMS value of acceleration. This method has been applied with limited success for the detection of localized defects. Some statistical parameters such as probability density and kurtosis have been proposed for bearing defect detection. The probability density of acceleration of a bearing in good condition has a Gaussian distribution, whereas a damaged bearing results in non-Gaussian distribution with dominant tails because of a relative increase in the number of high levels of acceleration.

Local defects can also be detected in the time domain by displaying the vibration signal on an oscilloscope or plotting it on a chart recorder and observing the presence of periodic peaks due to impact of the rolling element with the defects. Gustafsson and Tallian proposed a method of defect detection based on the number of peaks crossing a preset voltage level. Some band-pass filtering techniques have also been proposed in the time domain.

The shock pulse method

The shock pulse method, which works on this principle, uses a piezoelectric transducer having a resonant frequency based at 32 kHz (some instruments based on resonant frequency around 100 kHz have also been used). The shock pulse, caused by the impact in the bearing, initiates damped oscillations in the transducer, at its resonant frequency. Measurement of the maximum value of the damped transient gives an indication of the condition of rolling bearings. Low-frequency vibrations in the machine, generated by sources other than rolling bearings, are electronically filtered out.

Frequency-domain approach

Frequency-domain or spectral analysis of the vibration signal is perhaps the most widely used approach of bearing defect detection. The advent of modern Fast Fourier Transform (FFT) analyzers has made the job of obtaining narrowband spectra easier and more efficient. Both low- and high-frequency ranges of the vibration spectrum are of interest in assessing the condition of the bearing. The interaction of defects in rolling element bearings produces pulses of very short duration whenever the defect strikes or is struck owing to the rotational motion of the system. These pulses excite the natural frequencies of bearing elements and housing structures, resulting in an increase in the vibrational energy at these high frequencies. The resonant frequencies of the individual bearing elements can be calculated theoretically. It is difficult to estimate how these resonances are affected on assembly into a full bearing and mounting in housing [39].

Use of non-contact transducers

The literature discussed so far has mostly considered casing-mounted transducers, some researchers have also used non-contact type displacement or proximity transducers for condition monitoring of rolling element bearings. In these studies, the transducer senses the displacement of the outer race directly as the rolling elements pass under it. Thus, the extraneous vibrations of the housing structure are reduced or eliminated and the signal-to-noise ratio is improved. However, the installation of these probes is difficult as it not only involves drilling and tapping of the bearing housing but also fine adjustment of the gap between the probe and the outer race, which can change due to such conditions as vibration, dirt and thermal expansion.

4.3.3 Oil analysis (Tribology)

Tribology is the science and technology of interacting surfaces in relative motion. It includes the study and application of the principles of friction, lubrication, and wear.

Tribology plays an important role in manufacturing. A layer of lubricant, which eliminates surface contact, virtually, eliminates tool wear and decreases needed power by one third. Historically, Leonardo Da Vinci (1452-1519) was the first to enunciate two laws of friction. According to Da Vinci, the frictional resistance was the same for two different objects of the same weight but making contacts over different widths and lengths. The term became widely used following the Jost Report in 1966, in which huge sums of money were reported to have been lost in the UK annually due to the consequences of friction, wear, and corrosion. As a result, several national centres for tribology were created in the UK [40]. The tribological interactions of a solid surface's exposed face with interfacing materials and environment may result in loss of material from the surface. The process leading to loss of material is known as "wear". Major types of wear include:

- abrasion,
- adhesion (friction),
- erosion, and
- corrosion.

Wear can be minimized by modifying the surface properties of solids by one or more of "surface engineering" processes (also called surface finishing) or by use of lubricants (for frictional or adhesive wear).

Application of Dempster-Shafer (D-S) theory to oil monitoring

In order to solve the problem of diagnosing wear in tribosystem, evidence theory of Dampster-Shafer is applied to realize the information fusion of multi-parameter in oil monitoring. Two diesel engines model 8NVD-48A were monitored under running condition by the oil monitoring methods such as:

- spectrometric oil analysis,
- ferrographic monitoring,
- infrared spectrum analysis and
- oil quality testing.

According to the results from the monitoring experiment, the types of worn parts and the relevant monitoring characteristic are summarized [41]. The worn parts are mainly pointed to scoring, seizure and corrosion between piston (or piston ring) and cylinder liner; scratching, seizure, spalling and corrosion in gear; pitting, seizure and fatigue in gear.

Tribological failure types and their features

The monitoring experiment is conducted on two marine diesel engines that were mounted in a passenger ship. According to the monitoring results and some other monitoring examples of the same type engine, the wear types of parts and their features from oil monitoring are summarized and listed in Table 3.

Number	Parts Name	Failures Type	Information Characteristic from Different Oil Monitor			
			SOA	Ferrographic monitoring	Infrared*	Quality**
1	Piston & Cylinder Liner	Scoring	Abnormal in concentration of ferrous-element	Small cast iron cutting wear particle	Soot Increases	Benzene insoluble increases
		Seizure	Abnormal in concentration of both ferrous and nonferrous element	Cast iron and aluminum severe sliding wear particle with a rough surface		TAN increases
		Corrosion	Abnormal in concentration of ferrous-element	Corrosive wear debris	Sulfation increases	
2	Bearing	Scratching	Abnormal in concentration of nonferrous element;Silicon increase	Nonferrous cutting wear particles		Benzene insoluble increases
		Seizure	Abnormal in concentration of nonferrous element	Nonferrous metal wear particles with oxidation; Black oxides of iron	Oxidation increases	Viscosity increases
		Spalling	Abnormal in concentration of nonferrous element	Nonferrous metal fatigue particle		
		Corrosion	Abnormal in concentration of nonferrous element	Corrosive wear debris	Sulfation increases	TAN increases
3	Gear	Pitting	Abnormal in concentration of ferrous-element	Steel rubbing and fatigue wear particle		
		Scuffing	Abnormal in concentration of ferrous-element	Steel severe sliding wear particles with striations	Oxidation increases	Benzene insoluble increases

Table 3: Wear types on parts and information characteristics in oil monitoring [41]

For the tribosystem in diesel engine, wears of parts are the main tribological failure which include scoring, seizure and corrosion between piston and cylinder liner; scratching, seizure, spalling and corrosion in bearings; and pitting, scuffing and spalling in gear.

4.4 Sensors for continuous monitoring (CM)

In this section, some of the sensors used for continuous monitoring applied to the ALF industry are briefly presented to underline the importance of automatic monitoring as a tool to improve product safety and equipment reliability.

4.4.1 Conductivity sensor for cleaning in place (CIP) applications

In ALF industry, equipment cleaning represents a mandatory pre-requisite before equipment sterilization. The concentration of the fluids used to clean the product pipes need to be monitored and the conductivity sensor is the component for CIP (Cleaning-In-Place) applications to make sure that the quality of the fluid is within the specifications. This sensor provides the time and cost saving benefits of phase detection across all transmitted media, including aggressive cleaning agents (alkaline and acid solutions). It also guarantees transparency of the process at all times, plus protection against expensive errors in fluid handling. Nowadays a four-electrode technology gives an extended measuring range (0.1uS/cm to 500mS/cm) and this technology is particularly reliable since it eliminates the polarization phenomenon normally observed with two-electrode sensors.

4.4.2 Continuous monitoring of liquids

In ALF industry different liquids are used for different proposals:

- Hydrogen peroxide as sterilization medium to sterilize packaging material and piping surfaces in contact with food product
- Cooling water to cool down the sterile air through heating exchanger system and sealing systems
- Cleaning water to clean and rinse the product circuit after the production phase.

Continuous monitoring of these liquids allows the company to avoid manual checks depending on human factor, to increase equipment reliability and product safety through automatic control of critical parameters.

Continuous monitoring of liquid concentration

A new spectrophotometric technique allows the continuous monitoring of liquid concentration enabling to put under control the hydrogen peroxide, which is one of the most important process sterilization variables largely used to sterilize the packaging material in ALF industry. Inline spectroscopy also offers continuous monitoring of the concentration of liquids that consists of several components to ensure efficient process control. The mid-infrared spectrometer can directly be connected to the process to obtain reliable on-time liquid concentration measures that enable the equipment to activate corrective actions if the lowest concentration threshold is exceeded. These devices can efficiently be used to determines concentrations quickly and precisely and can even be used in hazardous area applications.

Water pH control

The pH of water, used in the ALF equipments, represents an important parameter to monitor to avoid problems with filters or mechanical parts. Corrosion of parts or cooling inefficiency, due to water residues, may depend on the quality of water and pH (acidity) measurement. A sensor for pH control allows the system to carry out a preventive detection of potential anomalies that can results in an equipment downtime. To overcome problems of pH control contamination, in the conventional pH monitoring systems, a solution using proportional hydroxide dosing and the implementation of Auto-Clean pH controller has recently been introduced. Sensors electrodes can be user-specified to ensure measurement reliability and maximum sensor lifetime.

Water treatment and bacteria measurement

The presence of some bacteria in the cooling water circuit can represent a real and critical problem to solve for some of the equipments used in food industry. A new method to monitor critical bacteria in the water is now available and this can be particularly useful in biotechnology and bioengineering. Researchers at Purdue University in the US verified a theory that copper is vital to the proper functioning of a key enzyme in the bacteria. This method senses minute changes in chemistry related to bacterial health and yields results immediately, unlike conventional technologies, which require laboratory analyses taking at least a day. This immediacy could make it possible to detect the bacterial load in the water and to alert the equipment operator through a suitable alarm signal.

4.4.3 Continuous monitoring of air quality through electronic nose

The measurement and estimation of human-related senses has become an established technique in sensor research, as well as in the practical design of measurement and control systems. The commercialization of the electronic nose began in 1993 as the concept became widely accepted as an effective instrument for detection and estimation of olfaction. Since extraneous elements, in the air of the ALF production room, could produce sensorial variations of the product packed or storage, these devices can be installed in different equipment or production areas to monitor the sensorial quality of the air. The general set-up of an electronic nose consists of an array of chemical sensors; an air flow system, which switches the reference air and the tested air; a signal analysis technique; and a presentation unit. To increase the complexity of the odours system, an array of mixed sensing principles is often designed, consisting of different types of sensor, in order to create differences in operating temperatures, flow conditions, and sensor response times [42]. This means that artificial human-related sensor systems could become the everyday tools for estimation of our own personal condition as well as that of the environment.

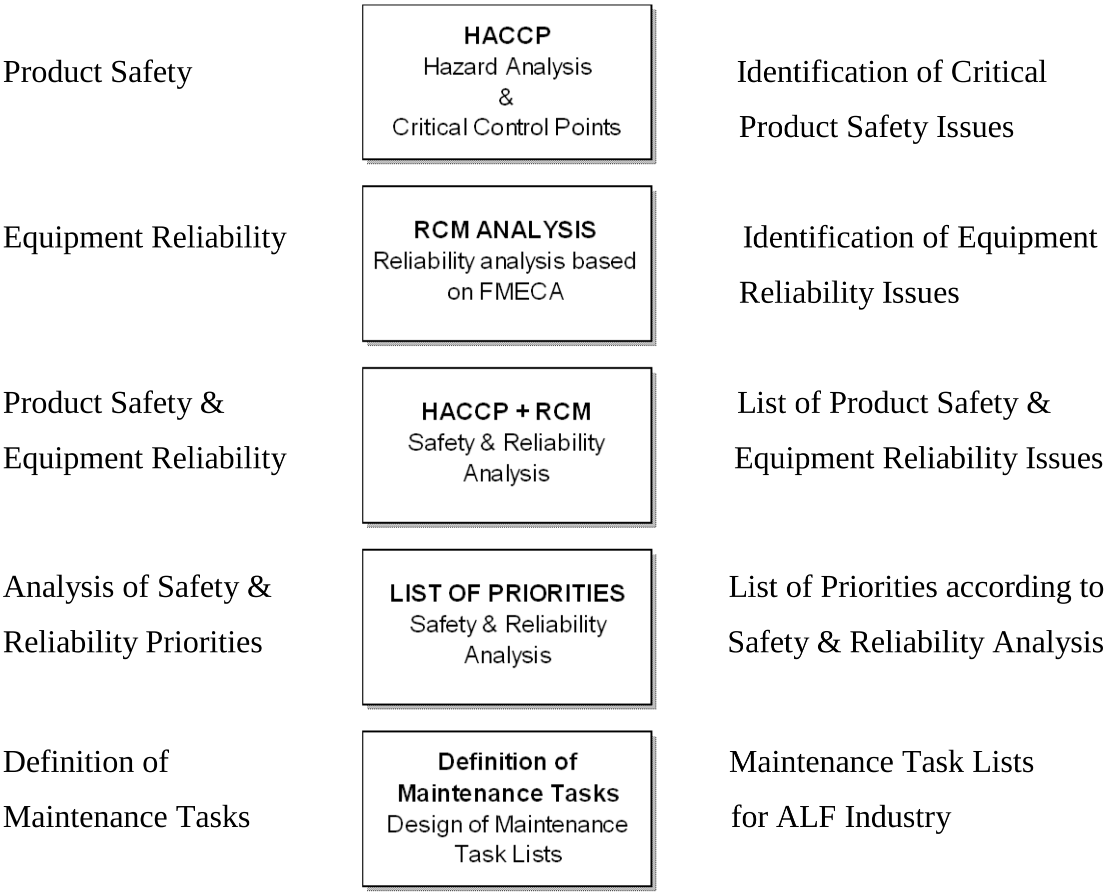
4.5 Conclusion

This chapter dealt with condition monitoring of critical machine variables to avoid component degradation and then equipment failure. Equipment critical functions can be monitored using different type of sensors to detect deterioration and avoid unplanned stoppages, and further damages. Some of the equipments used in the ALF industry, through specific sensors, automatically monitor critical parameters such as those linked with machine sterilization or package integrity. The automated production lines, in the food and beverage industry, normally make use of these sensors to monitor critical parameters both online or on request. Continuous condition monitoring and remote diagnosis systems have been presented to directly access the condition of critical functions and delivers data to equipment operators and to service technicians. Condition monitoring represents a reliable tool to monitor machine conditions, usually carried out on regular base, by expert technicians. The sensors used, monitor machine condition, analysing data and removing the need for periodical human inspection. Condition monitoring is changing manufacturing operations as maintenance is only needed once the condition monitoring sensor detects a variation linked with potential failure, whereas, in the past, routine maintenance was carried out whether machines were faulty condition or not. Infrared Thermography has been examined as a diagnostic tool to measure temperature variations on the surface of a body, producing images that reveal electrical and mechanical anomalies. Vibration sensor represented another important tool to recognize anomalies with mechanical components such as bearings in which the rolling element can cause problems. The analysis of these components in the past was completely manual and carried out by a vibration expert to examine details of the equipment regarding mechanical geometry and quality. Tribology was, at the end, examined as the science that studies the interaction of surfaces in relative motion. The study and application of the principles of friction, lubrication and wear is commonly applied in bearing design but it extends to any other product where one material slides or rubs over another and is affected by tribological interactions. To achieve the highest maintenance effectiveness, in some critical circumstances, thermography, vibration and tribology can be combined and integrated to make maintenance activity even more reliable.

5. THE PROCESS TO DESIGN MAINTENANCE PROCEDURES FOR ALF INDUSTRY

5.1 Introduction

In this chapter the different phases of the process identified to design maintenance procedures (task lists) for ALF industry are examined. The reliability concepts, the safety and the maintenance engineering techniques, presented in chapter three, have been compared and contrasted to identify the principles to be used in building up the design process. Hereafter the process blocks, highlighting the main maintenance design phases, are listed in sequential order.



This chapter examine the content of the maintenance process to design maintenance task lists for ALF packaging lines, the contribution of each phase is shortly described here below:

1) The first phase has been thought with the intention to identify and address all conceivable CCPs that could influence product quality and safety. The

application of safety methodologies such as HACCP and HAZOP can identify the existing equipment and process criticalities, to weight them to establish a list of priorities that have a direct impact on final product safety.

2) In the second phase the equipment reliability issues are deeply examined through the application of some maintenance engineering techniques to identify criticalities, belonging to equipment functions, and relative solutions.
3) The third phase addresses the need to highlight product safety and equipment reliability issues weighting both criticalities together in the same form. This phase contributes to link equipment reliability and product safety through the identification of global risk priority number which result from the analysis of quality and reliability risks.
4) In the fourth phase a list of priorities is properly developed according to the scoring resulting from previous analysis. This form represents a summary of the work done in the previous phases and is a document that list the items according to their criticality.
5) The fifth phase enables the design team to develop maintenance task lists able to control ALF criticalities dependent on product safety and equipment reliability.

As shown in Figure 32, the peculiarity of this process, compared to other processes used to design maintenance procedures for different industrial sectors, is its ability to link the end product quality together with equipment reliability issues to produce an outcome able to address every criticality of the ALF packaging line.

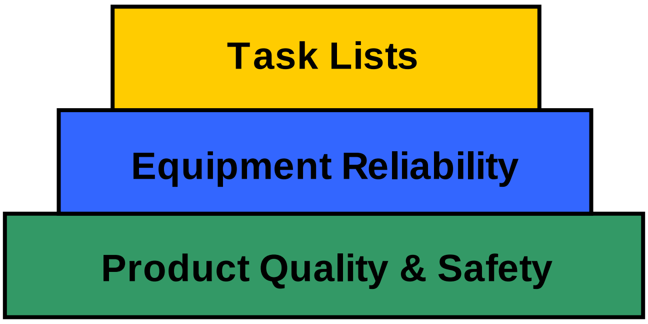


Figure 32: The maintenance design process goals

This process will strongly contribute to identify all critical process variables that have a negative impact on product safety, on equipment reliability and the maintenance solutions to put these criticalities under control.

5.2 Step one: application of HACCP methodology

As first step, through HACCP methodology, all critical machine parts and components (CCPs), that have a negative effects on product safety, are identified together with the risks associated to different failure modes. HACCP identifies and assess specific hazards, estimates risks and establishes control measures that emphasize product safety, though problem prevention and control, rather than reliance on end-product testing and traditional inspection methods. Machine parts or components, whose fault may produce biological, chemical or physical hazard, are examined to devise critical control limits and preventive maintenance countermeasures. As shown in Figure 33 below, at this design stage, all conceivable product safety hazards, coming from equipment operation and human behaviour must be identified, to ensure that:

- Equipment
- Human (operational) and
- External (service & utilities)

criticalities that have a direct impact on biological, chemical and physical modification of the product packed are listed and examined.

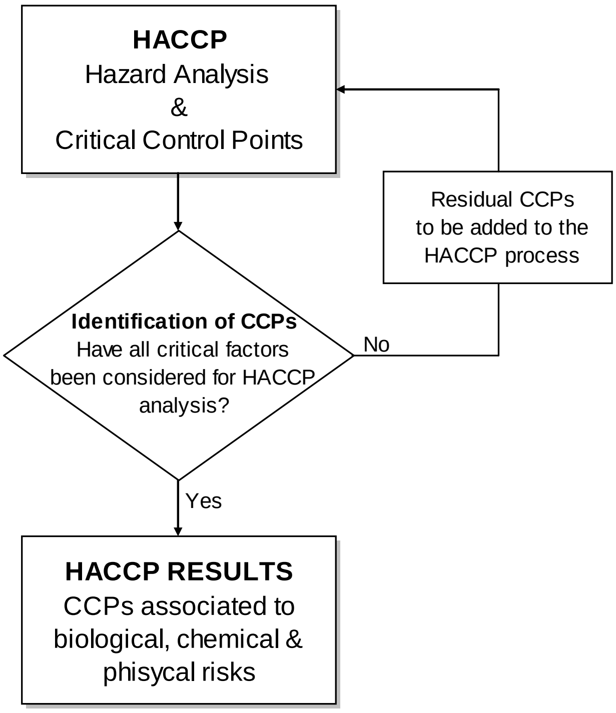


Figure 33: HACCP process blocks

To achieve this result, HACCP, HAZOP methodologies and GMP, suggested by ISO 22000 certification (Food Safety Management), have been analyzed to identify all critical equipment and operational conditions and the most effective way to manage all product safety risks. Despite HAZOP methodology is normally used to assure that catastrophic incidents (in chemical industry) will be avoided during the lifetime of a production line under review, it provides some useful guidelines to identify the operational situations or conditions where human error may occur. Our study will consider human errors mainly occurring during the operational phase (preparation, production and after production phases).

As first step, application of HACCP and HAZOP techniques will enable identification of the following critical issues:

- hazards, directly connected to the equipment/system/component functions
- identification of CCPs in the equipment operation
- critical limits for each CCP
- hazards in performing operational tasks
- preventive measures to carry out at every maintenance interval
- monitoring procedures or devices to detect loss of control at the CCP.

According to Figure 8, the development of a HACCP plan requires seven principal activities to be carried out by the HACCP team. These activities have to be applied to the process equipment and to operational tasks to identify CCPs and to establish adequate maintenance procedures. The seven principal activities are:

ACTIVITY 1

Conduct hazard analysis, on equipment functions and on operational tasks to identify hazards (biological, chemical and physical) and specify control measures

ACTIVITY 2

Identify critical control points (CCPs)

ACTIVITY 3

Establish critical limits at each CCP

ACTIVITY 4

Establish monitoring procedures or condition monitoring devices

ACTIVITY 5

Establish corrective action procedures

ACTIVITY 6

Establish verification procedures

ACTIVITY 7

Establish documentation procedures as appropriate.

Here below the HACCP activities are described with regard to the ALF environment.

ACTIVITY 1: Listing all hazards and considerations of any control measures to eliminate or minimize hazards depending on equipment functions and operational tasks

The hazards considered during this activity are the following:

- Biological hazards

It includes all potential sources of product contamination (direct and indirect) depending on equipment functions and operational tasks. This can include cleaning errors, depending on the equipment or human factors, lack of package integrity, wrong equipment settings, lack of preventive maintenance procedures and operator mistakes.

- Chemical hazards

It includes, among the others, cleaning compounds and sterilization agents.

Hydrogen peroxide, normally used to sterilize the packaging material, could come in contact with the food product if critical conditions of some components are not monitored and inspected through maintenance activities. Alkaline and acid solutions, used to clean the filling section of a filling machine, could come in contact with the food product that supplies other filling machines, if the seal of a valve is not working correctly.

- Physical hazards

It includes objects, such as metal fragments, glass, that can be found in the product packed, and that may cut the mouth, break teeth, or perforate the package. Since the filling section of filler is normally using a variable amount of moving parts, the analysis must consider all the critical components and operations to avoid that solid fragment (metals and plastics) could come in contact with the product packed.

The team involved in this activity, must consider all the conceivable sources of equipment and operational hazard, and list them under the three (biological, chemical and physical) main areas of risk.

ACTIVITY 2: Establishment of Critical Control Points

After all hazards have been identified, a CCP decision tree module is to be used to determine whether a CCP can be identified for the specific hazard. If a hazard has been identified for which no control measure exists, the machine part or component should be modified so that hazard is eliminated or reduced to acceptable or minimal levels. The module shown in chapter 3, Figure 8, is a HACCP decision tree normally used for establishing CCPs. If a CCP refers to an operational activity, carried out by the equipment operator, this have to be clearly described and specific hazards identified.

Critical operational practices need to be described without grey areas: adjustment, registrations, and mechanical settings must be verified and possibly monitored through automatic monitoring devices.

ACTIVITY 3: Establishment of critical limits for each CCP

Critical limits must be specified for each control measure at each CCP.

In some cases, more than one critical limit will be specified at a particular CCP. If a critical measure has a direct impact on other physical parameters, these need to be identified together with critical limits. It is recommendable that quantity variations are compared with target levels to ensure that critical limits are met. For critical operational pre/post-production or production practices that are directly linked to biological, chemical, and physical hazard, potential deviations need to be identified together with critical limits.

ACTIVITY 4: Establishment of monitoring system for each CCP

Monitoring is the periodic measurement or observation at a CCP to determine whether a critical limit or target level has been met. The monitoring procedure must be able to detect loss of control at the CCP. Automatic monitoring devices need to be used where a physical parameter under control can automatically be measured. To minimize the hazard, optical systems can also be used to monitor critical operational practices or physical conditions of critical equipment parts.

ACTIVITY 5: Establishment of corrective actions

Corrective actions are those actions that need to be taken either when monitoring results show that a CCP has deviated from its specific critical limit or target level or, preferably, when monitoring results indicate a trend toward loss of control. Corrective actions can either be referred to deviations regarding potential hazard or to loss of control at the specific CCP.

ACTIVITY 6: Establishment of verification procedures

Procedures for verification must be established to ensure that HACCP system is working correctly. Monitoring and auditing methods should be devised, for operational practices, to assess if criticalities, control measures and deviations are under control. Procedures, tests and analysis, can be used to assess if the activities designed fulfils the safety targets identified for each CCP.

ACTIVITY 7: Establishment of record-keeping and documentation

Adequate, accurate record-keeping and documentation are essential to the application of the HACCP system. Examples of records are: HACCP plan, CCP monitoring records; a file with deviations; preventive maintenance procedures, included in the check lists and check lists review.

Application of HACCP methodology represents a mandatory step in the maintenance design process, a basic tool to identify critical issues that may have a relevant impact on food product safety and quality.

5.3 Step two: application of reliability centered maintenance (RCM)

Basically, the outcome coming from the first step is the identification of criticalities associated to product safety and quality. After identification of CCPs (Biological, Chemical, and Physical risks) linked to the equipment parts and to operational practices, Reliability Centered Maintenance (RCM) has been used for the following reasons:

a) To make an analysis of the different failure modes and their effects on equipment operation: the application of Failure Mode Effect and Critical Analysis (FMECA) enable the identification of different priorities associated to different failure effects

b) Furthermore, RCM supply the right methodology to define the different maintenance approaches implemented through the task list content to effectively manage food product safety and equipment reliability issues.

As shown in Figure 34, RCM process should ensure that all types of failures and their effects are analyzed to design the most effective maintenance task for each failure type.

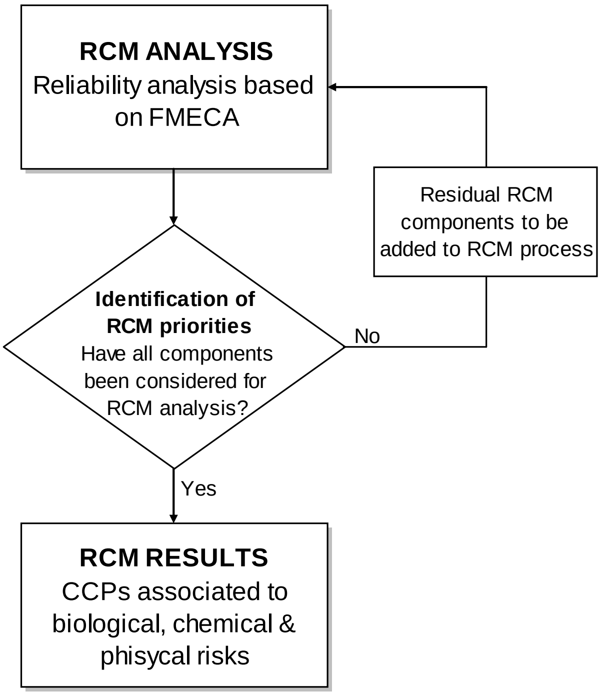


Figure 34: RCM process

In implementing an RCM design program, it is strongly recommended that one system at a time is taken under consideration. It is also important to choose a single system and take it all the way through each step of the RCM process before moving on the next. The customized approach chosen includes the following activities:

1. System selection
2. Boundary definition & Operational mode summary
3. Failure Analysis (quantitative & qualitative)
4. Functional and potential failure determination
5. Failure Modes and Effects Analysis (FMEA)
6. Maintenance history and technical documentation review
7. Task selection and frequency determination.

5.3.1 System selection

According to the results of HACCP analysis, safety and health issues should determine the priorities in the selection of equipment systems and sub-systems. The use of Failure Reporting, Analysis and Corrective Action Systems (FRACAS) technique can provide a framework for controlling corrective action processes and then to identify the priorities in choosing equipment systems and sub-systems. The FRACAS process may also be referred to as DRACAS (Data Reporting, Analysis, and Corrective Action System), or PRACA (Problem Reporting, Analysis, and Corrective Action System), as well as CA (Corrective Action) systems, and other acronyms. At its core, FRACAS is a comprehensive closed-loop corrective action system which can collect, quantify, and control a wide range of incoming failure reports, such as test data, breakdown and unsterility data, or repair data. Data coming from field experience should support HACCP analysis.

5.3.2 Boundary definition & operational mode summary

After identification of a machine system, as shown in Figure 35, groups and parts, directly linked to each sub-system, should be listed to define both components function and system boundaries.

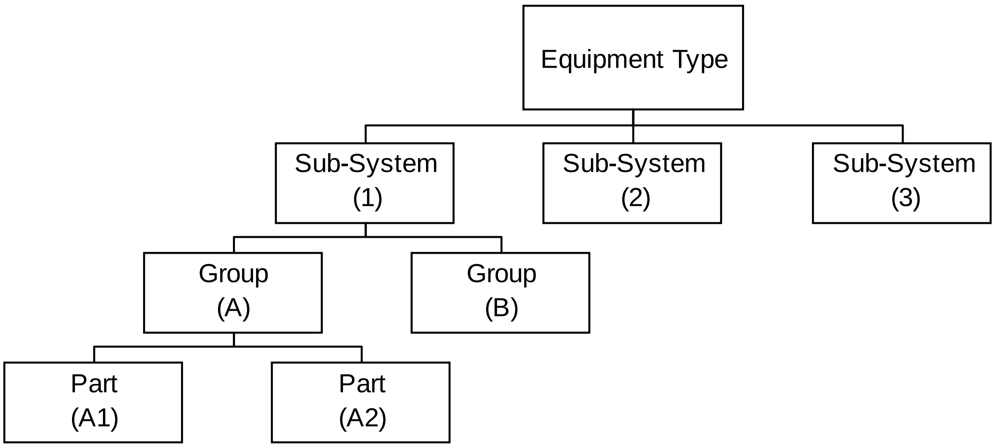


Figure 35: List of equipment sub-systems, groups, and parts

Looking at the equipment type as a simple process with a value-added transformation of inputs to produce some desired output will help determine the function.

Figure 36 shows a few examples referred to as an ALF filler.

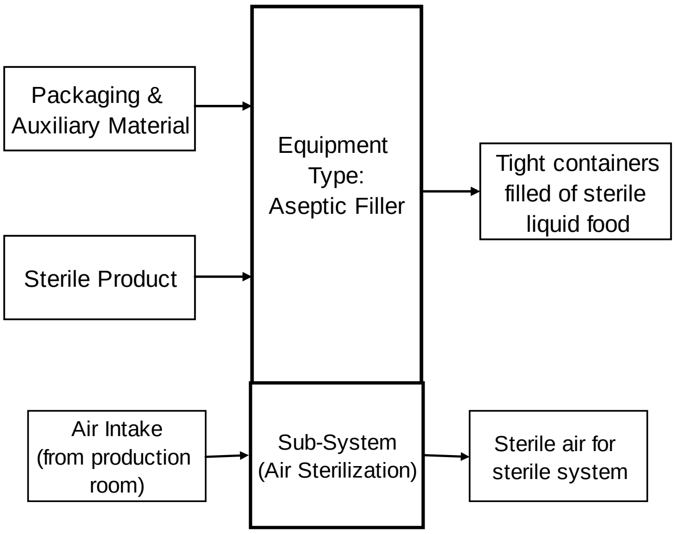


Figure 36: Transformation of inputs in outputs in an ALF filler

An operational mode summary is a description of the anticipated mix of ways the system will be used in carrying out its operational role. These data are used to establish the Reliability and Maintainability (R&M) characteristics of the system. In other words, it gives us a baseline to which our maintenance program must support.

5.3.3 Failure analysis

After system boundary definitions, this step has been introduced to identify the existing failures in the different equipment sub-systems.

- **Quantitative analysis of failures**

First, as we saw in chapter 3.4.3, the use of statistical analysis will permit a “quantitative analysis” to identify the different sources of variations existing in the equipment or in the production line. As shown in Figure 37, the different control limit thresholds used by SPC, can weight each failure type (Potential and Functional) and to define their probability of occurrence. Control Charts graphically highlight data points that do not fit the normal level of variation expected. It is standard that the Common Cause variation level is defined as +/- 3 Standard Deviations from the mean. This is also known as the Upper Control Limit (UCL) and Lower Control Limit (LCL) respectively and it is all based on probably figures.

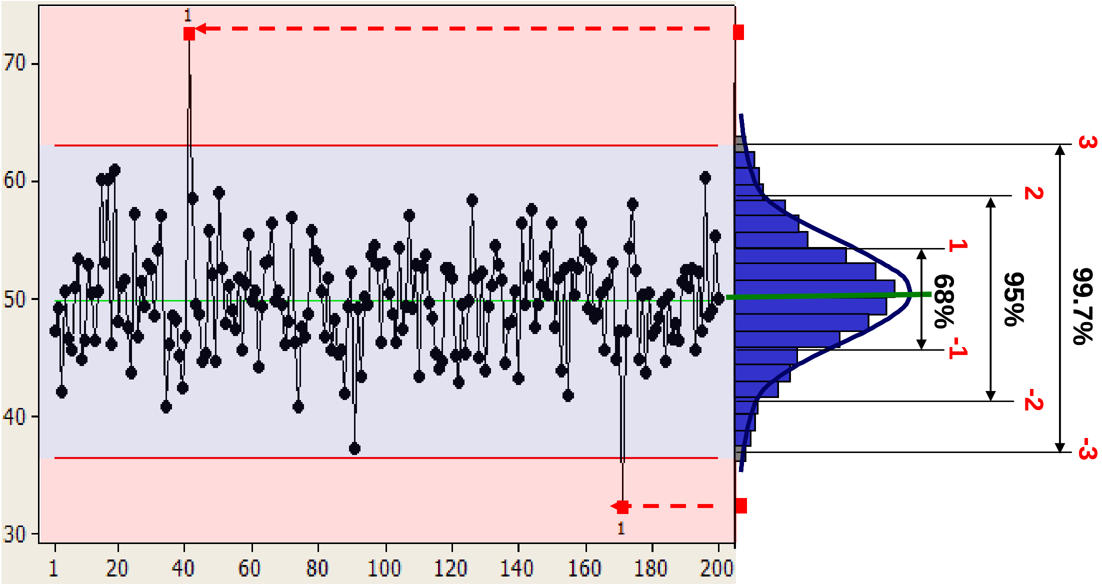


Figure 37: +/-3 Std.Dev. warning lines on SPC Control Chart

The use of SPC will provide two basic functions:

(1) Information on the performance of the process, tracking the events affecting the production line

(2) Information on special cause variations.

Since during the equipment operation we can experience both potential (P) and functional (F) failures, potential failures can be considered as variables monitored through condition monitoring, and functional failures as attributes that produce lack of equipment availability. Through SPC, variables are measured while attributes are counted. The Control Limits must be based on data coming from the past (historical figures) and depending on the sources of variation included in the subgroups, the control limits which detect the special cause variation will be affected. Normally we really want to have subgroups with only common cause variation, so if other sources of variation are detected, the sources will be easily found instead of buried within your definition of subgroups.

The use of warning lines, with lower and upper limits, and the action lines will provide a deeper knowledge about the causes that determine equipment stop and that produce potential and functional failures. The analysis of the information available normally shows variables (potential failures) and attributes (functional failures) to define the content of both: “inherent” variability of the process and the special causes that produce lack of equipment availability.

- **Qualitative analysis of failures**

As soon as the different types of failure have been identified, through statistical and historical analysis, and potential and functional failures been weighted, we are ready to proceed with a qualitative analysis of failures. The use of different quality tools will determine a clear understanding of:

- the links existing between causes and effects
- the reasons behind each cause
- the link existing between each cause and the global equipment and manufacturing context
- the logical order of the events that produce a failure.

First: Fault Tree and What's Different Analysis

The use of Fault Tree Analysis (FTA) establishes a connection between the different failure modes and a specific effect. The investigation to determine the underlying reasons for non-conformance to system requirements leads to the identification of non-conformance root causes necessary to define appropriate corrective actions. FTA is a graphical technique that identifies all potential failure causes. The fault tree starts with a top undesired event, which is the system failure mode for which one is attempting to identify all potential causes. The analysis then continues to sequentially develop all potential causes. The section 3.4.5 shows figures and symbols used by the fault tree technique.

After production of the tree that link potential failure causes to effects in a logical order, it becomes necessary to implement some supporting techniques to better identify the true failure causes. "What's Different" analysis is a simple technique that identifies changes that might have induced the failure. The basic premise of this analysis is that the system has been performing satisfactorily until the failure occurred; therefore, something must have changed to induce the failure. Potential changes include the analysis of all interacting factors such as:

- system design,
- manufacturing practices and processes,
- change of suppliers,
- change of equipment operators,
- quality change in the hardware lots, and
- some other factors.

As changes are identified they should be evaluated against the potential failure causes identified.

Second: Root Cause Analysis & Cause Mapping

The use of these two techniques ties problems to the global manufacturing organization context. Root Cause Analysis (RCA) is based on three fundamental questions:

- What's the problem?
- Why did it happen?
- What will be done to prevent it?

RCA starts from the result or from the symptom of the problem linking this to the underlying causes. Since starting an investigation with a single problem does not necessary reflect the global nature of a failure, cause mapping defines problems within the context of a manufacturing's overall goals. Looking at Figure 38, we see that the analysis breaks the problem down into its parts, analyzing a failure and breaking it down into specific cause-and-effect relationship.

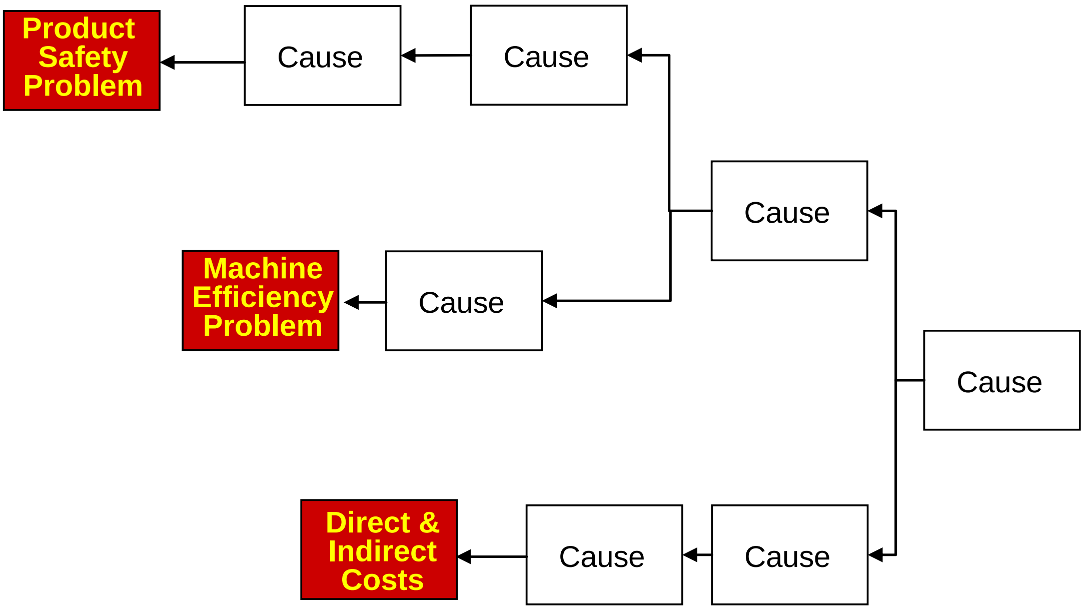


Figure 38: Cause Mapping applied to overall organization's goals

The Cause Map organizes the findings of any investigation visually into "effect" boxes on the left followed by a cause to its right. The cause, in turn, represents an effect of another cause, again placed to the right. For this reason, every box in a cause map can be viewed as both an effect and a cause at the same time. The fuel that drives the cause-map analysis involves “why” questions, which link together a chain of events.

Third: Ishikawa with his fishbone diagram

This technique helped visually to capture a problem and all possible causes. As we saw in Figure 15, the technique enables one to visually lay out the causes of a problem, grouping them under different root families: machines, methods, material, measurements, environment, people… Ishikawa begins with a problem and then identifies possible causes by separate categories that branch off like the bones of a fish. This complementary tool of RCA, defines one problem at a time and find causes enabling to gain a global picture of the causes grouped for categories. This technique does not show the cause and effect relationship in its dynamic evolution, as RCA does, but it creates a directory of causes behind each problem to display different causes split for families. Since, for instance, a training issue, grouped under “people”, can cause an operator to make an error that results in an equipment failure, grouped under “machinery”, details of any investigation must be sought linking Ishikawa to RCA. In conclusion Fault Tree Analysis starts with a top undesired event that is the system failure mode for which one is attempting to identify all potential causes, and link all potential causes in a logic tree through events and gates. Then Root Cause Analysis and Ishikawa enable one to identify the potential causes that produce a failure showing causes and effects and grouping them for families.

The Failure Funnel shown in Figure 39, represents the result produced by the key methods & technique (quantitative and qualitative) used.

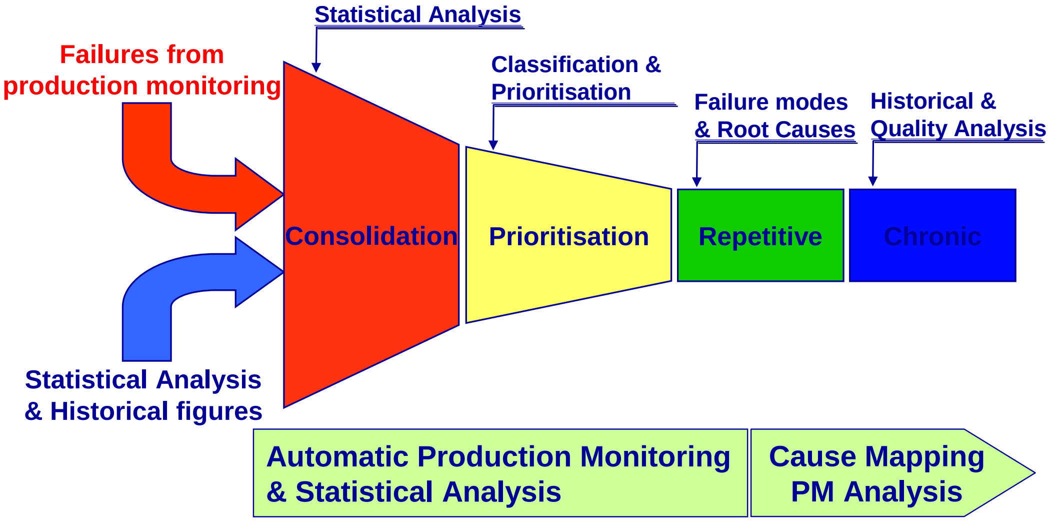


Figure 39: Failure Funnel

Through quantitative analysis we are able to identify and consolidate the different type of failures in a system. Through qualitative analysis we define the relationship existing between causes and effects, in the specific context, and then, as result, we are able to prioritize and classify the failures. The Table 4 below summarizes the repetitive and chronic failures showing their frequency, complexity and the potential causes with the main findings coming from quantitative and qualitative analysis.

	Repetitive		Chronic
Frequency	**High**	**Low**	**Low**
Complexity	**Low**		**High**
Cause	**• Mainly One Cause • Easy to Identify**		**• More than One Cause • Difficult to Identify**
	Known	**Sometimes Unknown**	**Unknown**
Tools	**Restore Basic Conditions & Stds**	**SPC, Ishikawa, FTA Cause Mapping**	**SPC, Historical Analysis & PM Analysis**

Table 4: Repetitive and chronic failures

5.3.4 Functional and potential failure determination

Once identification of failures has been accomplished, all potential failure causes are identified using the techniques presented in the previous section. These techniques help in converging on the causes of failure among many identified potential causes. Once the failure causes have been identified, the approach outlined herein develops a range of corrective actions and then selects and tracks optimum corrective action implementation. Because an unsatisfactory condition can range from the complete inability of an item to perform its intended function to some physical evidence that it will soon be unable to do so, failures must be further classified as either functional failures or potential failures.

- Functional failure

It is the inability of an item (or the system containing it) to meet a specified performance standard. This definition requires that we specify a performance standard, thus generating an identifiable and measurable condition for functional failures.

- Potential failure

It is an identifiable physical condition which indicates that a functional failure is imminent. The ability to identify a potential failure permits the maximum use of an item without suffering the consequences associated with a functional failure. In these circumstances items are removed or repaired/adjusted to prevent functional failures.

As an example, Figure 40 below shows how the operational condition of a ball bearing changes, from potential to functional failure, after potential failure is detected. From vibration deviation detection (potential failure threshold) down to total ball bearing breakdown (functional failure) there are different intermediate steps that need to be well known to define when a corrective action is to be implemented.

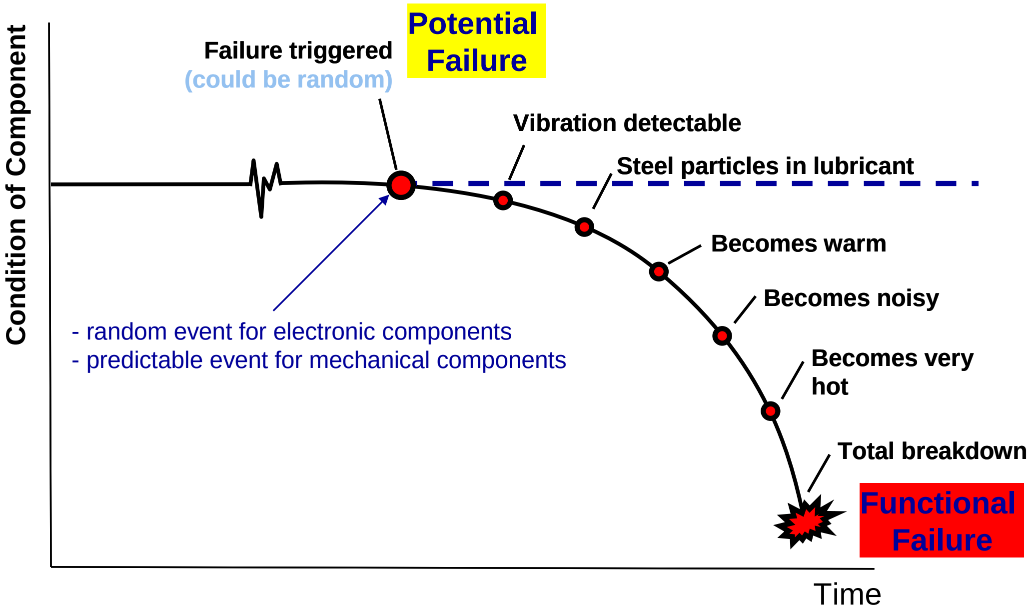


Figure 40: From potential to functional failure in a ball bearing

Prior to performing a FMEA analysis, the individual components, comprising the system, must be identified. Since there are so many possible failures a system can experience, it may be necessary to subdivide the system into manageable segments (components) in order to identify all possible failures. This process is known as a Work Breakdown Structure (WBS).

5.3.5 Failure mode and effect analysis (FMEA)

FMEA or FMECAs (Failure Mode Effects and Criticality Analyses) represent one of the most commonly used tools in reliability assessment programs. The basic components of a FMEA consist of some type of hierarchical breakdown, an outlining of all possible Failure Modes of all elements, and then a determination of the effects of these failure modes. The power in FMEAs is realized when this analysis is extended to include information relating to the risk of these potential system failures. The task is to be able to use a FMEA to assess which failure modes require effort to prevent, mitigate, detect, or ignore. This assessment of criticality in a FMEA lays the groundwork, for ALF industry, to develop an organized approach to risk management. By using FMEA to assign and categorize failure modes, the resulting categories can each have a defined plan of action. For example, high risk items, as those that may result in an unsterile container, must be flagged, and a plan to eliminate them formulated and deployed. Medium level items may require some type of detection mechanism to be designed. Low risk items could perhaps require no action. The issue then becomes how to adequately assess the risk levels of failure modes. Main approaches are based on:

1. Mode Criticality

Mode criticality is a numerical value that can be calculated and applied to each failure mode. Mode criticalities are based on a FMECA approach defined in MIL-STD-1629, a commonly used FMECA methodology.

2. Risk Priority Number (RPN)

Risk Priority Numbers or RPN are also numerical assessments of risk. RPNs are based on a FMEA such as those defined by SAE, AIAG, and Ford. RPN values range from 1 to 1000. To use RPNs, the analyst evaluates each failure mode and determines the Severity, Occurrence, and Detection level in each case. All three of these parameters are based on a 1-10 scale. A score of 10 indicates the most severe, most likely to occur, and least likely to be detected failure mode. The calculation of RPN is then defined as:

Risk Priority Number (RPN) = Severity x Occurrence x Detection

3. Criticality Rank

Criticality rank is an approach described in the SAE FMEA 5580 document. Criticality ranking provides a systematic way to rank failure modes. The criticality rank is a value based on a multi-criterion, Pareto ranking system. Failure modes are assessed by the analyst in terms of severity and probability of occurrence.

4. Risk Level

A risk level assessment technique is introduced in the book FMEA, Failure Modes & Effect Analysis, Predicting & Preventing Problems before they occur by Paul Palady (1997). This approach allows the analyst to group failure modes into established categories to ensure that the most critical items are evaluated. A graphical representation is used, where the X axis is a specified risk value such as severity. The Y axis is a secondary risk factor such as occurrence. The graph is broken into three distinct areas by lines that intersect both axes. By then graphing each failure mode, they will fall into one of the three graph areas: high, medium, or low. Figure 41 below shows a potential failure mode and effect analysis form used for this purpose.

Process FMEA-Potential Failure Modes and Effects Analysis

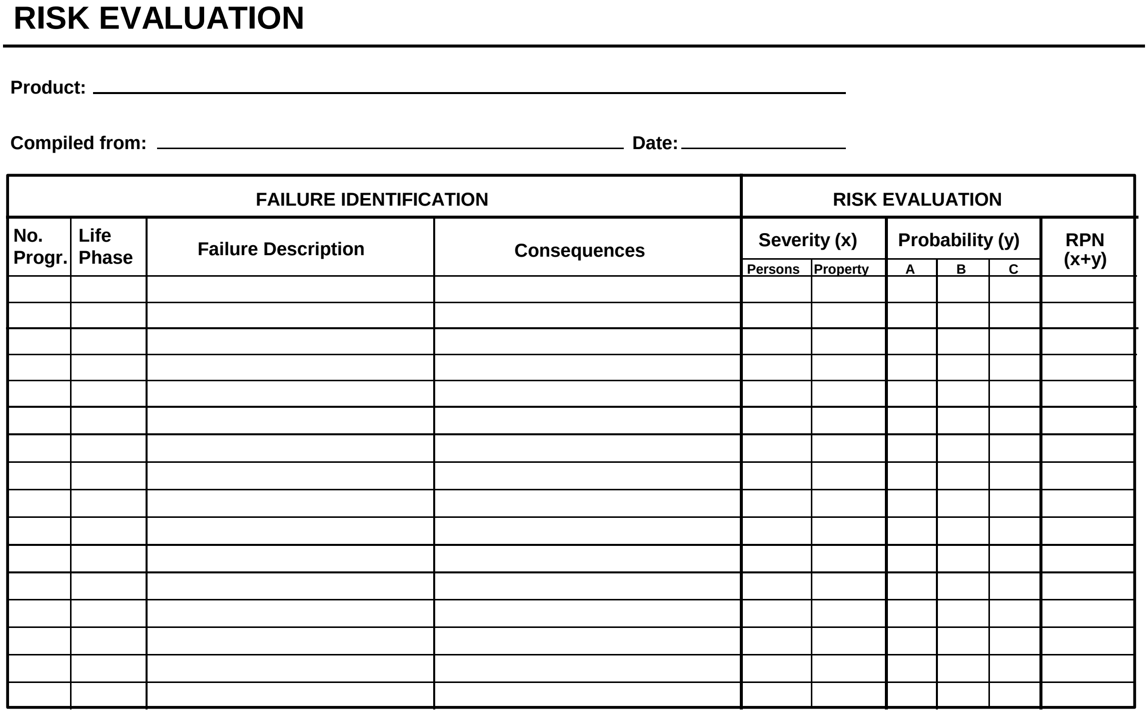
Part or Process Name/No	**Design/Manufacturing Resp.**	**Other Areas Involved**	**Suppliers & Plants Affected**
Homogenizer/Piston Head	Processing Department	Production , Maintenance	Production planning,Filling & Deliv.

Series No./Dev.Step	**Engineering Release Date**	**Prepared By**	**FMEA Date**	**Key Production Date**
20121-10215/010	10.02.95	Carlo Rossi	15.03.97	27.03.98

Process Descrip.	**Process Purpose**	**Potential Failure Mode**	**Potential Effects of Failure(s)**	**Seve rity**	**Potential Causes of Failure**	**Occur rence**	**Current Controls**	**Detec tion**	**RPN**	**Recomm. Action(s)**	**Area Individual Respons. & Completit. Date**	**ACTION RESULTS**				
												Actions taken	**Seve rity**	**Occur rence**	**Detec tion**	**RPN**
Mechan. treatm. of milk fat globules	Breaking of milk fat globules	Piston head breaking	No milk treatment leading to • bad milk quality • milk contamin.	7	• Mechanic. wear • Manufact. problems	4	Preventive actions to check: • teflon seal wear • mechanic. wear	2	56	Preventive checks: • teflon seal wear	Produc.dep. 5/4/98	Operator check every 250 work.hours	7	3	2	42
										• mechan. wear	Mainten. dep 6/4/98	Preven. maint. measur. added				
										• piston stroke	Mainten. dep 6/4/98					

Figure 41: Process FMEA form

The FMEA form identifies potential failures modes and assesses the potential customer effects of failures. As shown in Figure 42 below, this form develops a list of potential failure modes ranked according to their effect on the “producer” thus establishing a priority system for corrective action considerations.



RISK EVALUATION

Product: ____________________

Compiled from: ____________________ **Date:** __________

FAILURE IDENTIFICATION				RISK EVALUATION					
No. Progr.	Life Phase	Failure Description	Consequences	Severity (x)		Probability (y)			RPN (x+y)
				Persons	Property	A	B	C	

Figure 42: Example of a risk evaluation form [27]

Potential failure mode and effect analysis is a combination of different steps:

(a) Description of Failure mode (the manner by a failure is observed)

It describes the way the failure occurs and its impact on equipment operation. Each component has one or more failure modes and a separate analysis must be performed on each failure mode.

(b) Failure effect and Severity (the consequences)

This is the effect that a failure mode has on the operation, and on product produced. Criticality analysis is a procedure by which each potential failure mode is ranked according to the severity produced by the effects.

Severity is classified as:

- *Catastrophic*

A failure which may cause unsterility or equipment system loss

- *Critical*

A failure which may cause severe injury, major property damage, or major system damage which will result in operation loss

- *Marginal*

A failure which may cause minor injury, minor property damage, or minor system damage which will result in delay or loss of availability

- *Minor*

A failure is not serious enough to cause injury, property damage, or system damage, but which will result in unscheduled maintenance or repair.

(c) Probability of Failure Occurrence

Failure modes identified in the failure mode and effect analyses are assessed in terms of probability of occurrence when specific parts configuration or failure rates are not available. Individual failure mode probabilities of occurrence should be grouped into distinct, logically defined levels. They are:

-*Frequent*

High probability may be defined as a single failure mode probability greater than 0.20 of the overall probability of failure during the item operating time interval.

-*Reasonably Probable*

This is a moderate probability of occurrence during the item operating time interval. Reasonably probable is a single failure mode probability of occurrence which is more than 0.10 but less than or equal to 0.20 of the overall probability of failure during the item operating time.

-*Occasional*

This is a single failure mode probability of occurrence which is more than 0.01 but less than or equal to 0.1 of the overall probability of failure during the item operating time.

-*Remote*

An unlikely probability of occurrence of a single failure mode which is more than 0.001 but less than 0.01 of the overall probability of failure during the item operating time.

-*Extremely unlikely*

This is a failure whose probability of occurrence is essentially zero during item operating time interval (less than 0.001 of the overall probability of failure).

By combining the severity of the failure and the probability of occurrence, a matrix can be constructed which will indicate a priority of failure modes. During research and development, those failure modes possessing the highest priority should be redesigned if possible.

(d) Failure Detection

To assign detection rankings, the process or product related controls for each failure mode need to be identified and then assign a detection ranking to each control. Detection rankings evaluate the current process controls in place. A control can relate to the failure mode itself, the cause (or mechanism) of failure, or the effects of a failure mode. Controls can either prevent a failure mode or cause from occurring or detect a failure mode, cause of failure, or effect of failure after it has occurred.

The Detection ranking scale, like the Severity and Occurrence scales, is on a relative scale from 1 to 10.

Furthermore, the consequences that a failure mode had on operation or machine function must be analyzed. Then for each failure a critical analysis is to be done to identify a critical number that is derived by the failure severity, occurrence and detection classification. MTBF was a basic data element needed for RCM analysis. This number is derived by the following formula:

$$\frac{\text{Production Time}}{\text{Number of Equipment Stops}}$$

5.3.6 Review of maintenance history

The various steps of the RCM analysis require a variety of input data, like design data, operational data, and reliability data. In this step we examine the necessary reliability data input. Reliability data is necessary to define the criticality, to mathematically describe the failure process and to optimize the time between PM-tasks. Reliability data include a mean time between failures (MTBF), mean time to restore (MTTR), and failure rate function. As we saw, in many cases the failure rate will be an increasing function of time, indicating that the item is deteriorating. In other cases the failure rate may be decreasing, indicating that the item is improving. There are also cases where the failure rate is decreasing in one time interval and increasing in another. For repairable systems, the situation may be even more complex with a time dependent rate of occurrence of failures. The failure distributions (Gaussian, Weibull…) are rather flexible, and may be used for detailed modelling of specific failure mechanisms. However, for most applications the class of Weibull distributions is sufficiently flexible to be the preferred distribution. The operational and reliability data are collected from available operating experience and from external files where reliability information from systems with similar design and operating conditions may be found. The external information available should be considered carefully before it is used, because such information is generally available at a rather coarse level. In conclusion, this step is necessary to summarize:

- the equipment stops that have occurred,
- the causes
- MTBF and failure distribution.

From information gathered during the review of maintenance history and the results of the failure modes and effect analysis, a maintenance approach for each of the failure effects can be determined. The value of MTBF, the failure rate and its distribution will give us an idea of the reliability of the part. More specifically, we can:

1. Calculate the failure rate of each failure mode and decide whether a design review is desired on a developmental item, and
2. Decide when the part should be replaced if scheduled replacement is required.

Failure distribution or dispersion around the mean must be considered when deciding whether to replace or inspect the component at fixed intervals. Similarly problem, phenomenon or physical mechanism pursues the elimination of chronic failures through the following activities:

- problem definition
- physical analysis of the problem
- identify the likely causes of the problem
- equipment, materials and methods assessment
- develop techniques for analysis and inspection
- eliminate disturbing factors
- devise proposals and improvements.

5.3.7 Determine maintenance approach for each failure effect

There are four major maintenance components of the Reliability Centered Maintenance program, they are:

- Reactive Maintenance (Corrective Maintenance),
- Preventive Maintenance,
- Predictive Maintenance (Condition Monitoring), and
- Proactive Maintenance.

The RCM logic tree can be used as a guide to determine the maintenance tasks and to logically work through the tasks likely to be needed to develop RCM program. After creating a logic tree, four distinct types of maintenance tasks usually result in:

- **Time Directed Tasks (all preventive maintenance procedures)**
  This task is generally applied to failure modes that can be restored without the need to replace the part. Examples in this area include; re-machining, cleaning, flushing, sharpening, re-positioning, tightening and adjusting. Sometime preventive maintenance task can include calibration where this is done on a hard time basis.

- **Condition Directed Maintenance (preventive and CBM)**
  This task aimed at detecting the onset of failure or the potential failure. Often referred to as CBM or On-Condition Maintenance, the goal is to ensure that the occurrence of failure modes that have undesirable consequences are predicted so that they can be mitigated through planned activities.

- **Failure Finding**
  This task suggests replacing a physical component in order to restore its function. As with preventive restoration tasks, these are also hard time tasks. Common examples of tasks include greasing bearings, changing oil filters and oil (if done on a time basis), and routine light bulb replacement (often but not always).

- **Running To Failure (decision to run certain components to failure)**
  These are tasks that are done to detect whether an item has already failed so that action can be taken. These tasks are only used with items that have hidden functions. For example with protective devices such as circuit breakers, stand by pumps, switches on conveyor systems and High-high level switches. These tasks are only used within the four categories on the Hidden side of the RCM decision diagram and are not referred to in the four categories on the evident

side at all. Detective maintenance tasks include proof testing of critical instrumentation and the occasional running of stand by pumps. Although often associated with safety related failures this is not always the case. Within RCM it provides the last line of defence for routine maintenance when a failure mode cannot be predicted or prevented.

<u>RCM logic tree for task selection</u>

One of the most important things in defining an RCM task is the comprehension of the nature of failure, and the assignment of routine maintenance tasks. From the original RCM report we provided four basic routine maintenance tasks.

Task selection can be supported by the correct application of different “decision logic trees” which provide the pathway to identify the right maintenance approach for each failure pattern [8]. A simple decision logic tree, for task selection, shown in Figure 43, can be used to identify the criteria needed to apply condition monitoring and time directed task. This tool takes into consideration evident or hidden failures and consequences (effects) on product safety and on direct and indirect costs. As result it suggests different maintenance tasks according to potential failure effects.

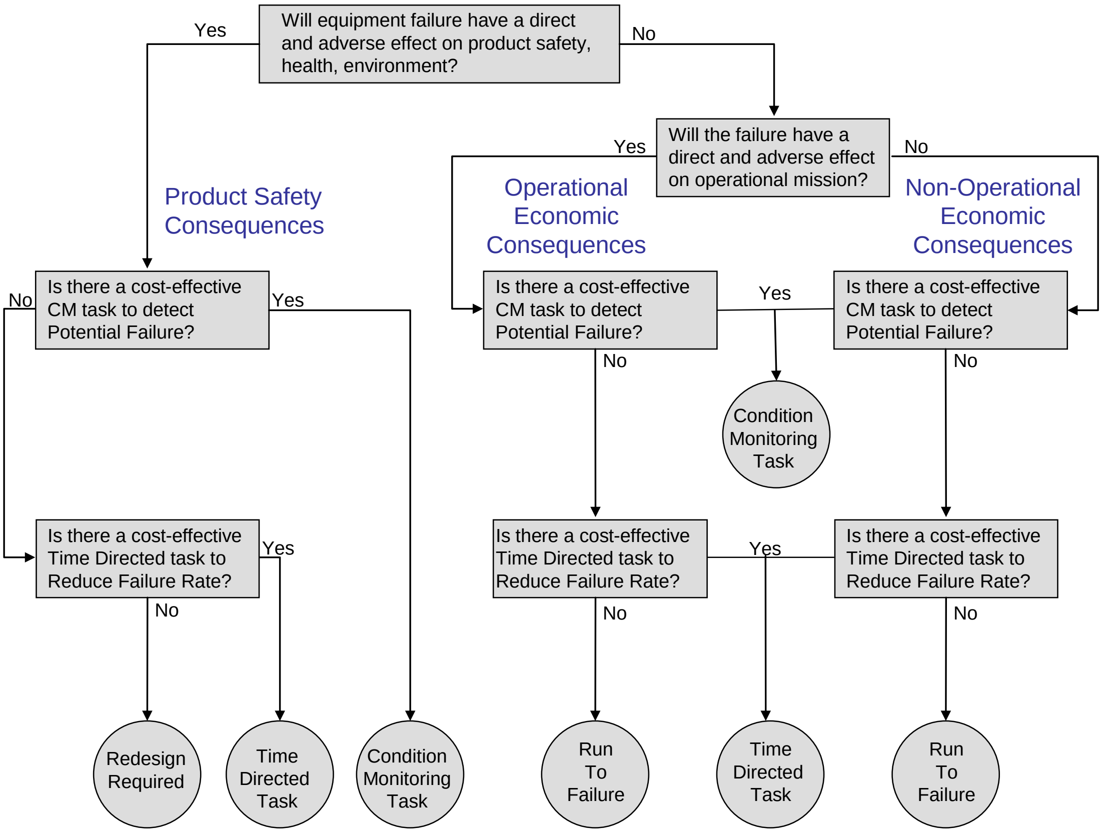


Figure 43: Decision logic tree for task selection

Determining the task interval

On-condition maintenance relies on capability to detect failures before they happen so that preventive maintenance can be initiated. Many failure modes exhibit signs of warning as they are about to occur. If, during an inspection, maintenance personnel can find evidence that the equipment is approaching the end of its life, then it may be possible to delay the failure, prevent it from happening or replace the part at the earliest convenience rather then allowing the failure to occur and possibly cause severe consequences. In this section the methodology to estimate the P (Potential) and F (Functional) interval or Failure Detection Threshold (FDT), which are two typical ways to describe the detectability of a failure, is introduced [43]. As shown in Figure 44, the time range between P and F, commonly called the P-F interval, is the window of opportunity during which an inspection can possibly detect the imminent failure and address it. P-F intervals can be measured in any unit associated with the exposure to the stress (running time, cycles, miles, etc). For example, if the P-F Interval is 200 days and the item will fail at 1000 days, the approaching failure begins to be detectable at 800 days.

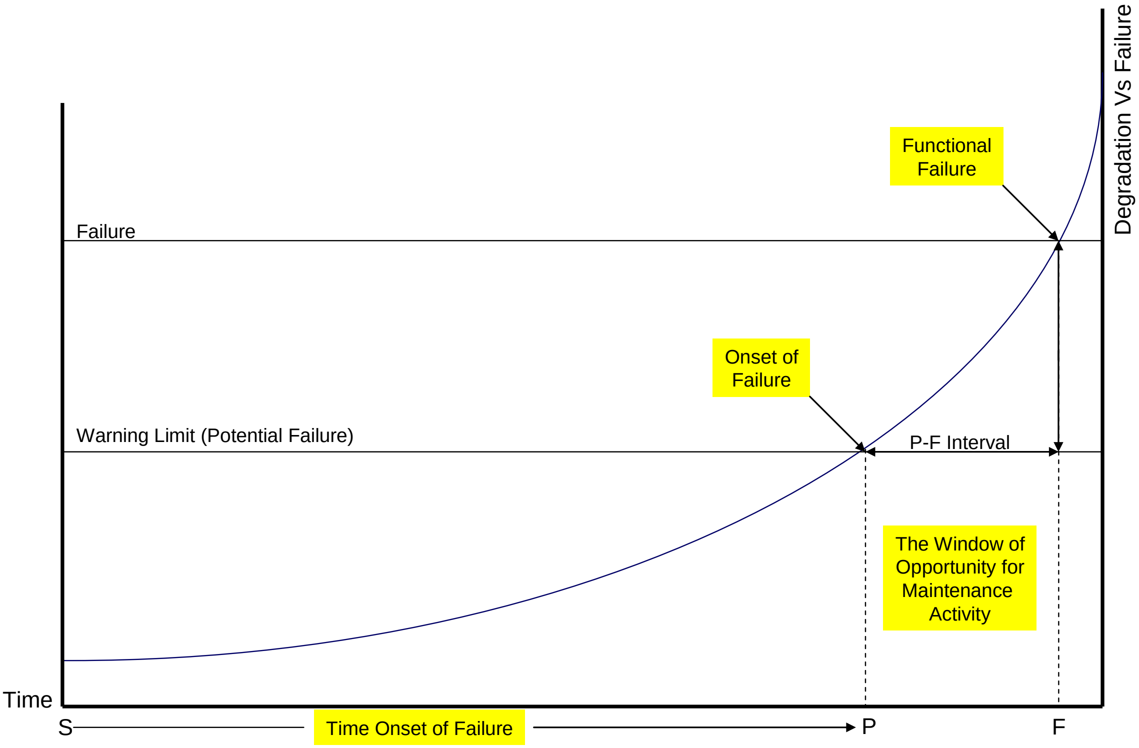


Figure 44: Degradation versus Failure (P-F curve)

In addition to P-F intervals, the indication of when the approaching failure will become detectable during inspections can be specified using a factor called the Failure

Detection Threshold (FDT). FDT is a number between 0 and 1 that indicates the percentage of an items life that must elapse before an approaching failure can be detected. For example, if the FDT is 0.9 and the item will fail at 1000 days, the approaching failure becomes detectable after 90% of the life has elapsed, which translates to 900 days in this case (0.9x1000=900). Estimation of the P-F interval or FDT can be achieved using condition monitoring, experience of people who design, manufacture and operate the equipment and through statistical analysis of historical figures. Note that estimation of P-F Interval or FDT should be done on one failure mode at a time. Many failure mechanisms can be directly linked to the degradation of a component or part. Weibull degradation analysis enables the analysis of degradation data. Degradation analysis involves the measurement of the degradation of performance/quality data that can be directly related to the presumed failure of the part under examination. Assuming such data can be obtained, the FDT or P-F Interval can be estimated using this technique.

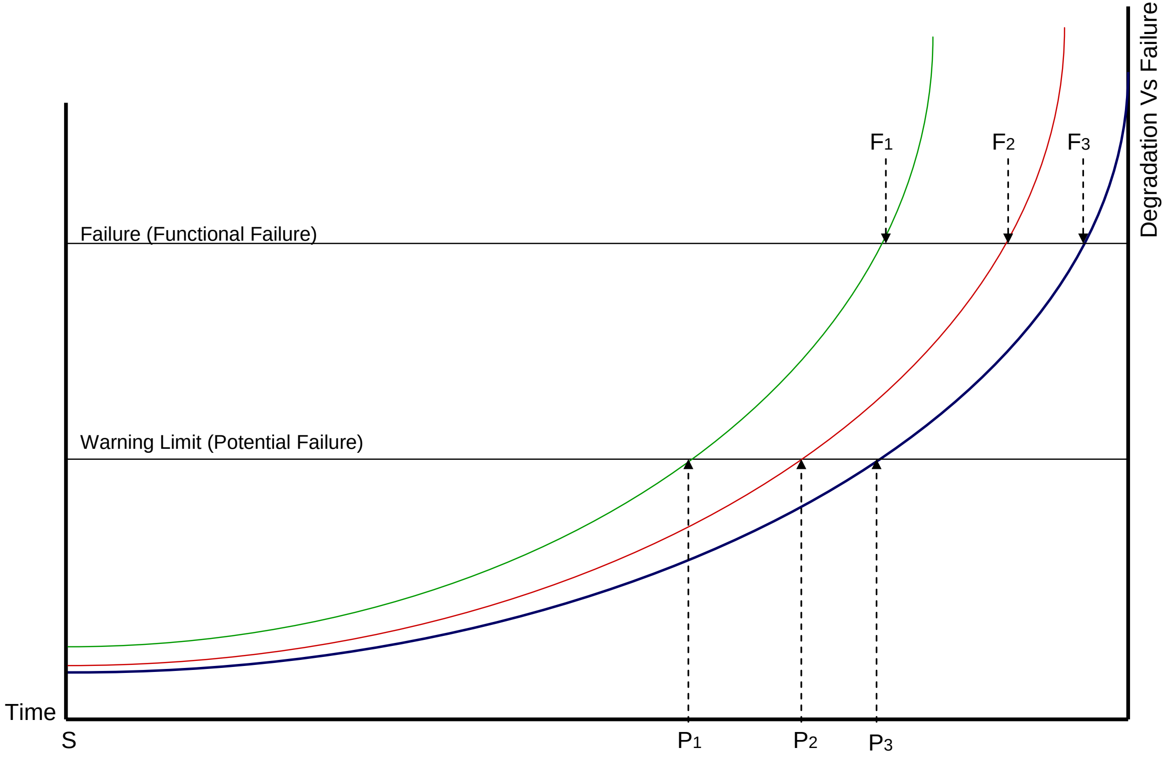


Figure 45: A plot of different degradations versus time

A plot of different degradations versus time, shown in Figure 45 above, enable to gain better knowledge of component or system degradation with relative P-F intervals.

In other words, if an inspection interval is based upon the time from potential failure to functional failure, a curve can be developed showing the time occurring from the onset of failure to functional failure. This time period is known as time from onset (Tos) that is the time at which potential failure is detectable. The beginning of Tos is the point on the slope at which a physical symptom (potential failure) appears. To assure that an inspection to detect impending failure will occur between the appearance of potential and functional failure, inspection intervals must be shorter than Tos.

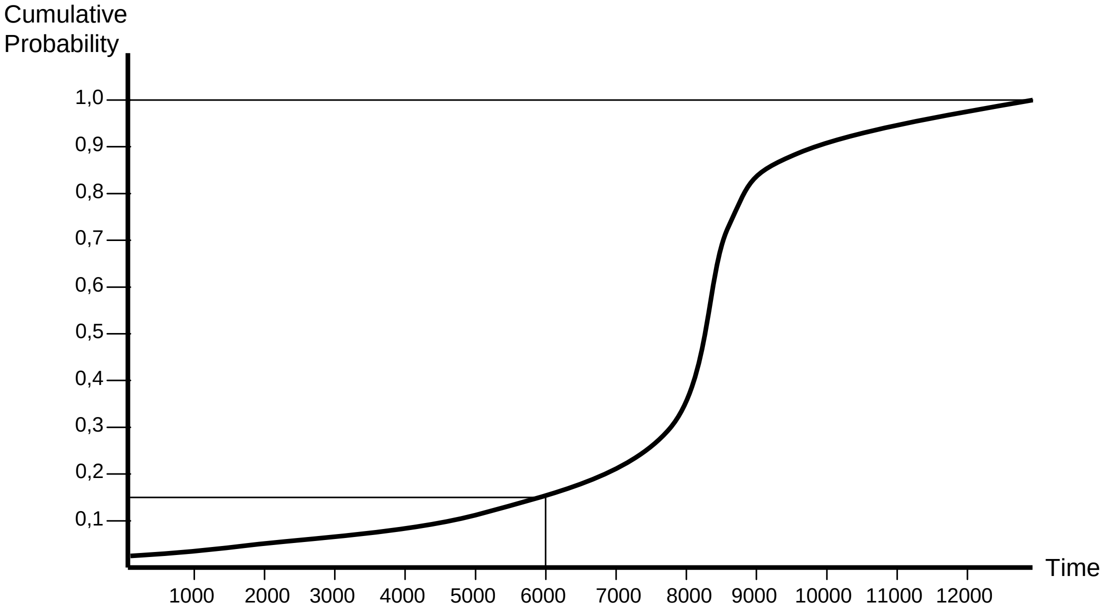


Figure 46: Inspection time interval

Since an inspection could fail to identify and correct the mechanical wear or symptom, there would be at least one more inspection before functional failure occurs. For critical machine parts or components (according to HACCP & reliability analysis), the inspection interval is to be established at 1/3 or 1/4 of Tos. Scheduling a replacement or overhaul task is an exercise based upon the curve shown in Figure 46 above, which indicates the cumulative probability of failure, for a specific component, at different lifetimes. In the example taken from the curve, the decision for replacement of a package sealing element occurs at 6,000 operating hours, where the probability of failure exceeds 0.15 (15%). This decision is mainly dependant on the evaluations of the effects produced by this critical components on product safety.. When historical data available shows that failures are evenly distributed around the mean, the MTBF could be used to schedule maintenance intervals. When failures occur in a narrow range, a normal failure distribution curve can be used for task scheduling. There have been many models, or combination of model, suggested to represent typical failure distributions, as described by the cumulative distribution function. Typical of those most frequently mentioned are the Exponential, Gamma, Erlang and Weibull distributions. After RCM application the team involved in the design process will be aware that any maintenance action, which does not improve the component's safety or reliability, should be eliminated.

5.4 Step three: safety & reliability analysis through HACCP & RCM

The design process started with the application of HACCP to identify the product safety critical issues, as a second step the application of RCM highlighted equipment reliability criticalities, now, at this point of the design process, HACCP and RCM techniques are combined together to carry out safety and reliability analysis. The purpose of this analysis is to identify the whole risk produced by the failure effects on product safety, on equipment reliability and then on production activity. The different risk priority numbers will give us the opportunity to weight the risks regarding total effects produced by a specific failure mode on:

- Final product (product safety problems),
- Equipment functions
- Production activity (interaction between equipment and packages).

This step has been thought for equipments or production lines operating in food industry where the analysis of risk could not be limited to the equipment reliability only, but needs to take into consideration all the conceivable critical factors associated to product safety.

Figure 47, in the next page, shows a form which combines both FMECA (Failure Modes Effect and Critical Analysis) with some of meaningful HACCP and HAZOP criteria and parameters. This form has been called FMEHA (Failure Mode Effect and Hazard Analysis) to display the integrated appraisal (measure) of product safety and equipment reliability criticalities. It provides a clear path, and opportunity to identify all conceivable problems depending on equipment and operational reliability, together with those depending on product safety hazards.

FMEHA - Failure Modes Effect and Hazard Analysis (FMECA + HACCP)

Part or Process name							Design/Manufacturing Resp.						Other Areas Involved			Suppliers & Plants Affected					
Series No./Dev.Step							Engineering Release Date						Prepared By			FMEHA Date					
Description of: (1) Part/Process (2) CCP (3) Operational Practice	Process Purpose	Identify the Potential Hazards: (B) Biological (C) Chemical (P) Physical	Critical Limits for each CCP	Deviations	Potential Failure Mode	Potential Effects of Failure(s)	Severity	Potential Causes of Failure	Occurrence	Current Controls	Existing monitoring procedures	Frequency	Detection	RPN	Recommended Action(s)	Area Individual Responsibility & Completion Date	Actions Taken	Severity	Occurrence	Detection	RPN

Figure 47: FMEHA form designed for food industry

The purpose of this form is to record both equipment reliability and product safety issues to highlight all the criticalities, to gain, as result, a global view and a total Risk Priority Number (RPN) based on CCP and critical reliability issues identified in the design process. Here below a short description of the fields that build up this form with the information to be supplied and the scoring criteria to be used to find a final risk priority number for each item. Starting from the left side, this is the list of the fields that make up the form:

- **Description of: (1) part/process, (2) CCP, (3) operational practice**
  This is the description of the equipment part, or the Critical Control Point or the operational practice that should be provided with reference to a specific critical reliability or safety issue.

- **Process purpose**
  Process Purpose refers to a description of an equipment or process function or to an operational function (e.g. air sterilization or package forming).

- **Identification of potential hazards: (B) biological, (C) chemical, (P) physical**
  The type of the hazard, depending on the specific failure, should be identified and this has to be classified in the three HACCP categories:
  (B) stands for Biological hazard
  (C) stands for Chemical hazard
  (P) stands for Physical hazard.

- **Critical limits for each CCP**
  For each CCP the critical limits must be identified (e.g. air sterilization temperature thresholds or dimensional measures for packaging sealing/appearance).

- **Deviations**
  For each CCP or operational practice, potential deviations must be identified (e.g. incorrect numerical values, wrong application of operational practices).

- **Potential failure mode**
  The lists of potential failure modes, regarding the item under investigation, highlight the different ways through which the equipment part or CCP fails.

- **Potential effects of failure(s)**

  The effects produced by each failure mode must be identified to gain a clear understanding of the criticality associated to that failure mode.

- **Severity**

  According to Table 5 shown below, the number selected represents the severity of each failure mode, regarding either equipment reliability or product safety. This table considers not only the equipment reliability failure effects, but also the HACCP failure effects on product safety.

SEVERITY			
Score No.	**Severity Classif.**	**Failure Severity Assessment Criteria**	**Potential HACCP effects**
1	I	No damages on product packed and on people. Customer will not realize any failure effect	
2-3	II	Failure effects are not serious: minor potential warnings are detected (noise, package appearance…)	Small package shape/appearance problems
4-6	III	Failure effects are serious enough. There could be safety problems on product and the event will be noted by the customer	Ther could be random problems on product safety
7-8	IV	Failure effects are serious. Production must be stopped	Package integrity and product safety problems (defect rate > 0,1/100)
9-10	V	Failure effects are very serious. Failure effects infringe national laws on product safety	Package integrity and product safety problems (defect rate > 1/100)

Table 5: Failure severity classification table

Compilation of the table will be supported by the historical information available through FRACAS and statistical analysis (quantitative and qualitative).

- **Potential causes of failure**

  All the conceivable potential causes that determine a failure mode should be identified under this box.

- **Occurrence**

  According to Table 6, the score numbers introduced in these fields identify the failure probability of occurrence. Also in this case, compilation of the table will be supported by the historical information available through FRACAS and statistical analysis (quantitative and qualitative).

OCCURRENCE

Score No.	Failure Probability	Probability Of Occurrence	Failure Occurrence Assessment Criteria
1	1/10.000	A	Remote probability of failure occurrence Unreasonable to expect failure to occurr
2	1/5.000	B	Low probability of failure
3	1/2.000	C	It is difficult to experience a failure event
4	1/1.000	D	Occasional failure rate
5	1/500	E	Moderate failure rate
6	1/200	F	Medium failure rate
7	1/100	G	High failure rate
8	1/50	H	Failure event is often observed
9	1/20	I	Very high probability of failure
10	1/10	L	Failure event happen very frequently

Table 6: Failure occurrence classification table [27]

- **Current controls**

  The existing controls, intended to avoid the specific failure mode, must be listed to identify the actual status of the preventive maintenance designed for this item.

- **Existing monitoring procedures**

  The different monitoring procedures or systems used to detect the potential failure must be listed in this field. Manual and automatic condition monitoring procedures in place should be listed to show the actual status of the monitoring activity for each failure mode.

- **Frequency**

  The monitoring frequency must be described for automatic and manual procedures.

- **Detection**

  Table 7, shows the failure detectability assessment criteria to be used to identify the specific score number for each failure mode.

  Compilation of this field must be preceded by a deeper analysis of historical information regarding the failure mode detectability.

DETECTION

Score No.	Failure Detectability Assessment Criteria
1	Failure will surely be detected
2-3	Failure will probably be detected
4-6	Failure could be detected
7-8	Failure will not probably be detected
9-10	Failure will rarely be detected

Table 7: Failure detection classification table [27]

- **Risk priority number (RPN)**

  This number is the result of the product of three scoring numbers:

  (a) Severity

  (b) Occurrence and

  (c) Detection.

  E.g. Severity (7), Occurrence (4), Detection (2), RPN (S x O x D) = 56.

- **Recommended action(s)**

  If the RPN obtained, to multiply severity, occurrence and detection, shows a number which call for a corrective action to improve the global equipment reliability and product safety, then a recommended action is needed. As shown in Figure 48 below, for each failure mode should be advisable to identify different RPN thresholds to highlight a number above which a corrective action is needed.

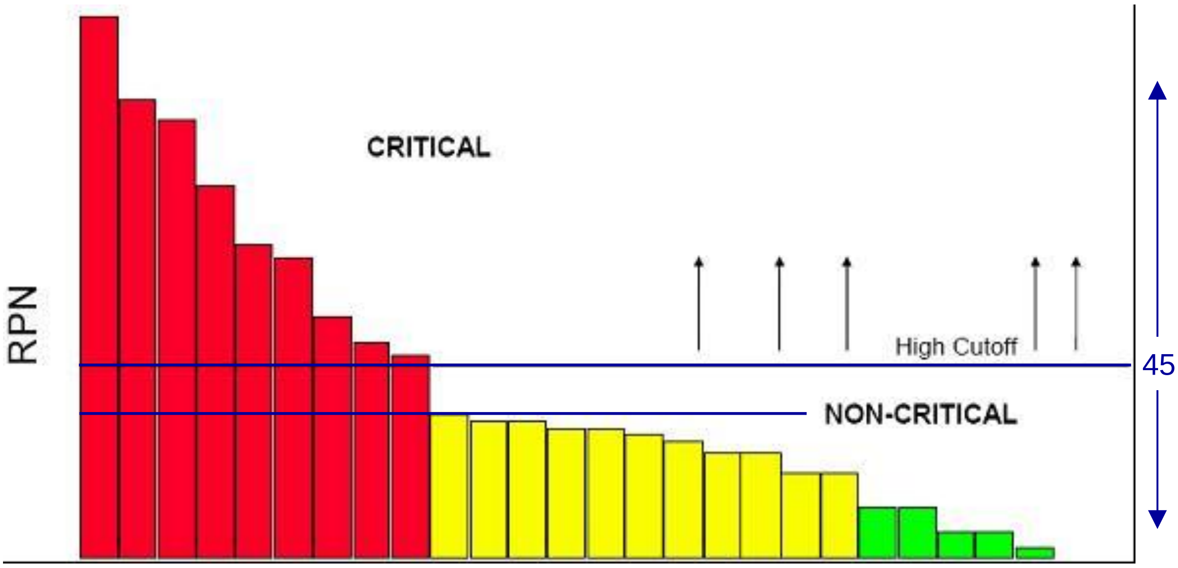


Figure 48: Example of RPN threshold

Recommended action normally means a preventive maintenance activity or an equipment or procedure modification able to reduce the total RPN to a level which shows that the specific failure mode is under control.

- **Area of individual responsibility & completion date**
  The person or role or department responsible to implement the recommended action is to be identified together with the completion date.

- **Actions taken**
  The specific practices linked to the recommended actions must be listed to deploy all the activities to be implemented.

- **Severity, occurrence, detection**
  The new score numbers will now reflects the improvement produced by the recommended actions and practices implemented as corrective actions.
- **RPN**
  Final RPN highlights if the corrective actions devised can reduce the first RPN which showed the problem and the need for a corrective action.

5.5 Step four: list of priorities (safety & reliability analysis)

As result of a combined analysis of product safety and equipment reliability issues, we now obtained a risk priority number which embody both HACCP and RCM criticalities. At this point of the design process we carry out the analysis of different failure modes effects, based on equipment reliability and on product safety, to produce a list of priorities based on RPN scoring.

List of Priorities (Safety and Reliability issues)

Equipment Name (System)						Design/Manufacturing Resp.		Sub-System		Areas Involved		
Series No./Dev.Step						Engineering Release Date		Prepared By		Date		
Part or Process Description	HACCP Hazard (B, C, P) & Reliability Risk	Severity	Occurrence	Detection	RPN	Potential Effects of Failure (to be kept under control)	Condition Monitoring Tools	Tools & Templates	Critical Limits or Warning Limits	Competence Level Required	Time/Cycle Interval	Maintenance Actions (Chk, Adj, Rep)

Figure 49: List of Safety & Reliability Priorities

The form shown in Figure 49 above, describes (from the left):

- the part or the process taken under consideration,
- the hazard type (B, C and P),
- the RPN found,
- the potential effects produced by that failure,
- the condition monitoring tools used
- the tools and templates available to carry out maintenance activities (objective tools for measurements)
- the critical or warning limits to be monitored or checked
- the competence level required (operator or technician, electrical, mechanical…)
- the time (working hours) interval or No. of cycles at which a maintenance need to be planned
- the maintenance action devised in the previous section.

Since through RCM analysis we already split the equipment/line or system into different sub-systems, groups, component functions and system boundaries, at this step of the design process, a list of priorities is to be defined for each sub-system. According to RPN scoring results, for each sub-system, the main maintenance priorities are defined to properly address the maintenance tasks intended to put under control the identified criticalities regarding product safety and equipment reliability. This activity will represent a sort of bridge between steps 3 and 5 to enable the designer to move forward in the design process and to display the criticalities in place within the different sub-systems defined in the equipment.

5.6 Step five: design of maintenance tasks

As result of the design activities carried out in the previous steps, we identified the functions that the equipment is intended to perform, the ways that it might fail to perform the intended functions and the evaluation of the consequences of these failures. The next step is to define the appropriate maintenance strategy for the equipment parts and components analyzed in the design process. The RCM guidelines include task selection logic diagrams based on the Failure Effect Categorization, this tool provides a structured framework for analyzing the functions and potential failure modes for the equipment parts under consideration in order to develop a scheduled maintenance plan that will provide an acceptable level of operability, with an acceptable level of risk, in an efficient and cost-effective manner. According to Figure 50, from the original RCM report, we are provided four basic routine maintenance tasks:

1. On Condition or Condition Based Maintenance task
2. Preventive or Scheduled Restoration
3. Preventive Replacement
4. Detective and Run to Failure Maintenance.

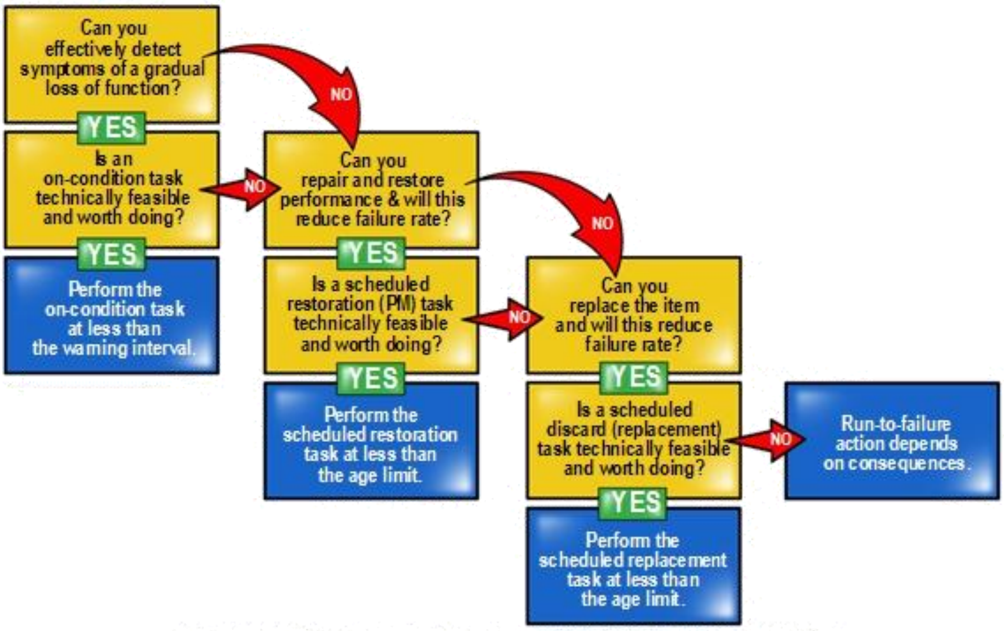


Figure 50: Decision Logic Tree [19]

- Predictive Maintenance

This task aimed at detecting the onset of failure or the potential failure. Often referred to as Condition Based Maintenance (CBM) or On-Condition Maintenance, the goal is to ensure that the occurrence of failure modes that have undesirable consequences are predicted so that they can be mitigated through planned activities. Where applicable, the use of on line and condition monitoring systems can detect the deviation of physical parameters (temperature, vibration, oil residues…) more effectively. Within RCM predictive maintenance tasks are the preferred option.

- Preventive Restoration

This is the task necessary to restore a machine original resistance to failure based on some measure of hard time, such as calendar hours, running hours, or litres pumped for example. This task is generally applied to failure modes that can be restored without the need to replace the asset. Examples in this area include: re-machining, cleaning, flushing, sharpening, re-positioning, tightening and adjusting. Often preventive restoration task can include calibration where this is done on a hard time basis. Within RCM these tasks are the second preferred option.

- Preventive Replacement

This task addresses the replacement of a physical part in order to restore its resistance to failure. As with preventive restoration tasks these are also hard time tasks. Common examples of preventive replacement tasks include greasing bearings, changing oil filters and oil (if done on a time basis), and routine light bulb replacement (often but not always). Of the standard routine tasks, preventive replacement is the least preferred within an RCM framework.

- Detective Maintenance or Run To Failure (RTF)

These are tasks that are done to detect whether an item has already failed so that action can be taken. These tasks are only used with items that have hidden functions. For example with protective devices such as circuit breakers, stand by pumps, micro-switches on conveyor systems and electrical switches. These tasks are only used within the four categories on the hidden side of the RCM decision diagram and are not referred to in the four categories on the evident side at all. Detective tasks include proof testing of critical instrumentation and the occasional running of stand by pumps. Although often associated with safety related failures this is not always the case. Within RCM it provides the last line of defence for routine maintenance when a failure mode cannot be predicted or prevented.

RCM provides the framework to define not only the four mentioned routine tasks, but also to define the three additional corrective tasks and calculate their expected frequencies. For example, in a predictive maintenance task the predictive task (PTive) is the task that we are going to apply at a given frequency in order to detect the onset of failure. However, there is also a corrective task: once we have predicted that a component or part is going to fail we need to plan, resource and execute a task to correct this situation [44]. This can be called the Predicted Task (PTed).

Within the time based tasks there is only one task, that of Preventive Restoration or that of Preventive replacement. However, in Detective Maintenance (DTive) tasks there are also corrective actions. Once we have determined that a detective maintenance task is required, RCM enables us to derive a frequency based on managing the risk of a multiple failure to a tolerable level. The Detective task is then performed on a routine basis to detect whether an asset has failed or whether it is still working. Regardless of whether the part under consideration is a switch, a circuit breaker, a sensor or a stand by pump, at some point we will detect that the asset has failed. This means that at some point there will be a corrective task, the Detected Maintenance task, which will normally be a replacement or repair of the failed asset. As with the Predictive Maintenance task we have allowed this to happen because it is the best failure management policy available to us and we are able to manage the consequences of the corrective task.

The last of the corrective tasks that we can derive from a standard RCM analysis is that of Run-to-Failure. In this failure management policy we have eliminated the likelihood of either safety or environmental consequences and have determined that the most cost effective strategy is to allow the component to fail. Any other action would cost more to carry out than to maintain the component itself. In this case the only task that we need to consider is the Run-to-Failure task itself which is obviously a corrective action.

Once a comprehensive RCM analysis is completed for an equipment-system, it can include up to seven planned tasks. Four are routine tasks, three are corrective tasks, but all are proactive tasks. All are the result of careful decision making regarding maintenance policy and strategy. This allows us to build what is known as a Proactive Whole-of-Life Model. To summarize the tasks describe above are:

- Predictive Maintenance - Routine
- Predicted Maintenance - Corrective
- Preventive Restoration - Routine
- Preventive Replacement - Routine
- Detective Maintenance - Routine
- Detected Maintenance - Corrective
- Run-to-Failure (RTF) – Corrective.

The whole of life cycle model is produced through calculating the resource burden of each individual task, then calculating this by the frequency of the task until the end of life event or threshold tine period. In the case of the routine tasks, because of support of statistical analysis and historical figures, we can be pretty sure that our estimates are correct. However in case of the corrective tasks these are often estimates based either on manufacturer’s data, our own maintenance history records and the experience of the people involved in the analysis. As time goes on we need to continue to collect data that will enable us to carry out further quantitative and qualitative analysis to become more accurate in our predictions.

5.7 Conclusion

In this chapter, the process used to design maintenance procedures for ALF industry has been examined. This research presents an original design process, conceived by the writer, which combine reliability concepts, safety and maintenance engineering techniques, to effectively manage product safety and equipment reliability issues. The reliability concepts, the safety and the maintenance engineering techniques found in the literature, and analyzed in chapter three, have been compared and contrasted and selected to identify:

(a) The process to design maintenance procedures and

(b) The techniques to be used in the design process.

Here below the contents of the maintenance design process and the benefits coming from each design step are briefly summarized:

Step one: application of HACCP methodology to manage product safety criticalities

The decision to start with this phase is based on the necessity to identify and address all conceivable Critical Control Points that could play a fundamental role in determining the final product safety. Through the seven HACCP steps, all critical machine parts have been identified (CCPs) and the use of HAZOP and GMP, suggested by ISO 22000, can highlight both critical areas depending on human errors and from production practices (GMPs). The main outcome of this phase is the identification of critical issues (equipment parts, human errors and production practices) that may influence the final product safety under biological, chemical and physical point of view. This step represents an original contribution to the maintenance design process since it addresses the critical practices and the equipment parts that can produce product safety hazards.

Step two: application of maintenance engineering techniques to manage equipment reliability criticalities

RCM is the basic maintenance engineering technique used to carry out the analysis of different failure modes and their effects on equipment or line operation. Starting from selection of system and sub-systems and definition of boundaries and the operational modes, equipment failures have been analyzed under quantitative and qualitative point of view. The use of statistical tools can identify and quantify the various types of failures, their distribution and component/part life time.

Qualitative tools like Fault Tree Analysis, Root Cause Analysis, Ishikawa, tied problems to the global context to identify the categories of causes and linking them to the effects produced on equipment and production activity. Potential and Functional failures have been identified to carry out Failure Mode Effect and Criticality Analysis (FMECA). The effects produced by each failure mode have been scored together with corrective and preventive measures. Failure rate and distribution, MTBF and historical information can, in the end, define the most convenient and effective maintenance task to be implemented for each failure mode. Some of the most important maintenance engineering techniques have been integrated in a new and original pattern to define a process able to cope with equipment reliability criticalities.

Step three: safety & reliability analysis to manage product safety and equipment reliability criticalities

At this point of the design process, HACCP (product safety criticalities) and RCM (equipment reliability criticalities) techniques have been put together for a global evaluation which identifies a Risk Priority Number that embodies both product safety and equipment reliability issues. A new and original Failure Mode Effect and Hazard Analysis (FMEHA) form has been devised to display all the criticalities examined in the previous design steps. This form satisfy the necessities to integrate product quality and safety with equipment reliability issues to gain, as result, a global scoring system which is appropriate to the Aseptic Liquid Food industry environment.

Step four: list of priorities (safety & reliability analysis)

This step have been conceived to produce a list of priorities based on RPN scoring which highlight the global criticality due to the effects produced by the different failure modes found during safety and reliability analysis. A form designed for this scope summarizes the key factors and parameters that led to the final RPN, the critical issues with limits and suggests the necessary maintenance activities. This activity, carried out for each equipment sub-system, represents a process rationalization which guide to the execution of next design step more effectively.

Step five: design of maintenance tasks

As result of the design activities carried out in the previous steps we now have all the information necessary to design the maintenance tasks to be implemented for each failure mode found. Predictive, preventive, detective and corrective maintenance tasks have been identified to increase resistance to failure and reduce, as much as possible, product safety risks and equipment failure probability. Routine tasks have been designed to prevent functional failure; corrective tasks are designed to manage hidden or unknown failures and to restore the equipment in the shortest time possible. The content of the tasks can be further improved through a continuous improvement activity based on collection of historical figures. Product safety hazards and equipment reliability criticalities need to be continuously investigated, through quantitative and qualitative analysis, to update and upgrade the effectiveness of the maintenance task lists designed through this process.

Figure 51 below summarizes the described process steps to design maintenance procedures.

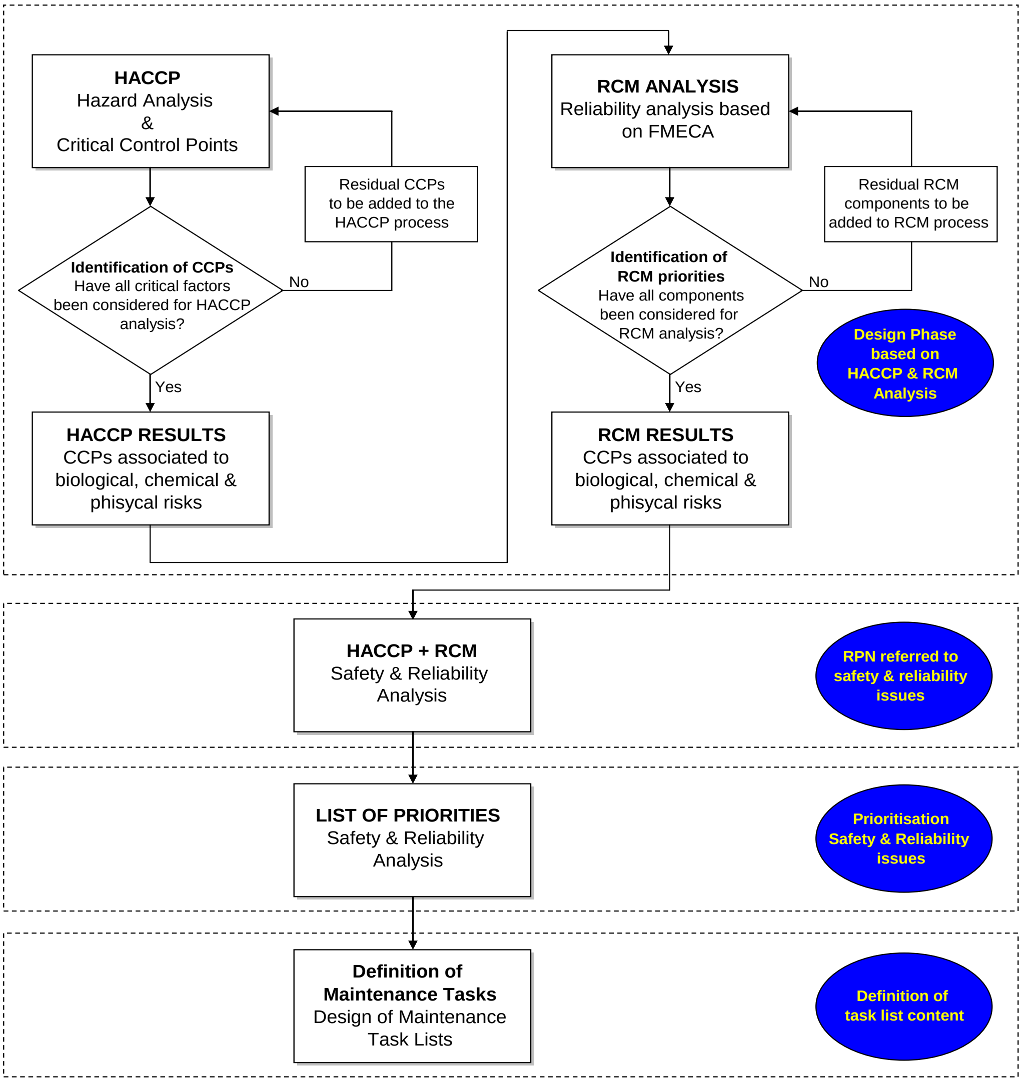


Figure 51: The process to design maintenance tasks for ALF packaging

6. THE PROPOSALS FOR AN IMPLEMENTATION MODEL FOR MAINTENANCE PROCEDURES

6.1 Introduction

The design activity could partially or totally be ineffective, during the implementation phase, if roles and responsibilities are not well defined according to specific needs and criticalities. The implementation model should address and answer to important questions like:

(a) Who is committed to carry out a specific maintenance task?
(b) When a specific task is to be implemented?
(c) How to perform the tasks and overcome the complexities?
(d) What are the critical elements which can reduce maintenance effectiveness?
(e) What are the KPI to be used to monitor maintenance implementation effectiveness?

Here below the main questions are properly addressed to find out, as result, the proposals for an implementation model able to maximize the outcomes and the benefits produced by the design process. This chapter presents the result of the writer’s own research intended to identify the problems existing in the ALF packaging and the solutions proposed to implement maintenance tasks effectively. The effort spent to design maintenance procedures, the results obtained in the design phase, with the production of reliable task lists, needs now to find its continuity through proposals which effectively address and solve technical and cultural problems during maintenance tasks implementation.

6.2 Analysis of different implementation principles

In this section some of the implementation techniques, described in chapter 3.5, are examined to identify the implementation criteria that best address and solve problems and constrictions placed by the ALF environment. Among the techniques and methodologies taken under consideration we find:

(a) TPM (Total Productive Maintenance)
(b) RCM (Reliability Centered Maintenance)
(c) TQMain. (Total Quality Maintenance)

(d) Terotechnology principles and
(e) WCM (World Class Manufacturing) criteria.

While RCM provides its maximum contribution in the design phase, playing a fundamental role in the design of maintenance task lists, the implementation of different maintenance activities must be done to achieve, as result, equipment reliability, product quality and safety. The implementation process should be able to catch, address and solve not only reliability issues, but the:

- complexities linked to the technologies used, to pursue higher equipment reliability,
- organizational and cultural limits, to pursue higher competence and proactiveness
- critical points linked with product safety and quality.

The outcome of the analysis will emphasize the necessity to develop an implementation model which embodies a choice of techniques able to pursue higher reliability, product safety and quality with the right people at the minimum cost. TPM, which had its genesis in the Japanese car industry, was originally thought to incorporate Total Quality Control (TQC), Just In Time (JIT) and Total Employee Involvement (TEI). At that time became obvious that TPM was a critical missing link in successfully achieving not only world class equipment performance to support TQC (reduction of variation) and JIT (lead time reduction), but was a powerful new means to improving overall company performance. Since the early 90s, TPM is now having a major impact on bottom-line results by revitalising and enhancing the quality management approach to improve capacity while reducing not only maintenance costs, but overall operational costs. Statistical Process Control (SPC), supported by “Quality at Source”, was introduced to ensure quality right first time so to provide maximum customer value. The quality approach changed to “Prevention at Source” by controlling process variables, equipment performance, discovering problems in the earlier phase and detecting quality deviations to avoid non conformity products. Since production and quality departments demand for equipment availability, quick response time from maintenance and quality right first time, TPM emphasized “prevention at source” through equipment operator’s empowerment. Equipment operators are trained and motivated to be responsible for identifying problems at the earliest possible point in the process to minimize rectification costs. The words Total Productive Maintenance correctly interpreted the mean of:

- Total (all employees and parties involved)
- Productive (creating higher production effectiveness and grater return on investment)
- Maintenance (by caring for the plant & equipment to maximize its performance, safety and output).

Ultimately operators become responsible for the overall equipment effectiveness (which combine equipment efficiency with product safety and quality) through caring for equipment at the source, to ensure that the "basic equipment conditions" are established and maintained and preventive & predictive maintenance implemented. This does not mean that the operators carry out all maintenance activities, but that they are responsible for knowing when they need to implement simple preventive & predictive maintenance services and when they should call in maintenance specialists (experts) to repair or solve problems which they have clearly identified. As result TPM recognises that the maintenance function alone cannot improve equipment reliability and that quality function alone cannot improve product safety and quality, but that both, maintenance and quality functions, have to support equipment operators to establish "prevention and quality at source". In this regard RCM provides the path for failure findings through techniques which enable a deeper knowledge of failure causes and effects, but TPM involve production, maintenance and quality functions to enable the equipment operators to implement prevention, quality and safety immediately at source.

World Class Manufacturing (WCM) is a philosophy which provides the path to aggregate everyone in the organization and motivate the people to constantly pursue continuous improvement. It challenge the involved parties to look for improvement opportunities and see a "problem" linked to quality, cost, organization, maintenance, etc. as a chance for innovation, higher effectiveness and profitability. Kaizen, which means gradual and never-ending improvement, is the key word that makes use of different quality and engineering tools to create competitive success. The temple shown in Figure 52 below, shows the main pillars that focus on maintenance, quality, training, continuous improvement etc. but it emphasize the necessity to build up a problem solving culture which stands at the base of whole temple.

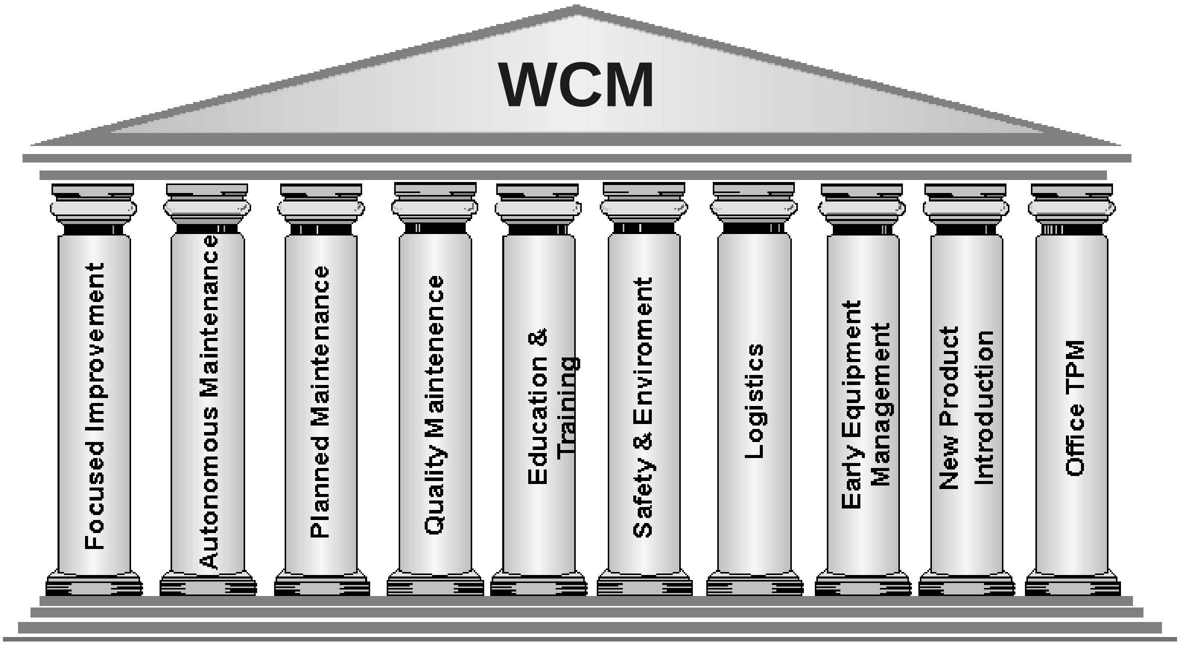


Figure 52: World Class Manufacturing temple [45]

Starting from assessing the current situation, to identify improvement areas and bottlenecks, WCM guide the people involved to restore the basic conditions where we normally find the cause of many chronic problems. Afterward the eradication of sporadic and chronic losses represents the central steps which make use of engineering techniques able to identify both cause and solutions for eradication of multiple forms of losses.

Through the implementation of TPM Autonomous Maintenance, World Class Manufacturing guides the equipment operator to become the main actor in pursuing the eradication of equipment losses.

The last step to the achievement of "zero defects" philosophy and its consolidation makes use of six sigma methodology. In conclusion WCM is particularly useful to build up the cultural values necessary to motivate the people to work as a unique team for the achievement of highest result at a reasonable cost.

Total Quality Maintenance (TQMain) put its focus on condition monitoring (CM) recognizing that where critical component breakdown can produce serious effects on process reliability and product safety, on-line measuring devices should be used. The use of CM devices can provide reliable facts and figures on equipment performance and, as shown in Figure 53, through a holistic view of the production process it is necessary to involve all the interested parties in pursuing continuous improvement projects.

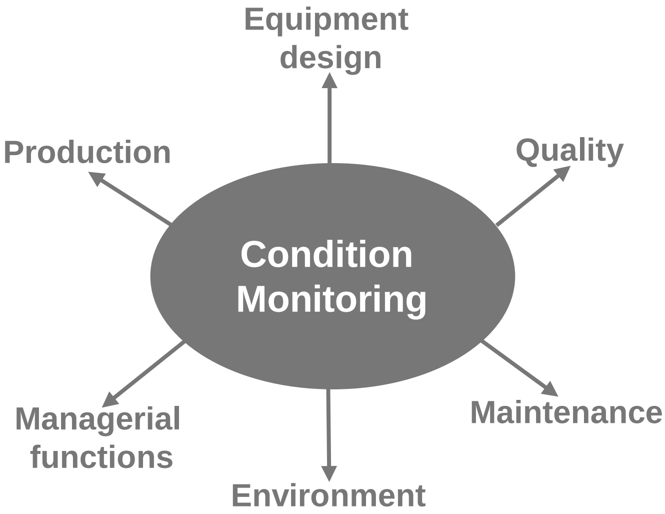


Figure 53: The TQMain interaction

Continuous improvement necessarily call for wider involvement of those who play different company roles, but those identified as key enablers to push projects forward for the achievement of highest results. A modified version of the OEE, named Overall Process Effectiveness (OPE) can be used to get a performance based not only on a single line or piece of equipment, but based on the whole process. The Deming cycle (Plan-Do-Check-Act), used in TQMain process, is an effective tool to pursue a continuous improvement of the task lists through on-line monitoring and feedback from the filed.

Terotechnology highlights the importance of revision of scheduled activities as result of experience: it recognises that the original task lists, designed by the equipment designers, can be improved through feedback coming from the field. Feedback loops are also the base to constantly introduce equipment design improvements. Moreover, maintenance it is not a cost to be measured through Life Cycle Cost (LCC), but since it generates a real profit it needs to be measured through Life Cycle Profit (LCP) to highlight its contribution to the company’s profit. To pursue this objective, direct & indirect maintenance costs and loss of revenue issues are monitored to identify the areas where maintenance generates its maximum profit.

6.3 The design proposal of a maintenance implementation model for ALF industry

The design of an implementation model, able to maximize the effort spent in the new maintenance task lists design, can be done only if the ALF constrictions and opportunities are well defined regarding to the three main company's dimensions:

(a) Technical
(b) Organizational and
(c) Cultural.

Threats, opportunities, limits and constrictions need to be described to identify the problems and how the implementation model can provides positive answers for an effective implementation of the task lists designed. The scope of this activity is not limited to a production of an academic treaty on implementation, but its goal is the production of a tool able to provide positive answers to the different problems and complexities in the ALF environment.

6.3.1 Situation analysis

Situation analysis should be the first phase able to identify:

- All the restraining forces in the manufacturing environment
- All the driving forces to be deployed to overcome the restraining forces.

Problems identification is the first activity: the scope is to shoot a photograph to the whole production environment in order to capture problems and their nature making use of automatic data collection (to highlight problems coming from technical environment) and production audit with interviews (to highlight problems coming from organizational and cultural environment). Through the use of a production line monitoring system and KPIs available, it is possible to measure line availability, highlighting main production line bottlenecks and drawbacks. These systems collect all type of stops (normal, short, emergency stops…) and the relative time associated, to calculate efficiency through different formulas. Data can be collected over a period of two-four weeks. Stop reasons not automatically collected by these systems must be gathered manually. The information gathered can be elaborated by the computer to enable the team to proceed with a production audit to analyse production practices, procedures, training programmes etc. to compare and contrast technical figures with organizational and cultural facts.

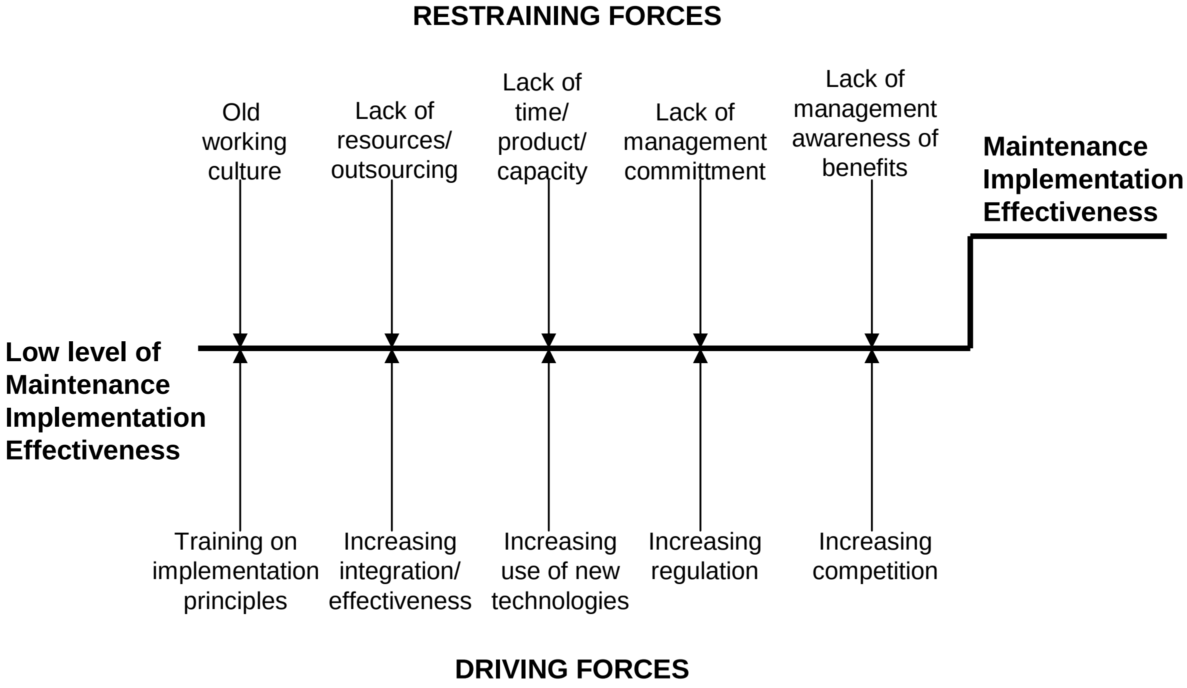


Figure 54: Restraining and driving forces

Figure 54 above represents just an example on how to display restraining and driving forces that work against and in favour of new maintenance implementation philosophy. In order to analyse the elements that form the context in which the designed maintenance tasks have to be implemented, a Force Field Analysis (FFA) technique can be used. This states that at any one point in time a situation in an organisation is likely to be in a state of equilibrium because all the forces acting on it cancel each other out. This equilibrium is maintained by two sets of forces that act on the situation. One set of forces (driving forces) would, if not opposed, induce change in the situation. Within the context of this research the present situation is the low level of maintenance implementation effectiveness within ALF industry. A more desirable situation would be the increased maintenance implementation effectiveness within the ALF industries. These two situations, existing and desirable, are illustrated in Figure 54. The driving forces that are pushing for an increased maintenance implementation effectiveness are:

- increasing competition and regulation

- increasing use of new technology (which calls for a more skilled labour force and well organised maintenance approach)
- increasing integration and effectiveness
- a structured training on implementation principles.

The forces that oppose, or restrain to an increased maintenance implementation effectiveness are:

- lack of management awareness of benefits
- lack of management commitment and support
- lack of time for maintenance due to lack of product and production capacity
- lack of resources and use of outsourced personnel
- old working culture with all barriers associated.

Figure 55 below shows a practical example on how to display some of the restraining and driving forces that work against the achievement of maintenance implementation effectiveness on a specific ALF packaging line.

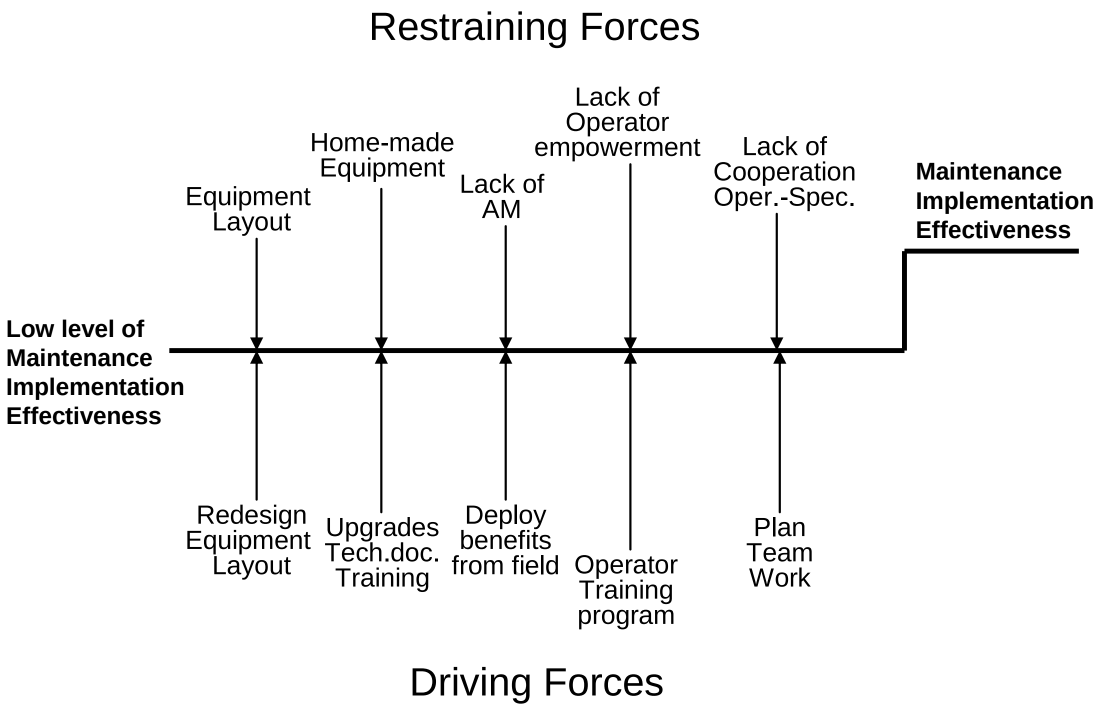


Figure 55: FFA applied to a packaging line

This analysis will produce, as a result, clear awareness about the restraining and driving forces in the manufacturing environment and then the ability to monitor each force in order to put them under control for the achievement of the targets.

6.3.2 Define the ALF mandatory requirements

ALF tends to involve complex systems in which the automatic machines, that make up a production line, interact with each other to satisfy production requirements. EEC directive 93/43, deals with critical operations and specific hazards of the process and require that appropriate measures for the prevention of failures can be applied to ensure the safety of food. Annex 5 of the directive states:

"*plant equipment, in contact with food, must be designed and built with materials that reduce, if maintained in a good condition and submitted to a regular maintenance programme, the risks of food contamination*".

The use of HACCP methodology leads to the identification of Critical Control Points (CCPs) of the process and to the design of maintenance procedures necessary to achieve process-product safety and reliability. At the same time GMP has two complementary and interacting components; the manufacturing operations and the quality control-quality assurance system. Both these components must be well designed and effectively implemented. In the second phase, the management roles should clearly define the requirements and respective actions associated with the two functions. While compliance with legal requirements represents a threat to the manufacturing unit, this could be converted to an opportunity to pursue a quality programme aimed at achieving better process reliability and product safety. Despite legal pressures, the implementation of maintenance, could be seen not only as a tool to comply with legal requirements, but as an opportunity to develop a real manufacturing competitive advantage.

6.3.3 Top management involvement and commitment

Implementation of new maintenance procedures has to be sold to the whole work force. In the third phase, top management has to inform all the company's employees and share their enthusiasm for the project. Experience showed a contradiction existing between theory and practice, therefore, since the beginning, top management has to put its effort to persuade the whole workforce about the real intention of the company to pursue a complete implementation of new maintenance procedures. This means that the implementation program must have a full support of top management in order to overcome resistances and conflicts coming from middle management, and promote the involvement of all company's employees. Because of mandatory requirements and results found in the situation analysis, implementation of new maintenance procedures, in the ALF environment, must be initiated as top-down process to enable bottom-up implementation.

6.3.4 Training & education campaign for implementation of new maintenance procedures

As fourth phase, training should start as soon as possible. Its purpose is to:

- train the different categories of people on new maintenance procedures philosophy (from design to implementation)
- train the people involved on new implementation model
- provide the necessary motivation to overcome early resistances.

Training should be used to present new maintenance procedures features and advantages, to gain the involvement of the workforce that consider this as a costly process and to show the advantages for all company's roles. This step should create a positive attitude towards new maintenance procedures and their implementation.

6.3.5 Design the organization to implement new maintenance procedures

The structure on new maintenance procedures is based on committees and project teams formed at every level of the organisation. To enable a good communication, every organisational level has to be connected with the others through observers that link the various levels as a sole body. In the fifth phase, team activities should be planned and links among them clearly identified to obtain a pro-active participation of the ALF managers that consider this implementation as threatening for their position. Regular communications, results, decisions have to be officially shared with the workforce involved in the implementation to promote a better ownership. Accurate planning and design of the activities, listed above, will enable the organisation to overcome the difficulties that will arise at different levels of the company's organisation. If the organisation decides to implement the new maintenance procedures, the selling effort must continue until these become the way of life. This will not happen quickly and should never be taken for granted. The people who have been convinced of the value of the concept and practice must keep in touch and be involved with the successes on an ongoing basis. The different design activities should not involve a complete redesign of the whole work system; this is an expensive process which is likely to be very unsettling to the workforce. A complete redesign would be a revolution, probably imposed by senior management. In contrast this is an evolutionary process.

6.3.6 Restore basic or standard conditions

The situation analysis identified deviations from the basics and from the standards (technical and organizational) due to the following issues:

(a) Technical deviations

- chronic and sporadic losses
- availability and efficiency problems
- quality and safety problems

(b) Organizational deviations

- operator and maintenance specialist roles
- claims management
- KPI,s and measurement system
- Support & Improvement teams.

In the sixth phase, correlation between technical and organizational deviations enables us to gain a deeper understanding on the causes and effects produced by the deviations from the standards, both on technical and on organizational environments. Restore the basic and standard conditions, under technical and organizational point of view, is the first preliminary and mandatory step before the implementation of new maintenance procedures. Implementation effort could be fruitless if standard and basic conditions are not properly established within the manufacturing organization.

6.3.7 Develop a scheduled maintenance check lists

In the seventh phase, implementation of new maintenance procedures, based on task lists, is to be considered one of the most important parts of the project: failure in reaching the target could be experienced if technical, human and cultural aspects of manufacturing environment are not taken into consideration.

Following the analysis of the implementation principles carried out in section 6.2, the Table 8, shown below, represents an important guideline regarding cleaning and maintenance activities and the roles responsible for their implementation.

Too often, after design of maintenance tasks, lack of a clear definition of roles & responsibilities produce uncertainty on:

- Who is committed to implement cleaning and maintenance tasks and
- The competence level required for each company's roles.

Activity	*Content*	*Competence*	*Role*
Routine Cleaning & Maintenance	(a) Daily (pre & post production)	Daily cleaning procedures	Equipment Operator
	(b) Weekly cleaning & inspection	Weekly cleaning & inspection	
Basic Maintenance	(a) Time based (daily & weekly)	Mechanical preventive & predictive maintenance based on low complexity systems and deviations	Equipment Operator
	(b) Based on No. of cycles, packages		
	(c) Based on Condition Monitoring deviations		
Advanced Maintenance	(a) Time based (250/500 running hours)	Mechanical-Electromechanical prev. & predict. maintenance based on medium complexity systems and deviations	Equipment Operator
	(b) Based on No. of cycles, packages		
	(c) Based on Condition Monitoring deviations		
Specialistic Maintenance	(a) Time based (1000/2000 running hours)	Mechanical-Electromechanical prev. & predict. maintenance based on high complexity systems and deviations	Maintenance Technical Specialist
	(b) Based on No. of cycles, packages		
	(c) Based on Condition Monitoring deviations		

Table 8: Guideline proposed for implementation of cleaning and maintenance activities

Operators and maintenance specialists have to be trained to safely perform tasks and share the execution of maintenance activities that can be performed either by operators and maintenance specialists. Maintenance performance optimisation, necessary to reduce maintenance cost and improve its effectiveness, can be achieved sharing maintenance task lists responsibility in this way:

- Daily cleaning and basic repair activities (carried out by equipment operators)
- Weekly task lists, based on cleaning, maintenance and basic inspections (carried out by equipment operators)
- 250/500 hours check lists, based on equipment running hours: preventive & predictive maintenance (carried out by equipment operators and shared by maintenance specialists)

- 1000 hours check lists, based on equipment running hours: preventive & predictive maintenance (carried out by maintenance specialists and shared by equipment operators).

The content of these check lists is coming from the result of the design phase, and each list is strictly linked to the others, to build up a unique task list structure. Definition of task list responsibility is to be done identifying the right role for the right maintenance task, improving then personnel commitment and maintenance effectiveness.

Moreover, according to the complexity of maintenance tasks, the table above shows how to split preventive and predictive maintenance tasks and the roles responsible for their implementation.

An effective implementation is based on ability to:

- Define the equipment operator and maintenance specialist roles
- Define who is responsible to implement cleaning and maintenance tasks
- Define how to record the result of each maintenance event
- Define the interaction existing among the parties involved and support provided by the manufacturing management.

All these activities have a strong impact on technical, organizational and cultural dimension of the company. In order to be effective, cultural values invoked by the WCM must be established and spread out within the whole organization. The organizational structure, itself, should facilitate the connection and make easy the dialogue among the parties involved, avoiding bureaucratic procedures and barriers.

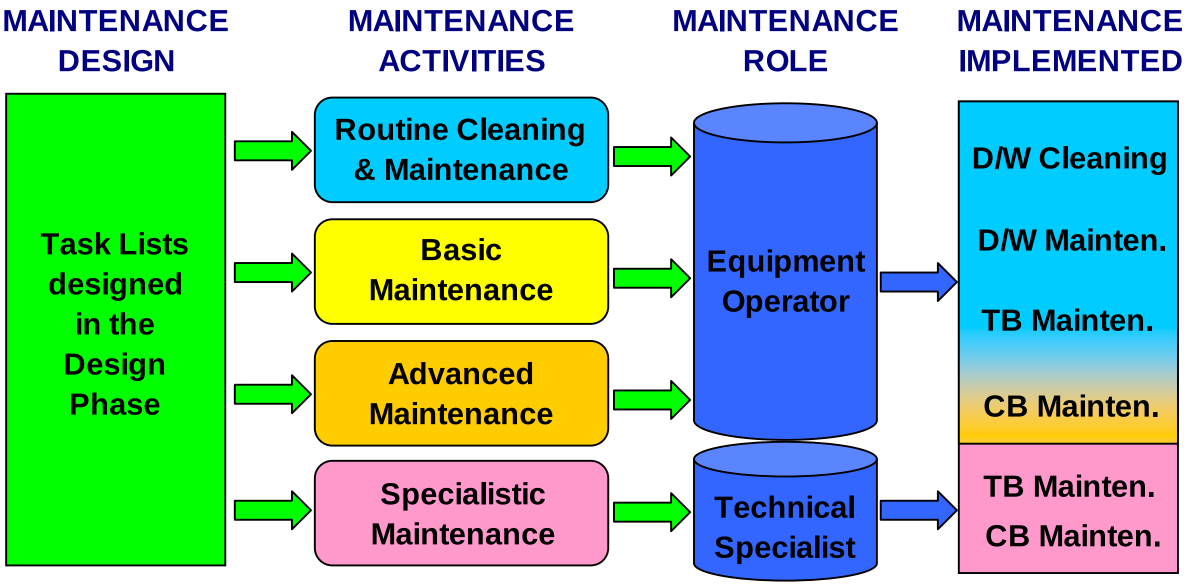


Figure 56: From task list design to maintenance implementation

Figure 56 above summarizes how the task lists designed need to be split for maintenance families in order to be allocated to equipment operators and to maintenance specialists for their implementation. Daily and Weekly (D/W) cleaning and maintenance, Time Based (TB) and Condition Based (CB) maintenance are implemented by the equipment operators or maintenance specialists according to the complexity of task list content [46].

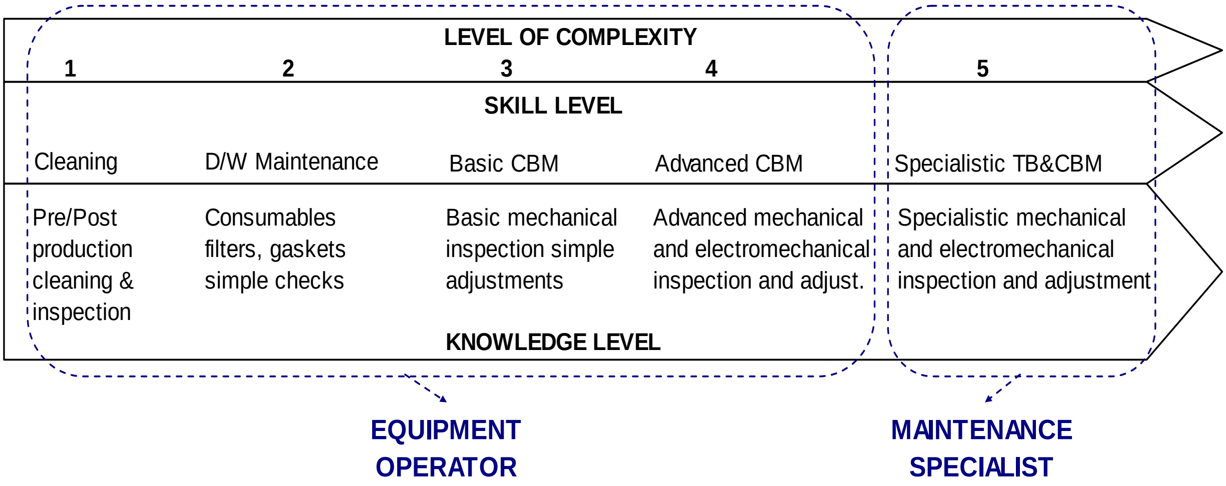


Figure 57: Level of task list complexity based on skill and knowledge

Figure 57 above highlights different levels of complexities based on skill and knowledge necessary to carry out the task list contents.

There is not a clear limit or threshold to define the skillness and knowledge level for operators and maintenance specialists, but manufacturing management should empower the equipment operators, through continuous training, to allow them:

- to achieve the highest possible level of competence and experience
- to effectively cooperate with maintenance specialists to carry out preventive, predictive and corrective maintenance.

Since prevention implemented by the equipment operator can avoid quality and safety problems on final product, operator empowerment should be a never ending process to increase product safety, reliability and quality image of the company.

If in a mechanical industry an operator mistake can produce bolts or screws with some non conformity’s problems compare to technical specifications, an operator mistake, or a lack of prevention in food industry can have serious effects on public health and huge damage to the quality image of the company.

As shown in Figure 58, cooperation between operators and maintenance specialists represents a mandatory pre-requisite to carry out some maintenance activities where every role alone could experience serious difficulties without the support of the other.

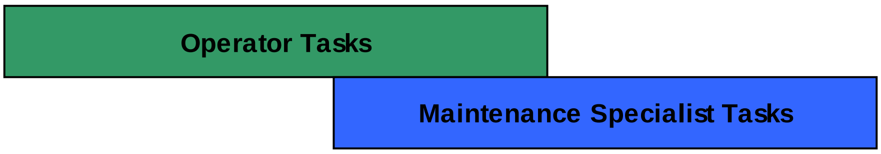


Figure 58: Overlap between operator and maintenance specialist

To pursue a real integration between these two complementary roles it should be advisable to enable the operators to implement some maintenance specialist tasks and maintenance specialist to implement some operators tasks. This will produce, as result, a better awareness of the complexities linked to each role, the ability to better understand limits and constrictions of the other role and reinforce an effective cooperation. The simple figure above shows an overlap which represents the area where maintenance tasks can be implemented both by the equipment operators or by the maintenance specialist.

Condition-based maintenance and specific PM activities, which required good electrical & mechanical skill are mainly performed by maintenance specialists. Equipment operators implemented the same maintenance techniques for low-medium complexity maintenance tasks, normally listed in the weekly and in the 250/500 hours check lists and assist maintenance specialists in the implementation of more complex task lists.

Table 9 shows an example of the check list to be used to list the maintenance task lists designed. The main fields indicate what follows:

Equipment group/subgroup: **01. Sealing Unit**								
Section/ Description	*Action*	*Role*	*Documentation*	*Interval*	*Av.Time (minutes)*	*Pos. No.*	*Result*	*Notes*
Knife integrity	check/change…	EO-MS	Maint.Manual page…	250 W.Hours	15	10010	changed	
Inductor profile	clean/measure/ replace	EO-MS	Maint.Manual page…	250 W.Hours	10	10011	cleaned	

Table 9: Check list structure

- Equipment group/subgroup

This field list the name of the equipment group or subgroup taken under consideration: this means that the task lists that will follow will be referred only to that equipment group.

- Section/Description

A short description of the maintenance task designed is listed under this field

- Action

The action designed is listed in this section and this could be: check, change, inspect, clean, measure, overhaul…

- Role

The roles identified to implement the specific task list are listed here and they could be: Equipment Operator (EO) or Maintenance Specialist (MS)

- Documentation

Since section/description can contain only a very short description of the maintenance task to be implemented, this field will indicate the page number and reference of the document name where drawings, technical specifications and maintenance activities are listed.

- Interval

This field indicate the interval between every task, based on working hours, number of cycles or packages produced

- Average Time (minutes)

This field shows the average time normally necessary to carry out the specific maintenance task

- Position Number

This field contains the progressive number that makes the task list traceable

- Result

The result of the maintenance activity is listed under this field and this could be: adjusted, changed, replaced, cleaned…

- Notes

Where necessary this field can contain notes regarding the activities done or to be done at the next available opportunity.

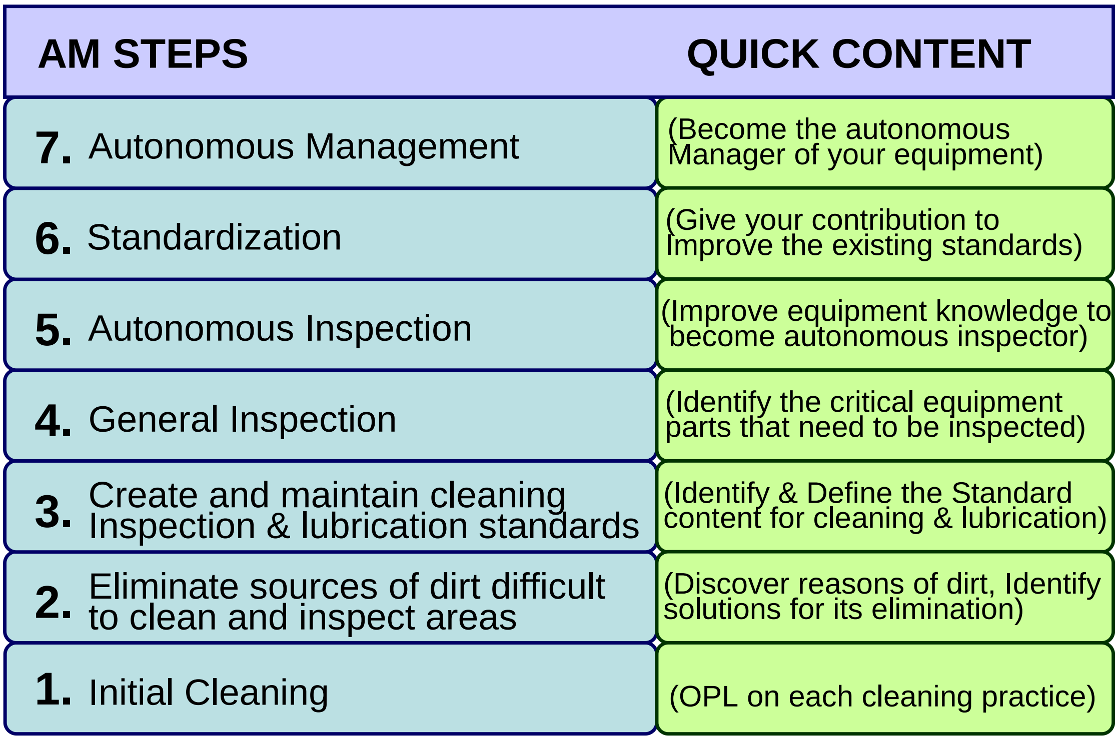
Further fields can obviously be added to identify the tools and the templates to be used to carry out each maintenance task, but the most meaningful information are those listed in Table 9 above.

6.3.8 Develop autonomous & specialist maintenance integration

The implementation model acknowledge that the role of the equipment operator is one of the most critical and meaningful one for the achievement of a sustainable equipment effectiveness. This statement is particularly true in the ALF environment where the equipment operator plays a major role in implementing some critical preventive maintenance tasks that can maintain the equipment under HACCP control.

According to TPM methodology the operator empowerment represents the basic condition to satisfy to implement preventive and predictive maintenance procedures effectively. The role of the operator is designed according to the basic maintenance needs foreseen in the design model.

Autonomous maintenance (AM) carried out by the equipment operator is the sharp weapon against equipment breakdown, Figure 59 here below shows a full description of the different incremental steps to pursue to implement this methodology in the ALF environment.



AM STEPS	QUICK CONTENT
7. Autonomous Management	(Become the autonomous Manager of your equipment)
6. Standardization	(Give your contribution to Improve the existing standards)
5. Autonomous Inspection	(Improve equipment knowledge to become autonomous inspector)
4. General Inspection	(Identify the critical equipment parts that need to be inspected)
3. Create and maintain cleaning Inspection & lubrication standards	(Identify & Define the Standard content for cleaning & lubrication)
2. Eliminate sources of dirt difficult to clean and inspect areas	(Discover reasons of dirt, Identify solutions for its elimination)
1. Initial Cleaning	(OPL on each cleaning practice)

Figure 59: The route for Autonomous Maintenance

1. Initial cleaning

Despite cleaning activities are not generally recognized as professionally qualifying, in food industry these practices play a more important role compare to some other industrial realities. Since cleaning represents a fundamental pre-requisite for an effective surface sterilization, manual cleaning of surfaces not automatically cleanable by the Cleaning In Place (CIP) system must be done by the equipment operator.

Through the use of “One Point Lesson” (OPL) the implementation of each cleaning practice must be defined regarding the materials to be used and the operational practices to be put in place.

2. Eliminate sources of dirt and difficult to clean and inspect areas

Among the equipment operator tasks there is the ability to:

- discover the reason of dirt and
- identify reliable solution for its elimination.

Dirt and residues can be produced by friction and can reveal anomalous behaviour of components, but dirt and powder can also be produced by product leakages and can represent an important input to discover leakages in the pipes.

Sometimes it is possible to find difficult surfaces or areas to clean where the packaging material could be contaminated or dust residues produced and not cleaned that could come in contact with the product packed. The equipment operator task is to devise simple but effective solutions to avoid dust and dirt production: these solutions could be represented by cleaning practices or by simple equipment modifications to improve the equipment reliability.

3. Create and maintain cleaning, inspections and lubrication standards

Through improvement team meetings, equipment operator gives its precious contribution to identify and define the standard contents for cleaning, inspection and lubrication. No one better then those who are committed to carry out cleaning and lubrication practices, on daily and weekly base, can define and improve the relative standards. New ideas on how to inspect and detect potential problems can properly be conveyed to improve the effectiveness of the existing standards. Every standard can be dynamic and be submitted to regular analysis to improve its consistency and efficiency. Standards should serve the company and company should not serve the standards: standards are important to define the best way to execute a specific activity and they are essentials to avoid personalisms and uncertainty on how to implement new maintenance procedures.

4. General inspection

Inspection carried out by the equipment operator does not cover only activities linked to cleaning, but also connected to some critical mechanical and electromechanical functions necessary to form and seal the final package. The equipment operator must be trained and then supported to verify if the CCPs identified in the design phase are under control or if some potential deviations need to be preventively managed to avoid loss of control. Again, no one better then the equipment operator can give its maximum contribution in this area and the whole company should promote the operator involvement in training and in participating to the improvement team activities.

5. Autonomous inspection

The equipment operator empowerment starts with a basic training that enables him to know:

- the working program of the equipment (preheating, sterilization, production, cleaning…) the dynamic functions of the different groups and sections of the equipment
- the critical functions and measures of the sterilization unit and the forming and sealing units
- how to prepare, clean and maintain the equipment
- how to carry out quality control checks (destructive and non destructive) during production phase and before and after every type of stop
- how to fix the basic problems regarding short stops and how to adjust groups and components to avoid appearance and leakage problems on the final package.

This type of training represents the "basic investment" that enables the equipment operator to gain the standard knowledge of the equipment and how to carry out quality control and basic maintenance. Moreover, to pursue a real operator empowerment, the equipment operator will be trained to implement basic and advanced maintenance. The theoretical training must be followed by practical training and a maintenance specialist should assist and support the execution of the task lists implemented under the responsibility of the equipment operator. A final training regarding equipment trouble shooting should empower the operator to autonomously fix the basic troubles that produce equipment short stops due to the equipment failures or to the problems on the final package.

The ability to grow in its role and to gain a wider possible autonomy, depends on stimuli coming from:

- continuous training
- continuous support and dialogue with maintenance and quality specialists
- continuous participation to the improvement team activities
- continuous information about its performance.

The autonomous inspection, effectively carried out by the equipment operator, represents the outcome of the investment that the company's management should plan, support and monitor for every equipment operator.

6. Standardisation

This step represents the ability of every company's role to give its contribution for the achievement of standard procedures, practices and operations. To avoid grey areas depending on personal opinions, practices and ways to work, the equipment operator should be challenged to pursue continuous improvement, but following the procedures established to standardise each activity. New ideas to save time, money, or to improve safety, quality and reliability should be regarded not as a disturbance but as an opportunity to improve the existing standards. Trough its proactive participation to the improvement team activities, the equipment operator can play an important role in defining and improving the company's standards and the standardisation process. No one better then him can know what to do, how to do and when to do the right things to operate and maintain the equipment effectively.

7. Autonomous management

At the end, autonomous management of:

- equipment operation (pre-post production, production and cleaning practices)
- equipment maintenance
- product safety and quality
- continuous improvement activities

is carried out by the equipment operator.

An effective program to pursue a real operator empowerment produce as result the ability of the equipment operator to become a "manager" of the equipment/line able not only to operate the equipment, but to maintain and to ensure safety and quality of the end product. This result is based on different activities or investments which point out to an increase sense of equipment/line ownership based on training, collaboration, involvement and continuous improvement.

The Good Manufacturing Practices (GMP) implemented through AM represent the best organized and proactive way to produce a direct positive impact on HACCP criticalities and on reliability issues. The synergy shown in Figure 60 emphasizes that while equipment operator is taking the responsibility of cleaning, basic and advanced maintenance implementation, maintenance specialist implements complex preventive and predictive task lists which require higher mechanical and electrical competence.

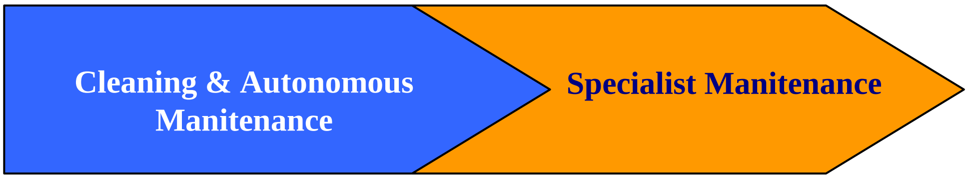


Figure 60: Synergy between equipment operator and maintenance specialist

The task lists implemented under the responsibility of maintenance specialist should be performed, when possible, together with equipment operator: this will enable him to gain a wider view of the equipment and share his experience with the maintenance specialist. Interaction and integration between these two roles represents a fundamental pre-requisite to establish a powerful tool for the achievement of highest product safety and equipment reliability. The implementation model summarized in Figure 61 identifies the main steps that enable the whole company to be committed for an effective implementation of new maintenance procedures.

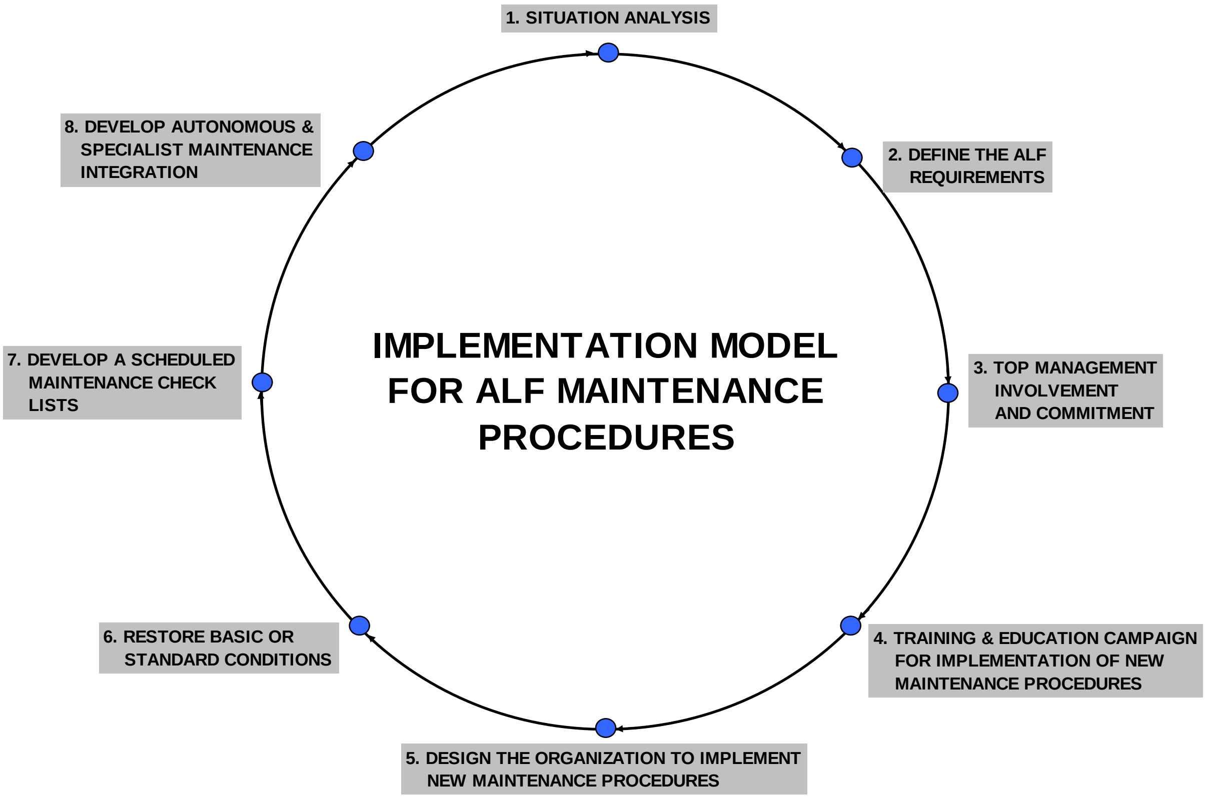


Figure 61: Implementation model for ALF maintenance procedures

If, after some years from the implementation, the company feels the necessity to revitalize the implementation commitment and sensitivity of those involved, then the process could be restarted from the first step, to discover the existing drawbacks, down to the last step, to consolidate the equipment operator and maintenance specialist integration.

6.4 The key performance indicators (KPI) to monitor production and maintenance effectiveness

What performance indicators should be measured and who should be committed to measure maintenance effectiveness? The identification of the KPIs, that highlight the status of maintenance effectiveness of a packaging line, is discussed in this chapter regarding not only to technical reliability, but to quality and safety reliability. Some of the difficulties in gathering measurable information will be highlighted to identify the easiest way to gather and monitor meaningful ALF KPIs.

6.4.1 Definitions

The following definitions will be applied to the different KPI used to measure production and maintenance effectiveness:

Actual capacity

It defines the amount of product produced per hour, during production time, without any stops, e.g. number of filled packages in a filling machine (including filled packages ejected through the drop chute in aseptic filler).

Nominal capacity

It defines the capacity of the equipment as stated in the specification.

Equipment

It defines the equipment chosen to be investigated, i.e. single machines, part of a production line or a whole production line.

Approved package/container

It defines a package that is approved during production. (e.g. if an approved package later, in case of aseptic packaging, turns out to be unsterile, it is still to be regarded as approved). The total number of approved packages also includes approved packages taken as samples during production for quality control purposes.

Filled package/container

It defines a filled package to be regarded as a sealed package, filled with product to intended volume.

Packaging material loss

It defines the packaging material that has entered the equipment, but does not come out as approved packages sellable in the market.

Phases

The period of time that the equipment is studied for can be divided into the following four phases:

(a) Preparation phase

Preparation means: "any work or enforced waiting time that necessarily occurs at the start of a work period before production can begin". The preparation phase starts with the first attempt to prepare the equipment for planned production and ends when the production phase starts.

(b) Production phase

Production means: "when the intention is to produce filled packages or product".

The production phase starts with the first attempt to produce product or packages with the equipment and ends when planned production is done or when for other circumstances a production interruption is decided and production is stopped.

(c) After Production phase

After Production means: "any work or enforced waiting time that necessarily occurs at the end of a work period after production has stopped."

The after production phase starts with the first attempt to run the after production program and ends when intended tasks in the after production phase have been completed.

(d) Planned Maintenance phase

Planned maintenance means “The maintenance and cleaning procedures carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of the equipment”.

The planned maintenance phase starts at the beginning of the first preventive action and ends when planned maintenance has been carried out.

Here below is presented Figure 62 which shows the four phases under investigation, followed by a short description.

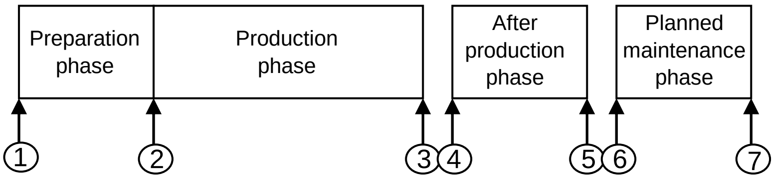


Figure 62: Preparation, production and maintenance phases [33]

1. First attempt to prepare the equipment for production
2. First attempt to produce product or packages
3. Planned production is done or stopped
4. First attempt to run the after production program
5. Intended after production tasks has been carried out
6. Beginning of first planned maintenance task
7. Planned maintenance has been carried out.

Stop reasons

In this section the different equipment stop are listed and defined.

(a) Equipment stops

A stop caused by a failure in the equipment itself. An equipment stop can exist during all phases. We refer to all corrective maintenance activities depending on the equipment and due to functional failures.

(b) Other stops

Stops caused by reasons outside the equipment itself. Other stop time can exist during all phases. We refer to stop events as:

- Stop caused by other equipment (different from the one under observation)

- Meals
- Missing information for operating the equipment
- The time necessary to change the product
- The time necessary to change package design, package volume, and packaging pattern
- The equipment stopped by the operator for unknown reasons
- Lack of packaging material, or opening devices and other materials
- Lack of services or utilities to the equipment (air, water, steam, electricity etc.)
- Operator mistakes.

(c) Time

Figure 63 below shows the different time segments under consideration and then a short description highlights the meaning of such definitions.

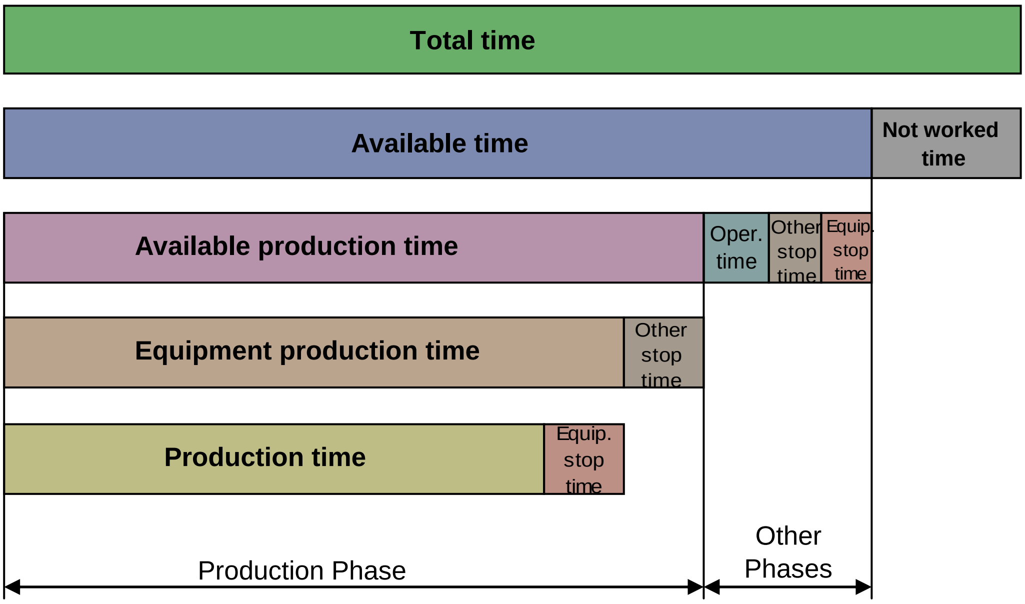


Figure 63: Total time segments for production activities [33]

Looking at Figure 63 above, the first consideration to be done refers to the identification of the two main phases: production phase which consider the preparation of the equipment and production, and other phases referring to after production and planned maintenance activities.

- Production time

  This is the time during which the equipment is performing a primary required function. E.g. producing product or filled packages.

- Equipment Production time

  This is the time during which the equipment could have been performed a primary required function if no equipment stop had occurred during the production phase.

- Operating time

  This is the time during which the equipment is performing a required function. Operating time can exist during all phases but is called production time in the production phase. E.g. Production time equals operating time in the production phase. For example, in preparation phase, the operating time can be a fixed value stated in the specification for each individual equipment.

- Equipment stop time

  This is the accumulated time interval from when an equipment stop occurred until the equipment is back in the same state as it was before the stop occurred, or when the present phase has ended. Equipment stop time can exist during all phases.

- Other stop time

  This is the accumulated time interval starting from a stop caused by reasons outside the equipment itself ending when the equipment is back in the same state as it was before the stop occurred, or when the present phase has ended. Other stop time can exist during all phases.

- Available production time

  This is the time during which the equipment could have been performing a required function if no equipment or other stops had occurred. I.e. Available production time = Production time + Equipment stop time + Other stop time. Available production time can only exist in the production phase.

- Available time

  The Available time = total time - not worked time (not planned).

- Total time

  This is the continuous time interval during which the performance of the equipment is considered. For example 24 hours, a week, a month.

- Not worked time

  This is the time interval during which the equipment is not used, and does not belong to any other time interval, previously explained. E.g. when there is no need or wish to produce or no production is planned.

6.4.2 Performance based on producer view

The indicators used in this paragraph enable the producer to highlight all the factors (technical, organizational...) that influence the performance of the plant operation where the equipment is installed and all kinds of stops that reduce the performance of the line.

Total capacity utilization

Total capacity utilization describes the share of production time out of the total time.

$$\text{Total capacity utilization} = \frac{\text{Production time}}{\text{Total time}}$$

Time utilization (TU)

Time utilization describes the share of production time out of available time.
It defines planning, operational and equipment effectiveness.

$$\text{Time utilization} = \frac{\text{Production time}}{\text{Available time}}$$

Another way to calculate the time utilization effectiveness is to consider the packages produced.

$$\text{Time utilization} = \frac{\text{Tot. Number of Filled packages}}{\text{Available time x actual capacity}}$$

Available production time utilization (APTU)

Available production time utilization indicates the time used for production phase.
It defines the equipment under observation and other equipment effectiveness.

$$\text{Available production time utilization} = \frac{\text{Available production time}}{\text{Available time}}$$

Production time utilization (PTU)

Production time utilization indicates the time used for production phase.

It identifies the time spent to produce commercial packages compared with the time available for production activity.

$$\text{Production time utilization} = \frac{\text{Production time}}{\text{Available production time}}$$

6.4.3 Performance based on equipment focus

The indicators used in this paragraph enable the producer to highlight all technical factors that influence the performance of equipment installed. The formulas used show the efficiency of the specific equipment or machine under observation.

Mechanical machine efficiency (MME)

It defines the machine efficiency over the production time available for the machine.

$$\text{MME} = \frac{\text{Production time}}{\text{Production time + Equipment stop time}}$$

Mean time between failure (MTBF)

It describes the mean production time existing between equipment failures.

$$\text{MTBF} = \frac{\text{Production time}}{\text{Number of equipment stop}}$$

Mean time to restore (MTTR)

It describes the average time necessary to bring the equipment into operation after equipment stop.

$$\text{MTTR} = \frac{\text{Equipment stop time}}{\text{Number of equipment stop}}$$

6.4.4 Performance based on packaging material used

In this paragraph the packaging material performance (packages, bottles or containers) is measured considering both the utilization and the efficiency.

Packaging material utilization (PMU)

It describes the ratio existing between the packaging material at the equipment infeed with the total number of approved packages or containers produced by the equipment.

$$\text{PMU} = \frac{\text{Total number of approved packages}}{\text{Number of packages into equipment}}$$

Packaging material efficiency (PME)

This formula describes the packaging material used to produce filled packages ready for the market. It defines the efficiency of the equipment regarding to the ratio existing between the packaging material at the equipment infeed and the approved packages delivered at the equipment outfeed. The formula refers to a specific machine taken under consideration and not to the other equipments (processing and downstream equipments).

$$\text{PME} = \frac{\text{Total number of approved packages}}{\text{number of packages into the equipment - number of packages wasted at other stop}}$$

6.4.5 Examples of calculation

In the Figure 64 below, a practical example of calculation is showed to explain how practical situations, like stops and operational activities, have to be allocated. This figure summarizes the following time periods (starting from left to right):

Pre-Production

During equipment preparation, different pre-production program steps must be executed to prepare equipment for production activity; this portion of time is defined as an “operating time”. The light green triangle (on the left) represents a part of pre-production program executed to rise up the program at the condition where the machine is ready for production. If, at a certain point, the equipment under consideration is stopped because of lack of compressed air, due to a compressor fault, this portion of time is stored under the group: “other stop time” represented by the yellow segment. If, in re-starting up the program, the equipment is not working correctly because of a failure in the sterilization system, then the portion of time used to restore the equipment is stored under the group: “equipment stop time”. The time spent to execute the last pre-production program steps, to reach the condition where the equipment is ready for production, is an operating time allocated to this group.

Production

Production starts with the first attempt to put the machine in production to produce filled packages or containers. If, during production activity, represented by the dark green colour, allocated to: “production time” group, another short stop is experienced because of lack of compressed air, then this portion of time will be allocated to: “other stop time” group. If, during production phase, the equipment program drops down to zero position because of a critical failure on the sterilization system, then the portion of time used to restore the equipment for production activity is stored under the group: “equipment stop time”.

Post-Production

If, after the production activity, the company is not working because of a local holiday, this time, represented by the light grey segment, is stored under the group: “not working time”. The activities carried out to clean the equipment, after production, are represented by the light green segments, and are stored under the group: “operating time”. If during this operating time a stop is still experienced because of air compressor fault, this portion of time, represented by the yellow segment, is stored under the group: “other stop time”.

The available time, represented by the blue segment, is the time available for production (pre-production, production, and post-production) activities without the planned time in which the company is not working.

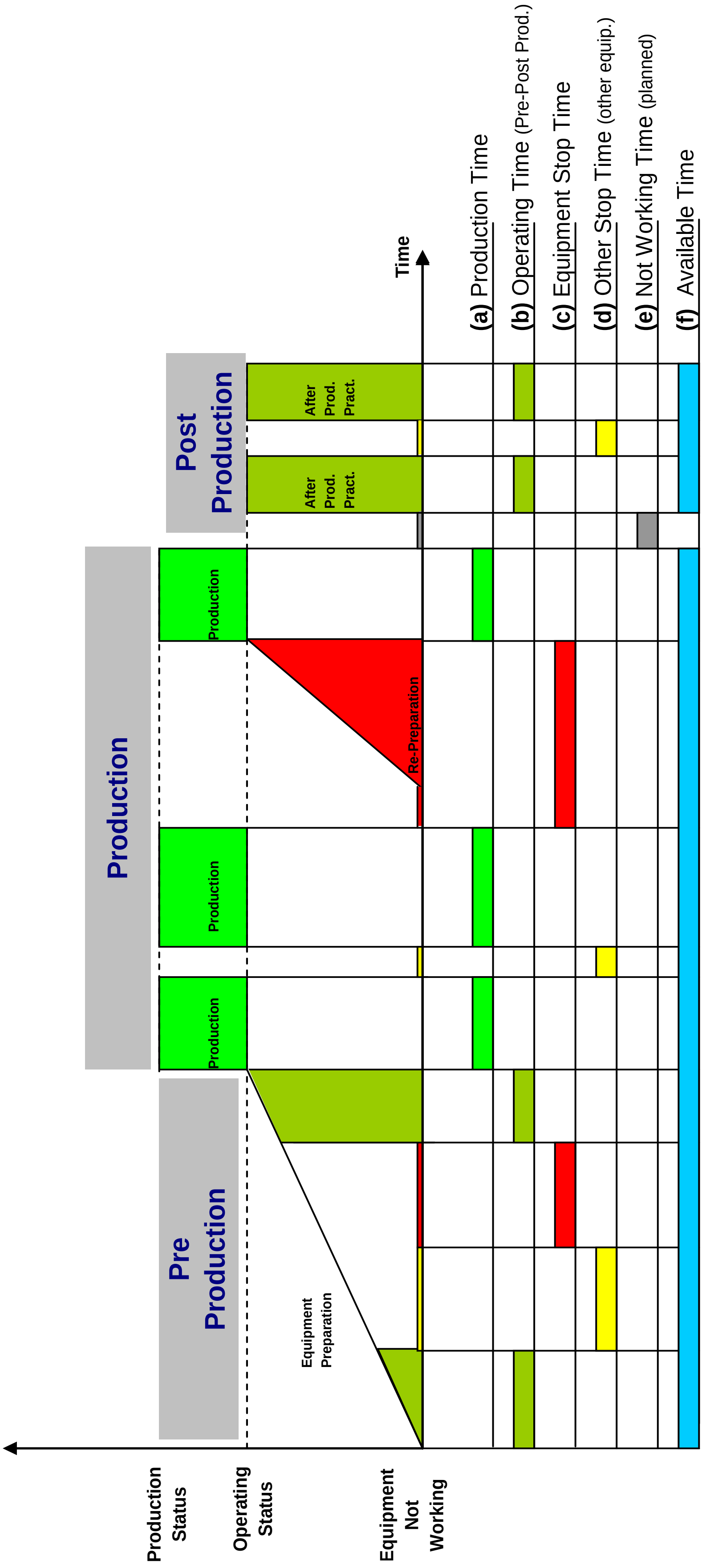


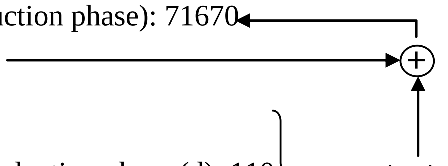
Figure 64: Production time frames

Examples of data collected to calculate the performance of the equipment

(a) Production Time: 10,5 h
(b) Operating Time (e.g. pre-production and cleaning activities): 2,5 h
(c) Equipment Stop Time (e.g. package out of design during production phase): 1 h
(d) Other Stop Time (e.g. missing operator input): 1 h
(e) Not Working Time (not planned): 9 h
(f) Available Time: 15 h

Number of stop during production phase: 5

Packages In (to the equipment): 72347
Packages In (to the equipment during production phase): 71670
Packages Out (from the equipment): 70520



Packaging loss at operating time (b): 575
Packaging loss at other stop time during production phase (d): 110
Packaging loss at equipment stop during production phase (c): 465

Tot. Packaging Loss: 1150

Note:

The difference between packages In (to the equipment) and the sum of packages Out (from the equipment) and loss during production stops are due to packages ejected during production phase.

Calculations based on collected data

Time Utilization (TU)

$$\text{Time utilization} = \frac{\text{Production time}}{\text{Available time}} = \frac{10{,}5}{15} = 70\%$$

Packaging material utilization (PMU)

$$\text{PMU} = \frac{\text{Total number of approved packages}}{\text{Number of packages into equipment}} = \frac{70520}{72347} = 97{,}47\%$$

Packaging material efficiency during production phase (PME)

$$\text{PME} = \frac{\text{Total number of approved packages}}{\text{number of packages into the equipment - number of packages wasted at other stop}} = \frac{70520}{71670 - 110} = 98{,}55\%$$

Mechanical machine efficiency (MME)

$$\text{MME} = \frac{\text{Production time}}{\text{Production time + Equipment stop time}} = \frac{10{,}5}{10{,}5 + 1} = 91{,}3\%$$

Mean time between failure during production phase (MTBF)

$$\text{MTBF} = \frac{\text{Production time}}{\text{Number of equipment stop}} = \frac{10{,}5}{5} = \text{2h 06min}$$

Mean time to restore during production phase (MTTR)

$$\text{MTTR} = \frac{\text{Equipment stop time}}{\text{Number of equipment stop}} = \frac{\text{1h}}{5} = \text{12min}$$

Figure 65 below, displays the interaction of indicators such as: MTBF, MTTR and MME, with the three legs that determine equipment Availability: Reliability, Maintainability and Supportability. The red cross identifies the existing interactions.

- MTBF is the indicator commonly used to measure equipment reliability. It is heavily dependent on equipment design, but also on maintenance effectiveness and operator ability.
- MTTR is the indicator used to measure equipment maintainability. While it is mainly dependent on equipment reparability and fault detection, it is also dependent on availability of spare parts, tools and templates to carry out corrective and preventive maintenance. This means that the quality of support system, available for production activities, is also interacting with MTTR.
- MWT (Mean Waiting Time) is the average time to wait before a service can be started. This is a difficult indicator to measure, but it could highlight some organizational drawbacks coming from shortage of competency or logistic problems in getting the right competence to carry out equipment trouble shooting.
- MME is an indicator, referred to a single equipment performance, that is dependent on the three main availability legs: Reliability, Maintainability and Supportability.

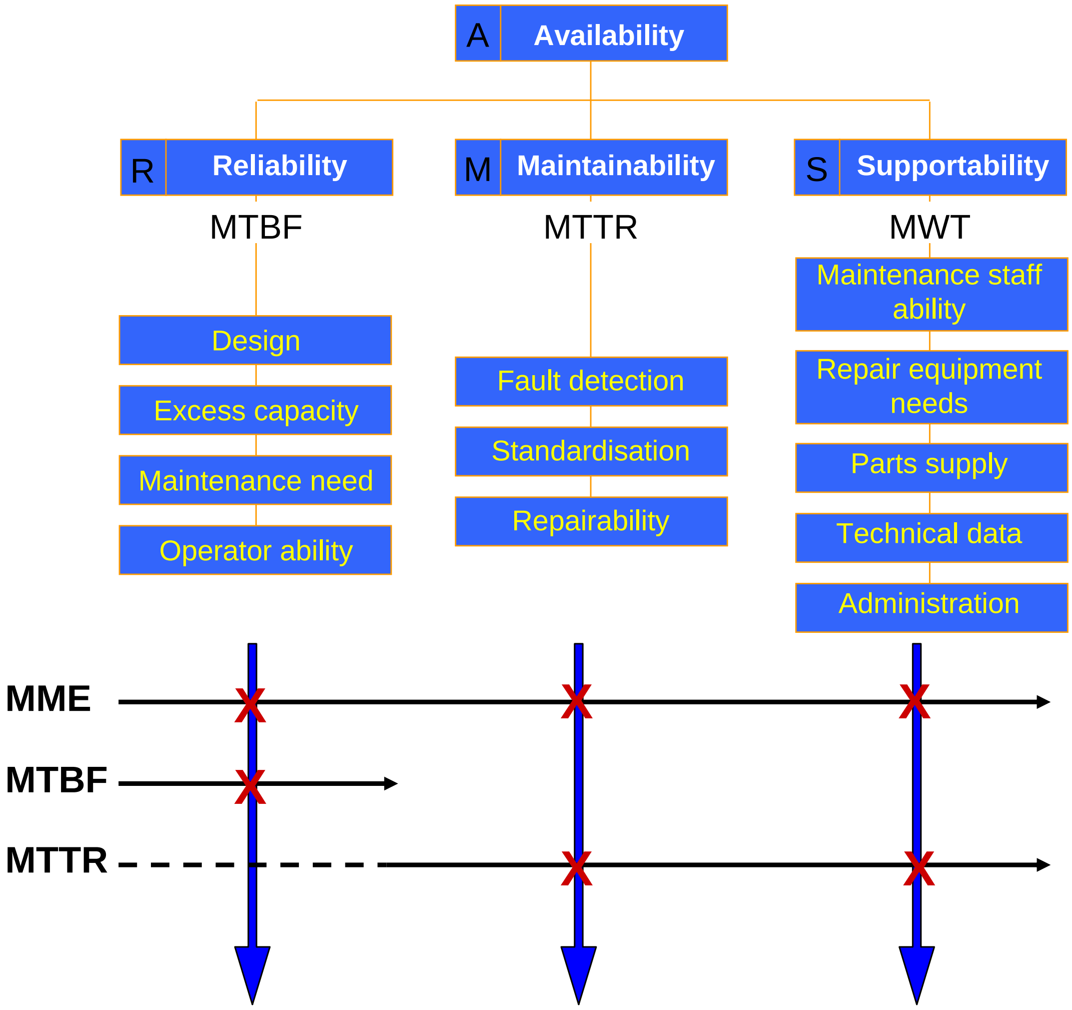


Figure 65: Equipment availability indicators

6.4.6 Overall equipment effectiveness

Overall Equipment Effectiveness (OEE) measures total performance by relating the availability of a process to its productivity and output quality. OEE addresses all losses caused by the equipment, including:

- equipment not available when needed because of breakdowns or set-up and adjustment losses
- equipment not running at the optimum rate because of reduced speed or idling and minor stoppage losses
- equipment not producing first-pass quality output because of defects and rework or start-up losses.

OEE was first used by Seiichi Nakajima, the founder of total productive maintenance (TPM), in describing a fundamental measure for tracking production performance. He challenged the complacent view of effectiveness by focusing not simply on keeping equipment running smoothly, but on creating a sense of joint responsibility between operators and maintenance workers to extend and optimize overall equipment performance. OEE is calculated by multiplying three factors: availability, productivity, and quality.

% OEE = (%Availability) x (%Productivity) x (%Quality)

The values used can reflect an entire processing plant, a process line, or an individual piece of equipment.

Equipment availability is not just assumed to be the length of the shift in which it is operated. Instead, it is based on *actual* operating time, as a percentage of the *possible* production time.

% Availability = actual production time / possible production time

Here is an example: An ALF line is operated 24 hours a day, 5 days a week (120 hours). Planned downtime for preventive maintenance is 1 hour each week. Unplanned downtime due to equipment failure and equipment adjustment is 7 hours.

% Availability = (120 - 1 - 7) / (120 - 1) = 112 / 119 = 94,1%

Productivity can be calculated by looking at the actual output produced by the equipment as a percentage of the theoretical output, given its optimum speed and actual running time. Here is an example: The sustained capacity of an ALF line is 40 millions of packs per year. Last year it produced 37 millions of packs.

%Productivity = actual production / optimum capacity = 37 millions / 40 millions = 92,5%

The quality rate used in OEE calculations is defined as:

% Quality = product produced - (scrap & rework) / product produced

For example, an ALF line produced 37 millions of filled packs on yearly base, but only 36 millions met the commercial specifications on the first pass.

% Quality = 37 - (37- 36) / 37 = 37 – 1 / 37 = 97,3%

OEE = availability x productivity x quality = 94,1 x 92,5 x 97,3 = 84,7%

6.4.7 How to measure maintenance effectiveness

As we saw in the previous sections, performance of the line is to be measured to identify if the effort spent on maintenance produces the expected results on the ALF line operation. In this regard a preventive maintenance program represents a real company investment and the line performance effectiveness the indicator used to measure the result of this investment. OEE measures the effectiveness of:

- Availability of the line (depending on reliability, maintainability and supportability)
- Quality of the line (depending on product waste and product quality).

The effectiveness produced by a serious maintenance programme will show a positive result on both, equipment availability and product quality and safety. At the end, as shown in Figure 66, line performance is the result produced by the equipment availability and product quality.

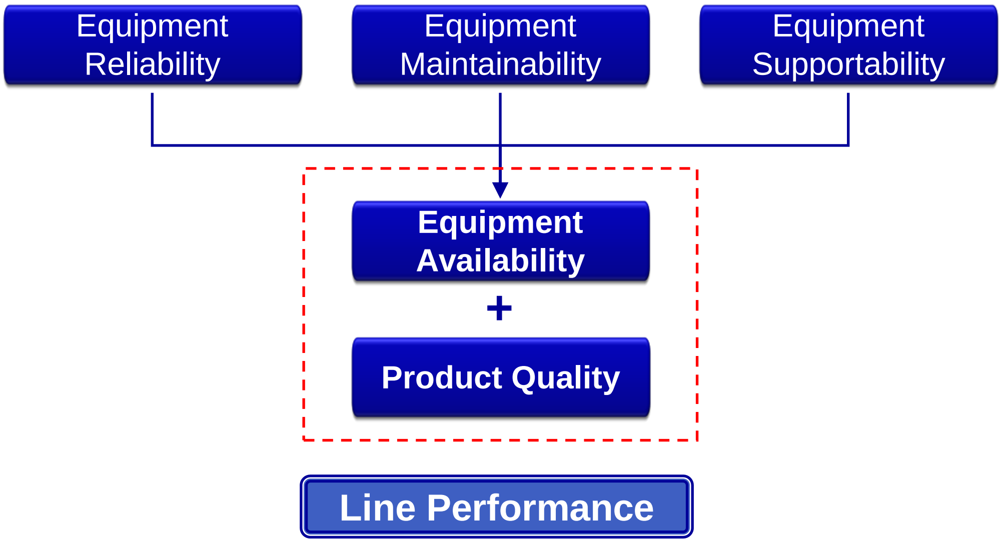


Figure 66: KPI to measure line performance [27]

While equipment effectiveness is the indicator used to measure the results produced by a specific maintenance program on the line performance, maintenance cost is used to identify the economical effort put in place to maintain the equipment. Basically, maintenance cost depends on:

- manpower used to carry out preventive and corrective maintenance
- spare parts used on different maintenance occasions
- any other tool or support used to maintain the equipment.

The manufacturing company's competitiveness is heavily dependent on both, line performance and maintenance cost. Figure 67 shows the LCP with maintenance cost which represents the investment that produce an added value measured through the key performance indicators that highlight equipment effectiveness and product safety.

- <u>Direct maintenance costs</u>

Direct maintenance costs are those related to manpower (salaries), spare parts, templates and technical documentation (this is the investment that should produce added value).

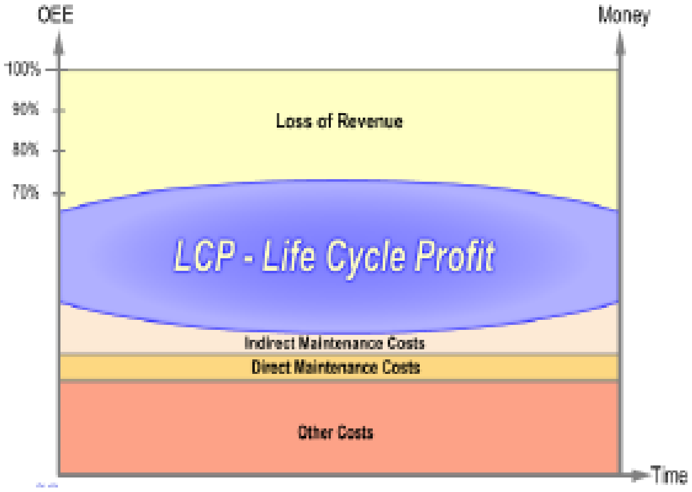


Figure 67: Life Cycle Profit (LCP) [27]

- <u>Indirect maintenance costs</u>

Indirect maintenance costs are all the costs generated by insufficient or lack of maintenance. Lack of maintenance affects not only maintenance costs, but also operational and capital costs. In the ALF industry these costs can be really heavy and could be due to non conformity products claimed from the market or even worse to product unsterility discovered on the company's warehouse or on the market. Packaging material and product waste represent another source of cost that can be produced by a poor maintenance program that increase manufacturing costs of an ALF plant.

- Loss of revenue

Every hour of equipment standstill or rejection of products should be interpreted as a loss of revenue. This loss can usually be measured through the net profit margin that the company should have earn in selling the packages not produced because of equipment failure. A maintenance program based on corrective approach only may result in poor equipment availability and unpredicted equipment downtime.

Here below an example, drawn from a real writer's experience, shows the deployment of indirect costs of company (A) that refuse to implement a preventive maintenance program, based on reliability and safety methodologies, with the cost reduction experienced by a similar company (B) that implemented a preventive maintenance program.

The cost analysis, carried out during a quality audit, have shown these main costs:

- *Indirect costs of company (A):*

(a) packaging material waste: 4% on 200 millions of packs/year = 850.000 Euro
(b) Product unsterility/year: No. 2 main cases = 35.000 Euro
(c) Non conformity product: No. 60.000 non conformity packages = 10.000 Euro
(d) Energy loss: due to equipment downtime = 2000 Euro
(e) Chemicals loss: due to cleaning phases following equipment failure = 5000 Euro.

Total indirect costs = 902.000 Euro.

- *Indirect costs of company (B):*

(a) packaging material waste: 2% on 200 millions of packs/year = 423.500 Euro
(b) Product unsterility/year: No. 1 small case = 10.000 Euro
(c) Non conformity product: No. 7.000 non conformity packages = 2.000 Euro
(d) Energy loss: due to equipment downtime = 1200 Euro
(e) Chemicals loss: due to cleaning phases following equipment failure = 2000 Euro.

Total indirect costs = 438.700 Euro.

- *Loss of Revenue*

If the net margin, for each filled package produced, is 10 Euro cents, and the packages lost (not produced) in one year, from company (A) compare to company (B), because of equipment inefficiency, are four millions higher, then the annual loss of revenue of company (A) compare to company (B) is 400.000 Euro higher.

- *Direct costs*

The direct costs, including among others, manpower, spare part costs, and external training and services costs, have shown that costs of company (B), compared to company (A), were higher than 40.000 Euro.

The costs comparison between these two similar companies emphasized that an investment of 40.000 Euro, in a new preventive maintenance program (direct cost), has generated the following savings on the other cost indicators:

- Indirect costs: 436.300 Euro
- Loss of revenue: 400.000 Euro.

The savings showed above represent the result of important changes in the company's (B). The tendency to overestimate direct costs without considering the potential savings that can be obtained on the other cost indicators, is self-explanatory of an old management culture unable to get an holistic view of manufacturing reality.

The graph shown in Figure 68, identifies the area where an optimum costs balance can be found. A short term cost view can often be seen as a way to reduce cost, especially during downturn time, but it can shows terrible effects on indirect maintenance costs and on loss of revenue.

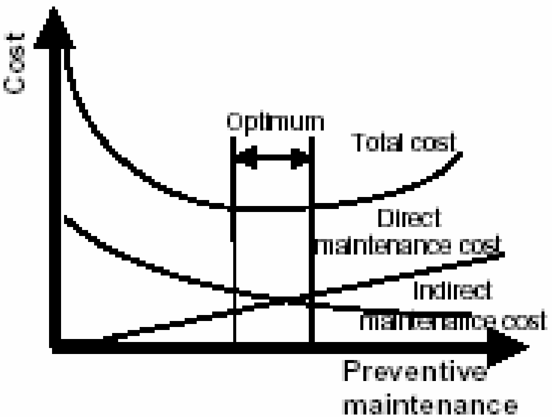


Figure 68: Maintenance costs

The operational cost for thousand packages produced can be calculated as shown in Figure 69 below.

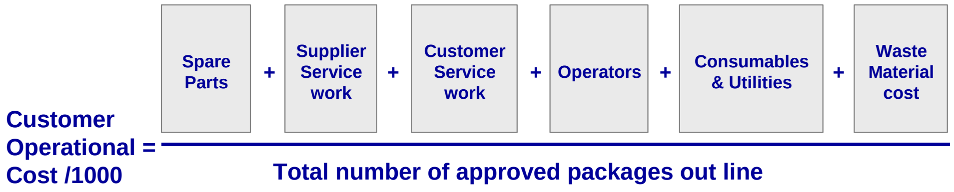


Figure 69: Manufacturing operational cost per thousand packages produced [33]

Because maintenance is sometimes perceived as a disturbance, some manufacturing units consider production as the sole added value activity that takes place in the shop-floor. Where this view prevails, management is characterized by a reactive approach based on short term problem fixing. As result the short term view of the company’s management does not allow the implementation of a competitive maintenance plan (investment) and to realize the benefits coming from less operational cost and higher product safety.

6.4.8 Analysis of KPI and task list improvement

The scope of this section is not only related to the analysis of KPIs, but to the identification of:

- a systematic monitoring routine that suit the ALF environment needs
- the team to be involved in the measuring activity
- the main topics to address during the analysis of KPIs
- the corrective/improvement activities to be put in place after analysis
- the task list revision process with the improvement procedures.

These activities represent the basic tool for the appraisal of maintenance task list effectiveness and for the continuous improvement of the task list design.

The improvement will regard both the working method and the content of maintenance tasks, according to the feedback coming from the field.

Since maintenance effectiveness is not a matter of a sole reliability, all the conceivable factors that could have a direct impact on effectiveness will be taken under consideration to maximize the implementation and then the maintenance effectiveness.

6.5 Conclusion

In this chapter, following the literature review, an analysis of different maintenance implementation models, normally used in industry, have been done. This analysis produced the identification of implementation principles to be used in the design of the implementation model proposed for ALF industry.

Here below a list of some of the benefits produced by this model:

- It provides a clear pathway to answer the question: “how to avoid to loose the advantages of an effective maintenance task design”. The threats that could limit the benefits coming from a reliable maintenance design phase and regarding the technical, organizational and cultural dimensions have been considered and managed.
- It provides the opportunity to gain the commitment of all the parties involved in pursuing higher equipment reliability and product safety at the minimum operational cost
- It represents a cultural evolution in pursuing the integration of different company’s roles to work as a sole body in implementing the different maintenance tasks
- It is a tool to empower the people involved through different training sessions and team activities carried out by equipment operators, maintenance specialists and quality experts
- It shows the opportunity to maximize the implementation effectiveness defining both maintenance task contents and the more convenient way to implement that tasks
- It shows the solution for an effective implementation of autonomous maintenance carried out by the equipment operator, that combine all maintenance activities, starting from cleaning up to inspection and autonomous equipment management.

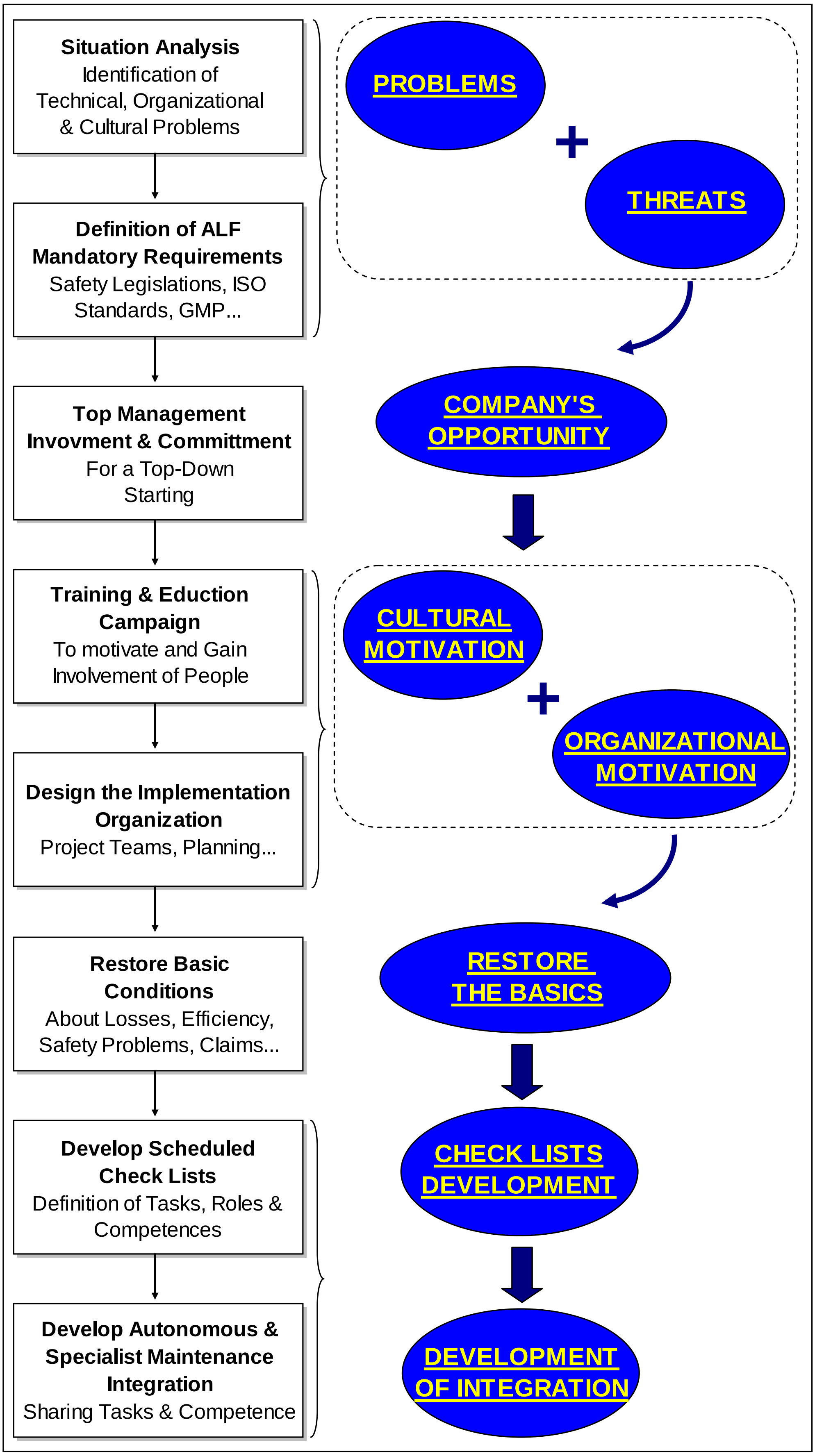


Figure 70: Proposal of a maintenance implementation model for ALF industry

The model proposed in this chapter and summarized by the diagram in Figure 70 above, represents an important and original tool to prevent that the outcome of maintenance design phase is just a good theory without the possibility of delivering real benefits in the real industry world. Since maintenance represents an investment and not a cost, in this chapter, the different KPI's used to measure maintenance and production effectiveness have been introduced and explained. The purpose of such indicators is to "measure" the effectiveness of a production line according to the customer/producer view and then to the equipment operation with a specific focus on equipment performance. The "Overall Equipment Effectiveness" (OEE) indicator has been introduced and its value explained.

At the end of this chapter, basic economical indicators such as: direct and indirect maintenance cost and loss of revenue, have been introduced to provide the tools useful to measure the Profit and Loss (P&L) of the packaging line and to assess if the investments done in maintenance produces the expected results.

7. CRITICAL FACTORS IN THE DESIGN & IMPLEMENTATION PROCESS WITH RELATIVE SOLUTIONS

7.1 Introduction

In this chapter, the most important critical factors that need to be managed during the design and implementation process have been identified and analyzed. Figure 71 below shows the three main manufacturing dimensions that need to be investigated to avoid that potential threats coming from each dimension could limit the achievement of maintenance and manufacturing effectiveness.

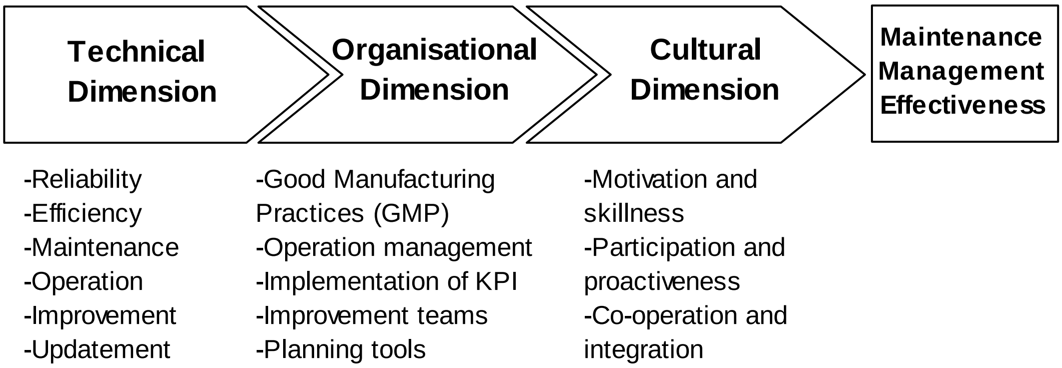


Figure 71: Technical, organizational and cultural dimensions for maintenance management effectiveness

The scope of this chapter is to determine a deep awareness in people involved in the project about technical, organizational, human, and cultural criticalities that prevent the achievement of targeted product safety through maintenance effectiveness because of the restraining forces. Technical, organizational, and cultural problems that could reduce the effectiveness of the design and implementation process are examined to identify the key arguments that need to be analyzed and solved.

The main questions that need to be addressed and solved are:

- What kind of technical problems could limit the effectiveness of the design and implementation process?
- What is the organizational model that enables an effective maintenance design and implementation?
- How to overcome the restraining forces due to barriers placed by the organizational and cultural inertia?

The guidelines and tools developed in this chapter represent the solution to convey each critical issue towards a model that provides a way to overcome obstacles and barriers in a structured way.

7.2 Technical drawbacks

With technical drawbacks we refer to:

(a) Technological or reliability problems placed by some of the equipments available in the production line
(b) Lack of technical documentation available for some equipments of the line
(c) Lack of training or service support for the equipment

7.2.1 Equipment reliability and technological problems

Sometimes equipments show reliability problems that produce real production line bottlenecks that cannot be overcome through a suitable maintenance program.

If we are dealing with home/tailor made or customized equipment with reliability problems, we have to be aware that involvement of the equipment designer represents a mandatory step necessary to identify both the unreliability causes and an improvement program to upgrade the equipment up to an acceptable reliability level. Since reliability design problems cannot be solved through maintenance it is very important to identify the inefficiency reasons that produce a poor line or equipment performance.

These reasons could depend on the following subjects:

- Old technology
- Equipment layout
- Services and utilities
- Complex or difficult equipment operational practices.

To gain a clear picture about the problems and relative causes that determine low line efficiency the following procedures should be implemented:

(1) Production audit

Through a production audit, carried out by a trained staff, it is possible to gather numerical figures that highlight the different causes behind production stops.

(2) Production stop categorization

Production stops related to equipment, to practices or utilities must be split for systems, sub-systems and stop category type.

(3) Production stop prioritization

The different stop reasons with relative categorization, must be weighted according to the intensity of disturbance produced during the normal operation

(4) Analysis of priorities

After a selection of main stop reasons, a deeper analysis of potential causes must be undertaken to identify the technical reasons behind every stop

(5) Equipment improvement

A detailed list of problems, with causes that determine equipment or line inefficiency will be examined by the equipment designer or supplier to identify the corrective design activities necessary to overcome technical drawbacks and produce better equipment performance.

7.2.2 Lack of technical documentation, training and service support

Sometimes lack of documentation determines equipment inefficiency due to the inability of people to manage technical matters according to standards and specifications that are missing. This lack could be referred to the following missing documentation:

- Operational Manual (to identify the operational standards: practices and procedures)
- Maintenance Manual (to identify the mechanical standards: settings and measures)
- Electrical Manual (to identify the electrical standards: settings and measures)
- Spare Part Catalogue (to identify parts and components specifications).

When this documentation or part of it is missing, the impact on equipment or line efficiency could be really meaningful. The inability to identify the technical standards to avoid tailored operational procedures and maintenance activities could determine a source of uncertainty that is quite often the reason of poor line effectiveness.

Lack of technical training based on reliable documentation, lack of qualified service engineers and service support for equipment upgrade or lack of a spare part catalogue, could be one of the reasons of low line efficiency.

To overcome these problems there are two possible solutions:

1. Produce, with the support of the equipment designer or supplier, the required documentation or
2. Establish a team of company's specialist able to develop the standard documentation and to support the personnel with the required training activities.

Sometimes because of:

- Equipment price competition and
- Immediate satisfactory equipment performance result,

technical managers do not verify if the technical documentation is complete and reliable and if technical and operational standards have been clearly defined by the equipment supplier. In the medium-long term the presence of technical and operational standards and specifications will play a very important role in ensuring both higher operational performance and product safety. Lack of clear technical specifications about mechanical and electrical settings will produce an unreliable maintenance approach; and, on the other side, lack of clear standards on operational and quality practices will result in a low production effectiveness and product safety. For this reasons the check list used by the technical managers to assess the equipment suppliers should mandatory contain these important requisites.

7.3 Organizational drawbacks

The organizational model for the ALF industry can give a great contribution to maintenance effectiveness if some important quality methodologies become the source of inspiration in promoting co-operation and best practices and in removing inertia and bureaucracy.

7.3.1 Lack of autonomous maintenance carried out by the equipment operator

The organization in place in some ALF plants shows traditional boundaries among different departments and narrow definition of roles and functions. Normally equipment operators are not involved in maintenance activities for the following reasons:

- Lack of the necessary skill, and

- Different company policy.

Regarding the equipment operator role, few companies normally establish a serious training program to enable the operators to grow to the level required to carry out autonomous maintenance. This situation emphasises that maintenance activities are considered the sole domain of technical specialists. The concept “*I produce and you repair*” is generally well established for the following reasons:

- Narrow view of equipment operator role
- Fear to increase equipment operator salary
- Fear to obtain lower equipment efficiency and availability.

Against operator involvement in autonomous maintenance activities, plays an important role the unavailability of technical and quality specialists to share their experience with equipment operators. Frictions among different departments is sometime another adverse force which leads the departments to limit their co-operation.

To be able to implement maintenance procedures effectively, the role of equipment operator must be designed to carry out autonomous maintenance and good manufacturing practices that have a direct impact on equipment criticalities identified in the HACCP process. To avoid this organizational drawback, top management must continue to support the whole organization and middle managers should ensure a wider participation of technical specialists for a real integration of company’s roles.

7.3.2 Lack of management commitment and involvement

Lack of management commitment, due to a poor knowledge and awareness of benefits coming from maintenance engineering, represents a problem that has a strong impact on ALF organization. The adjective *Total*, regarding the productive maintenance implemented, means that maintenance function is enlarged to the totality of the personnel working in the company. It is not the sole maintenance function responsible for its implementation, but all the company regularly motivated and supported by top management. One of the reasons for maintenance implementation failure resides also on the inability of the management to cope with the complexity of the implementation process. Sometime managers refuse their own commitment and involvement in supporting the activity of improvement teams, and this often is the reason of poor participation and poor maintenance and production effectiveness.

To overcome this problem it is very important to gain management commitment since the very beginning and design the involvement of management at different level of maintenance and production organization.

7.3.3 Lack of a planning & measuring system

Maintenance activities must be planned and someone should be directly responsible to develop and update a master plan in each department. A short term view of maintenance, based on a reactive approach, combined with the daily production pressure, could represent an obstacle for planning maintenance activities that have been designed for the line equipments. The maintenance activities designed must be planned and regularly monitored to verify if:

- They are regularly implemented
- They are effective, both in quality and in time
- Improvement or corrective actions need to be implemented.

A common production management drawback resides on inability to establish a management system based on measure. On the other side, a measurement system itself is not enough if the measures obtained are not analyzed and improvement and corrective actions applied. The KPI used to measure maintenance and production effectiveness should be regularly updated and shared with the people involved at different levels. These measures must be compared and contrasted to identify the areas where further improvement can be designed and implemented.

7.4 Cultural drawbacks

Lack of basic maintenance engineering knowledge, quite often, does not enable middle management to motivate company’s employees, to support them in overcoming problems during the implementation phase.

7.4.1 Old management culture

Because maintenance is sometimes perceived as a disturbance, some manufacturing units consider production as the sole added value activity planned in the shop-floor. In these realities, characterised by a reactive approach, based on short term problem fixing, emphasis is placed only on production: output has to be produced on time, at the minimum cost and in the ordered quantity. To support this culture, managers argue that the reliability of the technology available today enables reduction of equipment downtime and that corrective maintenance is the only maintenance approach needed in this context. As result the short term view of company's management does not allow to build up a competitive plant: lack of quality methodologies, bureaucracy and barriers among the departments determine poor equipment efficiency and product safety.

The analysis of the culture in an ALF company is an important prerequisite to carry out before maintenance engineering implementation can take place. If the forces which are ranged against maintenance design and implementation are not examined and managed in advance, implementation failure can be experienced.

Figure 72: Restraining forces and countermeasures

As pointed out by Andrew Leigh in the book "Effective Change 20 ways to make it happen" (1998), Field Force Analysis (FFA) technique [47], as shown in Figure 72 above, enables one to list the cultural restraining forces in place in the organization, to carry out an analysis for the implementation of different countermeasures necessary to move to a state of production effectiveness.

7.4.2 Workforce culture

Psychologists such as Maslow, Hezeberg, Adams and McGregor developed theories which identify human needs and how they affect job performance. TPM and WCM workforce culture are based on McGregor's theory Y (1960) which states that people have a hierarchy of needs (as specified by Maslow) that they naturally perform well in the service of objectives to which they are committed and that they learn and seek responsibility [48]. The substantial gap existing between Japanese and European job culture can be ascribed to:

- Japanese Human Resource Management (HRM)
- Collaboration between Japanese government and industry
- Japan’s position as a late developer

Mac Duffie [49] argued that HRM is particularly important in determining quality. Japanese employees typically enjoy much longer-term relationship with their employing organisations and hence have a much stronger sense of “shared destiny”. Work systems are based on team-working and quality circles and responsibility for quality lay with production workers. HRM policy is gauged by the sophistication of selection and training procedures, the extent of single-status conditions and the presence of “contingent compensation” performance-related pay. Despite in the last two decades many western companies implemented different TQM projects, the culture is still too much based on strong functional departments which make interdepartmental co-operation difficult. The culture in many European ALF industries is at the present too much based only on short term company results. Latest technology, marketing and commercial issues are considered the sole competitive tools able to produce higher market share. The human resources are a sort of necessary evil, but not a winning factor to manage for a higher market share. This suggests particular care in designing maintenance implementation plan, in defining training programmes and in team work formation.

7.4.3 Training for equipment operators and maintenance specialists

The implementation models suggested by TPM and WCM, has been modified to meet the requirements of ALF environment to embodies HACCP methodology, to satisfy both EEC legal requirements and maintenance effectiveness requirements. Autonomous maintenance, carried out by those who operate the equipment, must include regular monitoring activities of CCPs of the process. Furthermore GMPs already in place in many ALF environments suggest some tailoring activity in defining AM procedures for equipment operators. Because of low company’s status, suffered by the equipment operators and cultural boundaries existing between production and maintenance departments, strong effort has to be placed in supporting small group of activities.

Most industries today are organised with maintenance on one side and operations on the other. Although both sides have the same goal: to be a productive unit in a company making a profit, the organisational line frequency gets in the way, causing delays and production stoppages. According to Figure 73 below, operators and specialists each have clearly identified skills and both do only those skills designated as their own.

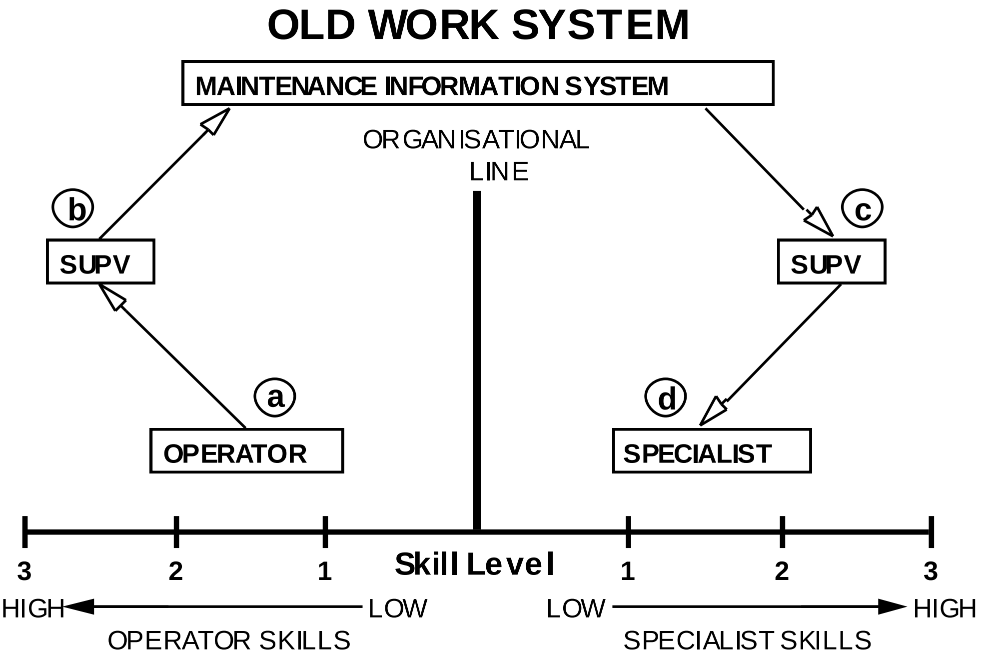


Figure 73: TPM that works [28]

TPM combines operators and maintenance personnel into a single team which identifies existing tasks that cause delays, create waste and reduce productivity. This figure illustrates the inadequacy of the old work system. If a machine operator observes that a cutting knife needs to be replaced, he or she reports the problem to his or her supervisor, who initiates a work request. The work requests is transferred through the Maintenance Information System (either electronically or on paper) to the maintenance supervisor, who will contact the specialist and assign the job. When the specialist arrives at the job site, he or she must find the operator and get him or her to come to the job site to replace the knife. At this point, the work can actually be done.

This example shows that the organisational line has required a tremendous communications effort for the completion of a simple maintenance task. This administrative system consumes much time, promotes inefficiency, causes longer downtimes, increases costs and decreases productivity. The production delays which are caused by this relationship, as it exists in most companies today, make the implementation of new maintenance procedures an essential tool to improve equipment availability and reliability. This approach, as result, shows that on as-needed basis, operators perform some tasks that were once thought to be exclusively “maintenance” tasks.

7.5 Conclusion

In this chapter the three main company’s dimensions (technical, organizational and cultural) have been examined to identify some of the critical factors that need to be managed to avoid design and implementation problems with the relative inefficiencies.

A common denominator that cross these three dimensions is strongly based on cultural drawbacks depending on:

- Lack of knowledge
- Short term view of manufacturing activities
- Reactiveness instead of proactiveness
- Lack of integration and communication
- Departmental boundaries and bureaucracy.

For each critical factor a solution has been provided, but a reliable and lasting solution will depends on ability to gain a wider participation of people through team activities and strong cooperation. Top and middle managers have the fantastic opportunity to shape the future according to their ability to listen, learn and share the vision with all the company’s functions. On the other hand, shop-floor workers need to know that their flexibility to share knowledge, to work with others and to give their positive contribution to the team work activities are the key ingredients to facilitate the bottom-up company’s change. Figure 74 below summarizes the technical, organizational and cultural drawbacks identified in this chapter and solutions found.

No.	*Problem Issues*	*Note*	*Solutions Proposed*	*Result*
1	**TECHNICAL DRAWBACKS**			
1.01	**Equipment Reliability & Technological Problems**		Production Audit	To gather numerical figures that highlight the different causes behind production stops.
	Old Technology	Obsolete/Old Equipment	Production Stop Categorization	Production stops split for systems, sub-systems and stop category type.
	Packaging Line Layout	Layout with Bottelenecks	Production Stop Prioritization	Stop reasons are weighted to identify the intensity of disturbance to normal operation.
	Services & Utilities	Unreliable Equipment	Analysis of Priorities	Analysis of potential causes to identify the technical reasons behind every stop.
	Complex Operational Practices	Complex and Unreliable Practices	Equipment Improvements	Identification of corrective design activities to overcome technical drawbacks.
1.02	**Lack of Technical Documentation, Training and Service Support**			
	Lack of Operational, or Maintenance Manual, or Electrical Manual	Lack of clear technical specifications	Produce the required documentation (with support of equipment designer/supplier)	Production of a standard documentation
	Lack of Spare Part Catalogue	Lack of spare part specifications	Establish a team of supplier or company’s specialist to develop documentation and training	Production of a standard documentation
2	**ORGANIZATIONAL DRAWBACKS**			
2.01	**Lack of autonomous maintenance carried out by the equipment operator**	Equipment operators are not involved in maintenance activities	Define the equipment operator role	Clear definition of equipment operator role
	Lack of the necessary skill	Narrow view of equipment operator role	Establish an AM training program for operators	Equipment operator trained to perform AM
	Different company policy	Fear to increase equipment operator salary	Top management support	Top management support the AM carried out by the equipment operator
2.02	**Lack of management commitment and involvement**			
	Poor knowledge and awareness of benefits coming from maintenance engineering	Lack of knowledge about advantages of AM	Management commitment towards the new maintenance implementation model	Management support the implementation program
	Management inability to cope with the complexity of the implementation process	Implementation drawbacks	Training program for different categories of management	Management trained to cope with the implementation complexities
	Poor participation due to lack of management support and participation	Poor participation of specialists in the project team activities	Management involvement in project team activities	Management fully support the project team activities with their participation
2.03	**Lack of planning & measuring system**			
	Short term view of maintenance based on a reactive approach	Lack of a reliable maintenance planning	Develop a maintenance plan to be regularly updated	Regular execution of maintenance activities according to plan
	Daily production pressures	AM not regularly implemented	Awareness of benefits coming from systematic AM implementation	Regular AM implementation
	Inability of management to establish a line management system based on measure	Lack of KPIs to measure maintenance and production effectiveness	Awareness of benefits coming from a management system based on measure	Definition of KPIs with regular measurement of production and maintenance effectiveness
3	**CULTURAL DRAWBACKS**			
3.01	**Old management culture**			
	Consider production as the sole added value activity	Lack of quality and maintenance engineering techniques	FFA to deploy the solutions	Maintenance activities are implemented with full support of management
	Reactive approach based on short term problem fixing	Bureaucracy and barriers among the departments	Implementation of product safety and maintenance engineering techniques	Management pursue the integration of equipment operators with maintenance specialists
3.02	**Workforce culture**			
	Lack of objectives and lack of rewarding tools like pay-performance systems	Lack of clear objectives and poor effort in pursuing production effectiveness	Define company's objectives and a pay-performance/rewarding system	Objectives difined and communicated and rewarding system implemented
	Lack of employee longer-term relationship and sense of "shared destiny"	Poor motivation and performance	Identify company's incentives that promote quality and efficiency	Company's incentives implemented
	Lack of working teams and quality circles	Poor integration and participation	Empower different categories of people for a higher proactive perticipation	Operator and maintenance specialist empowered and integrated through proactive participation
3.03	**Training for equipment operators and maintenance specialists**			
	Split organization with maintenance on one side and operations on the other	Cultural barriers among departments, poor integration and delays	Autonomous Maintenance (AM) to establish co-operation between operators & specialists	Product safety & Equipment reliability management through AM

Figure 74: Technical, organizational & cultural drawbacks with relative solutions

8. CONCLUSIONS

8.1 Introduction

The sections of this chapter summarize the findings based on research questions identified in the first two chapters: these emphasized research conclusions and relative benefits. The analysis of the background to the research and the definition of problems led to the identification of criticalities in the ALF industry and the need of a maintenance design and implementation process specifically designed for this industry. The analysis of case studies produced:

a) the research questions,
b) the research activities and then
c) the definition of the process to design and implement maintenance procedures for ALF industry.

The critical factors to manage in the maintenance design and implement process have been addressed through the integration of engineering and quality techniques that provided the answer to product quality and safety requirements and to equipment reliability problems. This chapter summarizes conclusions about:

- research questions
- research findings
- solutions found and implemented
- contribution to knowledge.

The primary and secondary literature review allowed to find the material used during the development of the process to design and implement maintenance procedures.

8.2 Conclusions about each research question

This section highlights the research questions arose in the first two chapters and the solutions found.

8.2.1 Solutions to manage the effects produced by equipment failures and downtime

This research showed that while in mechanical industry a machine stop could have a low economical impact on production cost, in ALF industry, equipment stop can have tremendous impact on company's costs. The analysis of the case studies produced the research questions which highlight the necessity to develop a maintenance design and implementation process to manage and overcome product safety problems and equipment reliability issues. The HACCP analysis showed that some equipment failures could have serious effects on quality of the product packed and eventually on consumer's health. The solution to the problems produced by equipment stops was the maintenance design and implementation process able to link product safety and equipment reliability issues to address the criticalities of the food industry lines. The peculiarity of this process, compare to processes used to design maintenance procedures for other industrial sectors, is based on capacity to identify:

- the critical product quality and safety issues
- the effects produced by these criticalities
- the weight of each failure effect on product safety and on equipment reliability
- the maintenance tasks for each failure type
- the maintenance organization and competence necessary to implement the task lists designed
- the way to overcome problems encountered during the implementation phase.

The starting requirement for the maintenance design process was the necessity to identify all conceivable CCPs existing in the manufacturing line, and that could influence the quality and safety of product packed. The application of the HACCP and HAZOP techniques represented the solution for the identification of the equipment and process criticalities that produce biological, chemical, and physical risks of product packed. Risks have been weighted to produce a list of priorities that have a direct impact on final product safety. Product safety and equipment reliability issues, with the relative criticalities, have been put together to gain a global picture on existing safety and reliability risks. As result, a list of priority has been developed according to the outcome coming from safety and reliability analysis. The development of maintenance task lists, able to control ALF packaging line criticalities, was the last design phase necessary to provide a solution to equipment stops and potential consequences on product packed.

The implementation constrictions coming from three main company's dimensions: technical, organizational and cultural, have been solved through the deployment of countermeasures coming from application of maintenance engineering techniques.

Top management involvement, training & education for different categories of people and organizational redesign led to the identification of deviations from the standards, and then to a restoration of basic conditions for a reliable implementation. Finally, autonomous & specialist maintenance integration was achieved through Autonomous Maintenance (AM) to effectively implement maintenance tasks that maintain the equipment under HACCP control. The maintenance design and implementation process represents the main answer to the problems produced by the equipment stops, which can determine product quality and safety non-conformities together with unpredictable economical losses.

8.2.2 Solutions to establish compliance with product safety directives and standards

As we saw in the first two chapters, pressures exerted by the EU legislation call food manufacturing companies to identify:

- the existing criticalities on production lines and
- the preventive maintenance actions to avoid product quality and safety problems.

Hazard Analysis of Critical Control Points (HACCP) is the production process control methodology selected, as a solution, to:

a) identify and assess specific hazards,
b) estimate risks and
c) establishes control measures that emphasize product safety prevention and control rather than reliance on end-product testing and traditional inspection methods.

HACCP application ensures that all conceivable risks depending on the whole production process are under control, and that corrective actions have been established to avoid product safety hazards. To achieve product compliance with safety legislation, the maintenance design process has been built to embody safety, reliability, and maintenance engineering techniques. The application of HACCP and HAZOP allowed the identification of critical control points dependent on human errors and production practices (GMPs). The design process identifies and quantifies:

- the various types of failures,
- the failures distribution,

- the component/part life time,
- the categories of causes and
- the link between causes and effects on product packed.

Potential and Functional failures have been identified and the effects produced by each failure mode have been scored together with corrective and preventive measures. Safety & Reliability analysis carried out through HACCP and RCM allowed a global evaluation of failures effects to identify a Risk Priority Number, which embodies both product safety and equipment reliability issues. The Failure Mode Effect and Hazard Analysis (FMEHA) form have been designed to answer the specific needs in the Aseptic Liquid Food industry. This form list Safety & Reliability priorities based on global criticality due to the effects produced by different failure modes found during the analysis. Predictive, preventive, and corrective maintenance tasks have been designed as solution to increase resistance to failure, to reduce equipment failure probability and to establish product safety compliance.

8.2.3 Solutions to risks depending on human factor

The research findings show that risks associated to human behaviour can be reduced through the use of condition monitoring systems and sensors to automatically monitor critical parameters normally under human control. To avoid loos of control of critical parameters, such as those linked with machine sterilization or package integrity, this research suggested the mandatory use of on-line monitoring systems. These represent the most cost effective approach, based on the evaluation of the following criteria:

- the frequency distribution of failure
- the effects of failure on product quality and safety
- the effects of failure on equipment and production activity
- the probability to detect the failure under consideration.

To reduce human error probability and improve maintenance effectiveness, different condition monitoring techniques, such as infrared thermography, vibration, and oil analysis have been examined to determine higher maintenance reliability. The integration of these techniques represents a solution where the high criticality under consideration does not allow to leave minimum risks depending on human factor.

8.3 Conclusions about the critical factors to manage during the design and implementation process

Figure 53, in Chapter Seven, displays the three main company's dimensions in food manufacturing companies. Maintenance design and implementation process could suffer of variations and instability if the critical elements identified as "restraining forces" are not managed through a holistic view of manufacturing reality. The solutions found to this problem have been showed in chapter seven and summarized here below.

8.3.1 Solution to technical drawbacks

One common drawback depending on lack of technical documentation and standards is normally referred to customized equipments. The problem identified depends on:

- lack of clear technical specifications on mechanical and electrical settings
- lack of reliable standards on operational and quality practices
- lack of training or service support
- poor equipment performance due to poor and unstable reliability.

This problem can easily determine an unreliable maintenance design together with low production effectiveness and product safety. The solution found suggested the involvement of the equipment designer to identify the unreliability causes and an improvement program to upgrade the equipment up to an acceptable reliability level.

A more structured solution found consists in the implementation of the following procedures:

1. *Production audit*
2. *Production stop categorization*
3. *Production stop prioritization*
4. *Analysis of priorities*
5. *Equipment improvement.*

If the equipment supplier is not available the above procedures can be implemented by the company's specialists.

8.3.2 Solution to organizational drawbacks

The problem found is based on inertia and bureaucracy introduced by traditional boundaries among different departments, on narrow definition of roles and functions, which not allows the equipment operators to be involved in maintenance activities. The concept: "*I produce and you repair*", well established because of narrow view of equipment operator role, is often the cause of low equipment efficiency and availability. The solution found to avoid this organizational and cultural drawback consists in the top management commitment in establishing the new operator role and in leading the whole organization to a wider participation of people for a real integration between equipment operators and company's specialists. This solution enables the maintenance function to be enlarged to include all personnel working in the company. A master plan for an effective maintenance implementation, a regular monitoring activity to verify if maintenance checklists are effectively implemented, represent some of the tasks under management responsibility.

8.3.3 Solution to cultural drawbacks

The problem found showed that lack of basic maintenance engineering knowledge about positive results on production effectiveness and product safety, is often the cause that prevents the company's management to motivate different categories of employees and support them in the design and implementation phases.

Solution to old management culture

The solution found to overcome problems depending on reactive approach, on short term problem fixing, consists in the use of Field Force Analysis (FFA) technique:

- to list the cultural restraining forces in the organization,
- to carry out an analysis of the negative forces
- to identify the positive countermeasures necessary to move from a state of inefficiency to a state of production effectiveness.

Figure 54, in Chapter Seven, shows the basic approach to this solution.

Solution to lack of workforce commitment

The research showed that commitment of workforce could be a problem if the hierarchies of needs that affect job performance and promote employees empowerment, as a key issue to achieve company’s objectives, is not well established in the company.

The solution found to get an effective commitment of every employee involved in the maintenance design and implementation process is based on:

- Ability to look for a longer-term relationship with company’s organisations and workforce
- A much stronger sense of “shared destiny” among the parties involved.

The research shows that work systems based on team working and quality circles, where the responsibility for product quality and safety lies with production workers, enable people to move from a position of “follower” to “enabler”.

Solution to establish a close co-operation between equipment operators and maintenance specialists

Despite maintenance design and implementation process call for a close co-operation between equipment operators and maintenance specialists, the problem shows that operators and specialists often have rigid pattern of skills and both do only those activities designated as their own. The solution, suggested the implementation of autonomous maintenance (AM) and GMPs, carried out by the equipment operators with the support and co-operation of maintenance specialists. The AM activities promote a real integration of these two roles removing the cultural boundaries existing between production and maintenance departments.

8.4 Conclusions about the research problem

The analysis of ALF production environment underlined the importance of maintenance in determining both product safety and equipment reliability. Primary and secondary literature search showed the research problem that no literature is available to address and solve the criticalities of the ALF production lines through a maintenance process.

The maintenance design and implementation process for ALF represents the answer to the main research problem because of the following conclusions:

1) The design process integrates product safety techniques, such as HACCP and HAZOP to put under control CCPs and to determine, as result, highest end product quality and safety
2) The integration of some maintenance engineering and product safety techniques enable us to weight product safety and equipment reliability risks
3) The qualitative and quantitative analysis done allowed to define a maintenance prioritization necessary to identify maintenance tasks that answer the need of safety and reliability at reasonable cost
4) The condition monitoring systems and sensors have been used to control critical equipment functions to improve the overall maintenance effectiveness
5) The empowerment of the equipment operator role, and its integration with quality and maintenance specialists produced, as result, the effective implementation of autonomous maintenance procedures able to address and control ALF criticalities.
6) The KPIs used to measure equipment and maintenance effectiveness allow to measure efficiency, quality and cost elements that make the process particularly effective for food industries.

8.5 Possible solutions

The application of the mentioned solutions can be done through a set of maintenance procedures to implement maintenance tasks in the aseptic liquid food packaging lines context. A maintenance system is not only made up by a set of maintenance procedures, but from three other basic components:

1) A software program which prints out the check lists and records the service results for each maintenance occasion (AM plus all types of maintenance).
2) A production line monitoring system to measure equipment effectiveness, and able to supply information for continuous improvement of maintenance check lists.
3) A working team responsible to implement and improve the maintenance check list content.

Figure 75 below shows the relationship among the different components which make up this maintenance system.

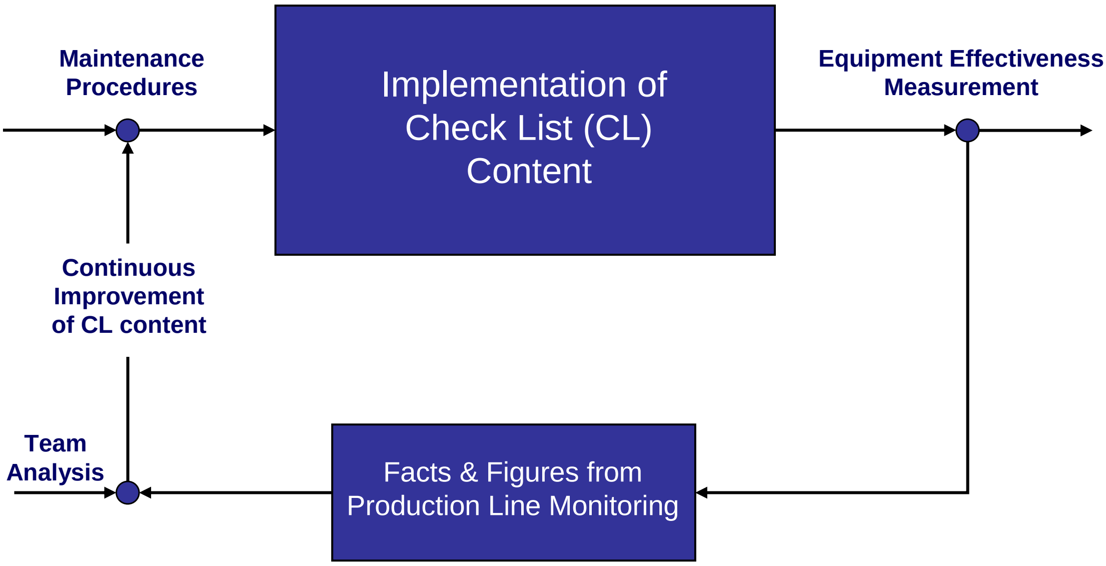


Figure 75: Check list implementation and improvement

Software Program

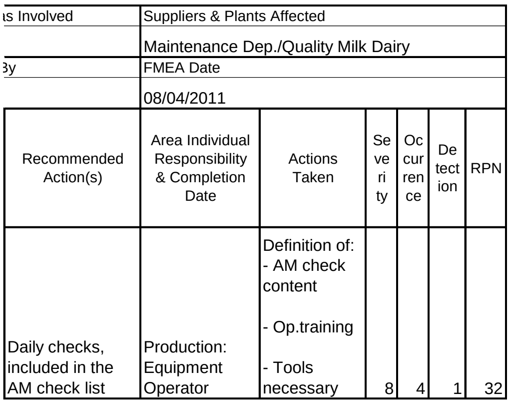
The maintenance tasks designed are normally stored in a software programme which enable to print out the specific check list for each service and to records the service results at each maintenance occasion.

Figure 76 below, shows a FMEHA form referred to a single component: since the RPN result is higher than the established limit (40), the corrective action decided is an AM check to be carried out by the equipment operator on a daily base. This improvement action produced an RPN reduction, from 64 to 32.

The maintenance design activities are stored in the software together with the maintenance check lists that show the maintenance tasks identified for each maintenance occasion.

FMEHA - Failure Modes Effect and Hazard Analysis (FMECA + HACCP)

Part or Process name							Design/Manufacturing Resp.						Other Area	
PACKAGE SEALING							A.Bianchi							
Series No./Dev.Step							Engineering Release Date						Prepared E	
20125/050V							6425/02							
Description of: (1) Part/Process (2) CCP (3) Operational Practice	Process Purpose	Identify the Potential Hazards: (B) Biological (C) Chemical (P) Physical	Critical Limits for each CCP	Deviations	Potential Failure Mode	Potential Effects of Failure(s)	Severity	Potential Causes of Failure	Occurrence	Current Controls	Existing monitoring procedures	Frequency	Detection	RPN
Sealing Inductors	Package Sealing	B	Electrical: (see EM 6.32) Mechanical: (see MM 5.20)	Electrical: +/- 10% Mechanical: +5%/-7%	(a) wrong settings (b) physical damages (c) Ca or PE residues	Bad seals Package with micro holes. Product unsterility	8	Electrical, Mechanical, Human error	4	Weekly 1000 hours	Electrical: continuous. Mechanical: W, 1000 work. Hours	Electrical: Automatic Mechanical: Weekly/ Manual	2	64



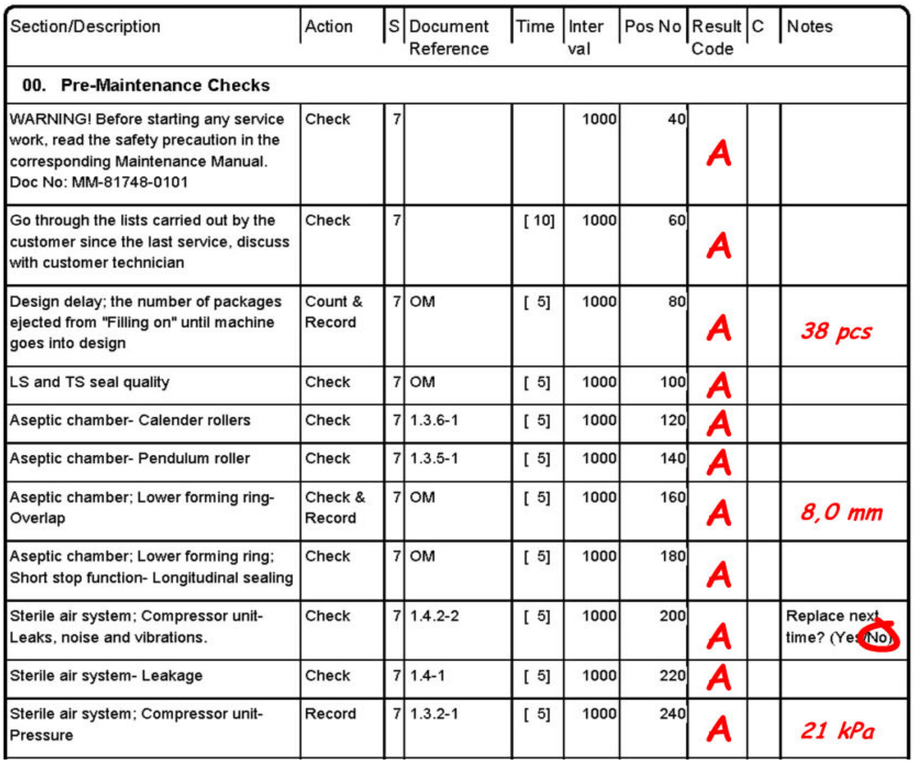
s Involved	Suppliers & Plants Affected					
	Maintenance Dep./Quality Milk Dairy					
y	FMEA Date					
	08/04/2011					
Recommended Action(s)	Area Individual Responsibility & Completion Date	Actions Taken	Severity	Occurrence	Detection	RPN
Daily checks, included in the AM check list	Production: Equipment Operator	Definition of: - AM check content - Op.training - Tools necessary	8	4	1	32

Figure 76: FMEHA form for sealing inductors

Figure 77 below shows an example of check list form with the following information:

- Description of maintenance tasks,
- Identification of technical documentation to be used as reference guide,
- Other information such as the time interval,
- A field to be filled with service result implemented
- A field with explanatory notes.

As soon as historical information are gathered, statistical figures can be obtained, to measure the component life time, the maintenance adjustment frequency, for each task, and the average time spent for each service activity.



Section/Description	Action	S	Document Reference	Time	Interval	Pos No	Result Code	C	Notes
00. Pre-Maintenance Checks									
WARNING! Before starting any service work, read the safety precaution in the corresponding Maintenance Manual. Doc No: MM-81748-0101	Check	7			1000	40	A		
Go through the lists carried out by the customer since the last service, discuss with customer technician	Check	7		[10]	1000	60	A		
Design delay; the number of packages ejected from "Filling on" until machine goes into design	Count & Record	7	OM	[5]	1000	80	A		38 pcs
LS and TS seal quality	Check	7	OM	[5]	1000	100	A		
Aseptic chamber- Calender rollers	Check	7	1.3.6-1	[5]	1000	120	A		
Aseptic chamber- Pendulum roller	Check	7	1.3.5-1	[5]	1000	140	A		
Aseptic chamber; Lower forming ring- Overlap	Check & Record	7	OM	[5]	1000	160	A		8,0 mm
Aseptic chamber; Lower forming ring; Short stop function- Longitudinal sealing	Check	7	OM	[5]	1000	180	A		
Sterile air system; Compressor unit- Leaks, noise and vibrations.	Check	7	1.4.2-2	[5]	1000	200	A		Replace next time? (Yes/[✓ No])
Sterile air system- Leakage	Check	7	1.4-1	[5]	1000	220	A		
Sterile air system; Compressor unit- Pressure	Record	7	1.3.2-1	[5]	1000	240	A		21 kPa

Figure 77: Maintenance check list form

Production Line Monitoring

The purpose of this system is to:

- measure equipment efficiency and effectiveness through the performance indicators already examined: MTBF, MTTR and MWT
- support continuous improvement of maintenance tasks through the analysis of the information provided by the system.

Working Team

A working team, composed by operators and specialists, responsible to carry out different maintenance activities, is a mandatory organizational tool to successfully implement the preventive, predictive and corrective maintenance procedures.

The team should be able to start and continuously improve the system. According to Figure 78, the activity of the team is not spent only in starting the system, but in pursuing its continuous improvement through the constant analysis of production line monitoring indicators.

Maintenance Improvement Team

- **Efficiency Improvement**
- **Task lists Improvement**
- **Elimination of Failures**
- **Predictable costs**
- **Reduction of Spare parts consumption**

Figure 78: Working team goals

Figure 79 below summarizes the main features of a maintenance management system which embodies the three main elements:

- software program,
- production line monitoring,
- working team.

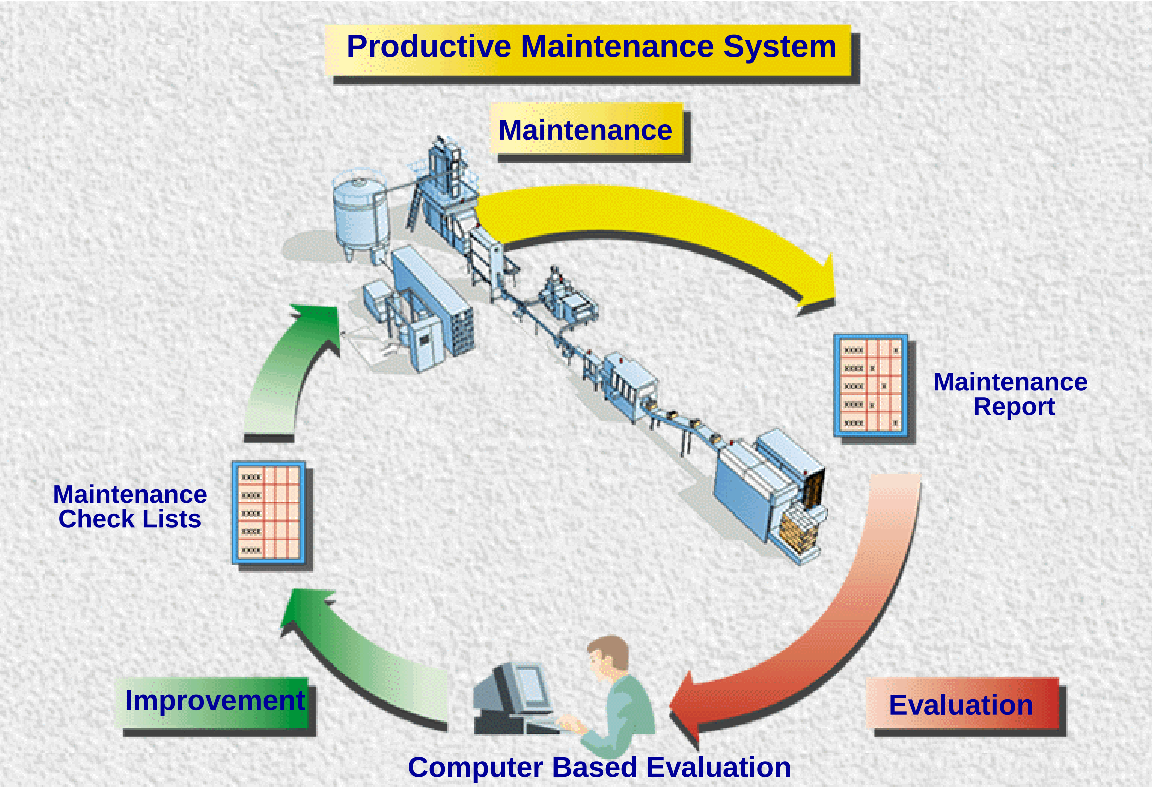


Figure 79: Maintenance Management System

The Figure above shows that:

- maintenance tasks designed are planned according to check lists content,
- a maintenance report, compiled by equipment operators and specialists, contains the service activities implemented,
- service results are stored in the maintenance software program,
- periodical analysis of KPIs enable the working team to identify the improvements areas where upgrades and updates can be introduced,
- improvements are stored in the system and spread in the check lists content.

8.6 Contribution to knowledge

Following a literature review, this research identified an important gap in the existing knowledge and regarding the lack of a maintenance process able to manage product safety and equipment reliability critical issues of the ALF packaging lines. Numerous researchers have focused their attention to maintenance engineering and reliability techniques highlighting the contribution of maintenance in achieving manufacturing effectiveness, but no maintenance process has been designed to manage the criticalities existing in the ALF production lines. Through the research methodology, based on analysis of different case studies, the research showed that low maintenance effectiveness could have dramatic effects on final product safety and on equipment reliability. The analysis showed that consumer's health could be affected by the biological, chemical, and physical risks existing in the packaging line, which can determine product safety problems. The scope of the research was to explore the gap existing between theory and real ALF maintenance status in industry to identify a process to design and implement maintenance tasks able to put under control food safety and equipment reliability critical points. The contribution to knowledge produced by this research is due to the definition of a maintenance process to design and implement maintenance tasks for the ALF packaging lines. This process allows to fill the knowledge gap providing a route map to design and implement maintenance tasks to manage ALF criticalities. Contribution to knowledge is mainly due to the following issues:

a) **Maintenance design based on safety and reliability analysis**

   The process to design maintenance tasks is based on safety and reliability analysis. HACCP, HAZOP, RCM, and other quantitative and qualitative techniques have been originally integrated to identify the equipment CCPs, their effects on product safety, on equipment reliability, and maintenance activities to put CCPs under control.

b) **Maintenance implementation based on autonomous maintenance for ALF environment**

   The autonomous maintenance (AM) has been designed to empower the equipment operator role to maximize maintenance implementation effectiveness for ALF packaging lines. The AM phases allow the equipment operator to become the main equipment owner in managing safety and reliability issues. The process identified represents an original way to implement maintenance tasks designed for ALF packaging lines.

c) **The KPIs used to measure equipment and maintenance effectiveness**
The KPIs, used to monitor equipment and maintenance effectiveness, measure availability, productivity, and quality factors to constantly monitor product safety and equipment reliability. The KPIs identified allow to display the added value of the maintenance process, the positive effects on product safety and equipment reliability.

8.7 Future research and work

This research identified a maintenance design and implementation process for aseptic liquid food industry. This process has been designed to address and manage the criticalities existing on production lines for packing liquid food intended for human consumption. Quality techniques, have originally been integrated with maintenance engineering techniques, to define a maintenance design process able to identify product safety risks and to design maintenance tasks to put these criticalities under control. The author of this research is strongly convinced that this work shown the way to manage the food industry criticalities, dependent on equipment and operational practices, through a reliable maintenance process. Future research can be done to continue the integration of maintenance engineering and safety techniques to pursue product safety and equipment reliability goals for food industry sectors. Further research could, perhaps, investigate different types of risks and find specific solutions to put these risks under control through maintenance. In this regard, maintenance is to be seen as a key tool to put product safety risks, dangerous for human health, under control. The implementation process has been designed to avoid to loose the benefits produced by the design phase and to add value through a proper definition of roles, tasks, and procedures to be implemented on the ALF equipments. Further research in this area can investigate if the conclusions of this research could be differentiated and customized for different food industry fields. This research drawn the way to highlight the role that maintenance can play in determining, through a maintenance design and implementation process, product safety and equipment reliability, we hope that this work could represent a modest contribution to create further stimuli for other activities in this important industry field.

The intention of the writer is to work on two future projects:

1. A design solution for maintenance tasks for food industry
This tool should allow to easily design maintenance tasks according to different types of criticalities taken into consideration.
2. An implementation solution for maintenance tasks
The process to implement the task list designed pointed out the need to empower the equipment operator role through AM and its integration with company's specialists. The definition of roles, activities, and the level of integration between equipment operator and other company's specialists represent another important area where this work can add further value.

8.8 Publications arising from this work

The work done with this research produced an article titled: "Product Safety & Equipment Reliability in Food Industry through Maintenance Engineering" and introduced in the appendix. This work summarizes the process, conceived in this research, to design maintenance tasks for ALF packaging lines, and it is addressed to all maintenance specialists and managers who wish to use maintenance as a tool to design product safety and equipment reliability.

This script has been published by the "Maintenance Engineering/Maintenance & Asset Management Journal, (UK) Issue 1, Jan/Feb. 2011. This script will also be published on Asset Management and Maintenance Journal (Australia) between July and October 2011. Another work, written by the author of this research, has been published in Italy, titled: "Maintenance Strategies for Liquid Food Equipments" by the magazine: "Food Technologies", Issue April/May, 1997.

8.9 Limitations

This research is addressed to ALF industry's environment, the maintenance design and implementation process have been conceived to provide a reliable answer to the hazards in this industry sector. Biological, chemical, and physical risks of products packed are the main criticalities taken into consideration and the focus given to this goal could represent a limitation to taking into consideration other critical factors normally in place in other industries. A maintenance design and implementation process for automotive industry, can, for instance, introduce different concepts of safety and reliability with different solutions to manage different degrees of safety and reliability. Moreover, within the food industry field, there could be different equipments and products with other type of risks that could require the application of other techniques necessary to better manage the criticalities not taken into consideration in this research.

8.10 Summary

This chapter summarized the research questions and solutions. The solutions found in the maintenance design and implementation process, enable the food companies to manage the product safety hazards and reliability problems existing in the ALF packaging lines. The analysis of equipment failures, of their effects on product safety and equipment reliability, has been done through HACCP, HAZOP, and maintenance engineering techniques. To insure a reliable management of biological, chemical, and physical risks of product packed, qualitative and quantitative analysis of failures have been integrated in a design process able to weight them, and their consequences. The design of maintenance task lists represents the answer to the research questions addressed by the analysis of different case studies. The maintenance design process fills the gap found in the literature, regarding lack of a maintenance process designed for ALF industry, and represents a reliable tool to use to put under control the critical variables of the ALF packaging lines. The technical, organizational and cultural criticalities, identified in the ALF environment, have been put under control through the implementation process designed to ensure an effective implementation of the maintenance task list designed. Condition monitoring systems and sensors were examined to answer the need to reduce the risks depending on human factors and to improve the global maintenance effectiveness. The maintenance implementation model identifies the key company's roles to implement maintenance tasks and calls the equipment operator to become the main equipment owner in the implementation of maintenance activities designed. Autonomous maintenance represents a powerful tool of the implementation model since it allows a reliable implementation of task lists designed through equipment operators and company's specialists. The KPI's identified in the implementation process provided the way to measure production line and maintenance effectiveness. The maintenance design and implementation process represents the answer to the gap existing in the literature and the solution to manage the ALF critical factors showed by the case study analysis.

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APPENDIX

Appendix A: Product Safety & Equipment Reliability In food Industry Through Maintenance Engineering

Introduction

Threats coming from increasing regulations on food safety, lead food industry to design and implement maintenance procedures able to put under control critical variables linked to food safety and equipment reliability. Since public health can be heavily impacted by the level of safety and reliability of the equipment used in food industry, the design and implementation of maintenance procedures represent a fundamental tool to reach this goal. The consequences produced by food contamination represent the leverage that call a food manufacturing company to design and implement maintenance through the use maintenance engineering techniques instead of relying on experience of expert craftman working in maintenance field.

The process to design maintenance procedures for food industry

The process used to design maintenance procedures for food industry, have to be thought in order to put under control all critical variables that might produce product contamination and low equipment reliability.

Reliability concepts, safety and the maintenance engineering techniques, have been examined to identify the principles that have to be used in the design process. Hereafter the process blocks, in Figure A1, highlight the main maintenance design phases, which lead to the production of maintenance check lists to be implemented in food industry. The peculiarity of this process, compare to other processes used in different industrial sectors, lays on the ability to link product safety and equipment reliability issues to produce an outcome able to address every criticality in place in a food manufacturing line.

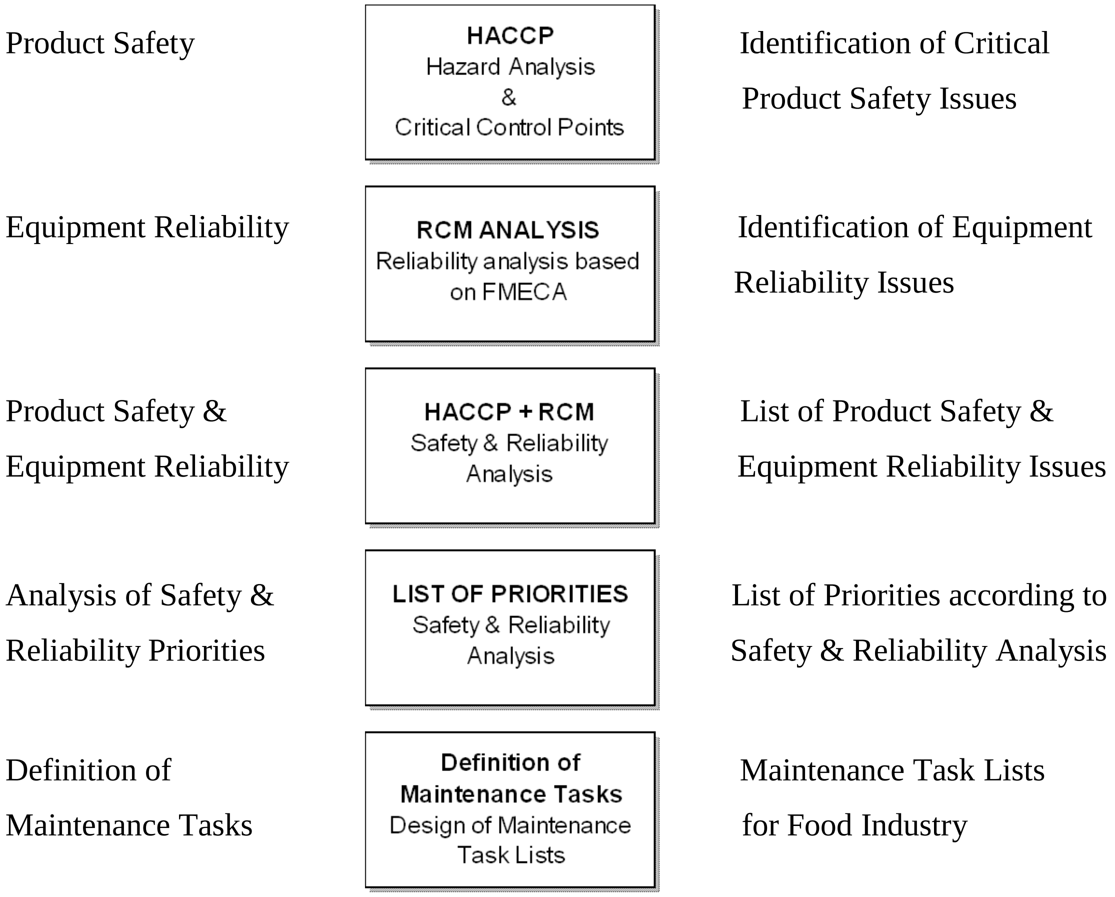


Figure A1: Maintenance design process for food industry

The first phase has been thought with the intention to implement Hazard Analysis and Critical Control Points (HACCP) to identify and address all conceivable Critical Control Points (CCP) that could influence the product safety.

In the second phase, the equipment reliability issues are properly examined through the application of some maintenance engineering techniques to identify criticalities owing to equipment components and functions and specific solutions. The third phase addresses the need to highlight the product safety and the equipment reliability issues showing both criticalities put together in the same form. In the fourth phase, a list of priority is developed according to the priorities coming from previous analysis. In the fifth phase, the design team can develop the maintenance task lists to control food criticalities owing to product safety and equipment reliability.

Step One: Application of HACCP methodology

Through HACCP methodology, all critical machine parts and components are identified (CCPs) together with the risk associated to the different failure modes.

HACCP identifies and assess specific hazards, estimates risks and establishes control measures that emphasize product safety through problem prevention and control, rather than reliance on end-product testing and traditional inspection methods. Machine parts or components, whose fault may produce biological, chemical or physical hazard, are examined to devise critical control limits and preventive maintenance countermeasures. At this design stage, all conceivable product safety hazards, coming from equipment operation and human behaviour must be identified, to ensure that:

- Equipment
- Human (operational) and
- External (service & utilities)

criticalities that have a direct impact on biological, chemical and physical modification of the product filled are listed and examined.

Application of HACCP and HAZOP (HAZard OPerability) techniques enable the identification of the following issues:

- hazards, directly connected to the equipment/system/component functions
- identification of CCPs in the equipment operation
- critical limits for each CCP
- hazards in performing operational tasks
- preventive measures to carry out at every maintenance interval
- monitoring procedures or devices to detect loss of control at the CCP.

The development of HACCP plan requires seven principal activities to be carried out by the HACCP team. These activities have to be applied to the process equipment and to operational tasks to identify CCPs and to establish adequate maintenance procedures. The principal activities are:

ACTIVITY 1: Conduct hazard analysis, on equipment functions and on operational tasks to identify hazards (biological, chemical and physical) and specify control measures

ACTIVITY 2: Identify critical control points (CCPs)

ACTIVITY 3: Establish critical limits at each CCP

ACTIVITY 4: Establish monitoring procedures or condition monitoring devices

ACTIVITY 5: Establish corrective action procedures

ACTIVITY 6: Establish verification procedures
ACTIVITY 7: Establish documentation procedures as appropriate.

Activity 1

Listing all hazards and considerations of any control measures to eliminate or minimize hazards depending on equipment functions and operational tasks. The hazards considered during this activity are the following:

- Biological hazards

It includes all potential sources of product contamination depending on equipment functions and operational tasks.

- Chemical hazards

It includes, among the others, cleaning compounds and sterilization agents. Chemicals, normally used to sterilize packaging materials, could come in contact with the food product if critical conditions of some components are not monitored and inspected through maintenance activities.

- Physical hazards

It includes objects, such as metal fragments, glass, that can be found in the product packed, and that may cut the mouth, break teeth or perforate the package.

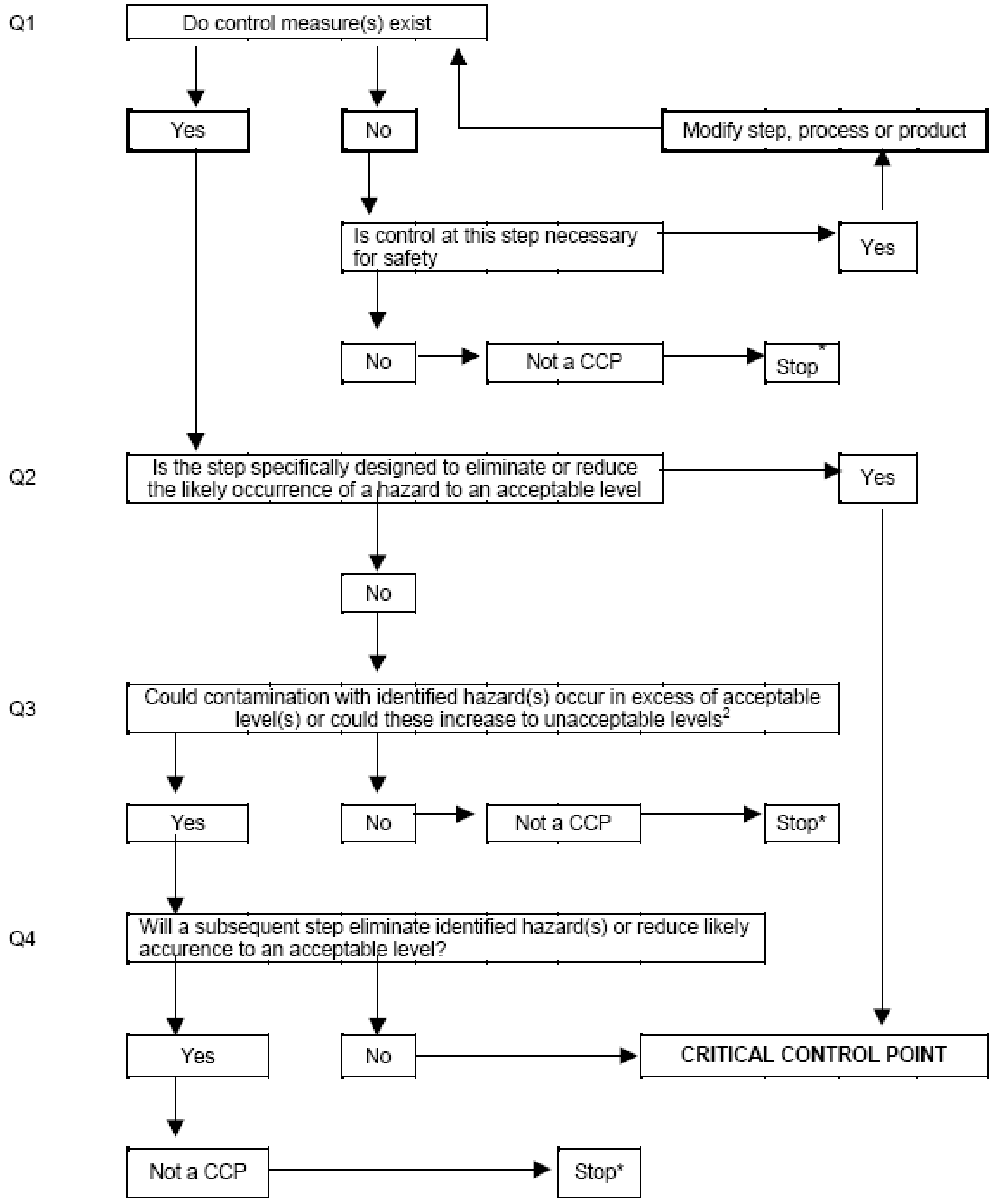
The team involved in this activity, must consider all the conceivable sources of equipment and operational hazard and list them under the three (biological, chemical and physical) main areas of risk.

Activity 2

After all hazards have been identified, a CCP decision tree module is to be used to determine whether a CCP can be identified for the specific hazard. If a hazard has been identified for which no control measure exists, the machine part or component should be modified so that hazard is eliminated or reduced to acceptable or minimal levels. The module shown in Figure A2 is a HACCP decision tree normally used for establishing CCPs. If a CCP regards an operational activity, carried out by the equipment operator, this have to be clearly described and specific hazard identified.

Diagram 2

Example of Decision Tree to Identify CCPs
(answer questions in sequence)



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[*] Proceed to next identified hazard in the described process

[2] Acceptable and unacceptable levels need to be defined within the overall objectives in identifying the CCPs of the HACCP plan.

Figure A2: HACCP decision tree to identify CCPs [9]

Critical operational practices need to be defined, without grey areas: adjustment, registrations, and mechanical settings must be verified and possibly monitored through automatic monitoring devices.

Activity 3

Critical limits must be specified for each control measure at each CCP. In some cases, more than one critical limit will be specified at a particular CCP. If a critical measure has a direct impact on other physical parameters, these need to be identified together with critical limits. It is recommendable that quantity variations are compared with target levels to ensure that critical limits are met.

Activity 4

Monitoring is the periodic measurement or observation at a CCP to determine whether a critical limit or target level has been met. The monitoring procedure must be able to detect loss of control at the CCP. Automatic monitoring devices need to be used where a physical parameter under control can automatically be measured.

Activity 5

Corrective actions are those actions that need to be taken either when monitoring results show that a CCP has deviated from its specific critical limit or target level or, preferably, when monitoring results indicate a trend toward loss of control. Corrective actions can either be referred to deviations regarding potential hazard or to loss of control at the specific CCP.

Activity 6

Procedures for verification must be established to ensure that HACCP system is working correctly. Monitoring and auditing methods should be devised, for operational practices, to assess if criticalities, control measures and deviations are under control. Procedures, tests and analysis, can be used to assess if the activities designed fulfils the safety targets identified for each CCP.

Activity 7

Adequate, accurate record-keeping and documentation are essential to the application of the HACCP system. Examples of records are: HACCP plan, CCP monitoring records; a file with deviations; preventive maintenance procedures, included in the check lists and check lists review.

Application of HACCP methodology represents a mandatory step in the design process: a basic tool to identify critical issues that may have a relevant impact on food product safety.

Step Two: Application of Reliability Centered Maintenance (RCM)

The outcome coming from the first step is the identification of criticalities associated to product safety. After identification of CCPs (Biological, Chemical and Physical risks) linked to the equipment parts and to operational practices, Reliability Centered Maintenance (RCM) technique enables the analysis of the different failure modes and their effects on equipment operation. Furthermore RCM supply the right methodology to define the different maintenance approaches implemented through the task list content to effectively manage food product safety and equipment reliability issues. The approach chosen includes the following activities:

1. System selection

Systems and sub-systems in the line will be selected according to HACCP results and to the priorities identified by the project team.

2. Boundary definition & Operational mode summary

After identification of a machine system, groups and parts directly linked to each sub-system should be listed to define both components function and system boundaries. Looking at the equipment type as a simple process with a value-added transformation of inputs to produce some desired output will help determine the function. An operational mode summary is a description of the anticipated mix of ways the system will be used in carrying out its operational role.

3. Failure Analysis

After system boundary definitions, the purpose of this step is the identification of the existing failures in place in the different equipment sub-systems. Quantitative analysis of failures through the use of statistical tools will enable to identify the different sources of variations existing in the equipment or in the production line. The different control limit thresholds used by Statistical Process Control (SPC), enable to weight each failure type (Potential and Functional) and to define their probability of occurrence. As soon as the different types of failure have been identified, we are ready to proceed with a qualitative analysis of failures. The use of different quality tools such as Fault Tree Analysis (FTA), Root Cause Analysis (RCA) and Ishikawa or fishbone diagram will enable to produce a clear understanding of:

- the links existing between causes and effects

- the reasons behind each cause
- the link existing between each cause and the global context
- the logical order of the events that produce a failure.

4. Functional and potential failure determination

Because an unsatisfactory condition can range from the complete inability of an item to perform its intended function to some physical evidence that it will soon be unable to do so, failures must be further classified as either functional failures or potential failures.

- Functional failure

It is the inability of an item (or the system containing it) to meet a specified performance standard. This definition requires that we specify a performance standard, thus generating an identifiable and measurable condition for functional failures.

- Potential failure

It is an identifiable physical condition which indicates that a functional failure is imminent. The ability to identify a potential failure permits the maximum use of an item without suffering the consequences associated with a functional failure. In these circumstances items are removed or repaired/adjusted to prevent functional failures.

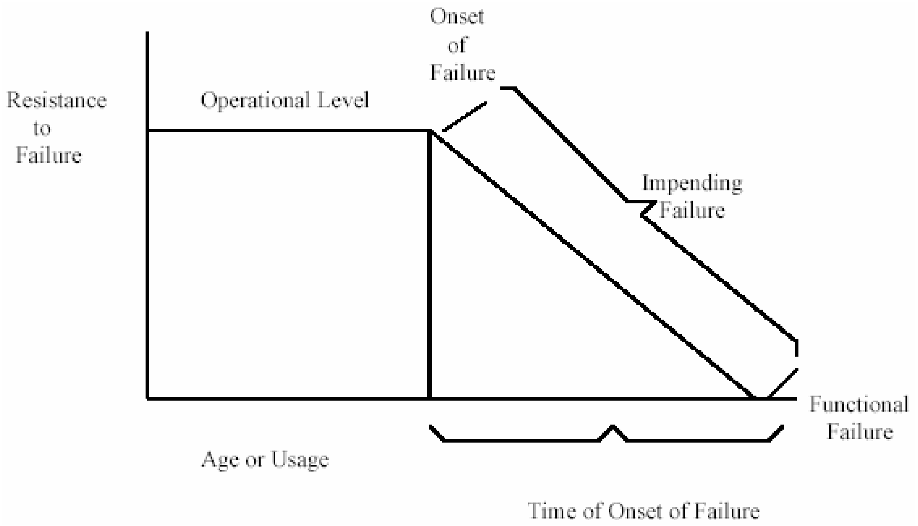

Figure A3: Functional and potential failure [15]

Figure A3 above shows the onset of failure regarding a potential failure and time between potential and functional failure. Since there are so many possible failures a system can experience, it may be necessary to subdivide the system into manageable segments (components) in order to identify all possible failures. This process is known as a Work Breakdown Structure (WBS).

5. Failure Modes and Effects Analysis (FMEA)

FMEA or FMECAs (Failure Mode Effects and Criticality Analyses) represent one of the most commonly used tools in reliability assessment programs. The basic components of a FMEA consist of some type of hierarchical breakdown, an outlining of all possible Failure Modes of all elements, and then a determination of the effects of these failure modes. By using FMEA to assign and categorize failure modes, the resulting categories can each have a defined plan of action. For example, high risk items, as those that may result in an unsterile container, must be flagged, and a plan to eliminate them formulated and deployed. Medium level items may require some type of detection mechanism to be designed. Low risk items could perhaps require no action. Main approaches are based on:

- Mode Criticality

Mode criticality is a numerical value that can be calculated and applied to each failure mode. Mode criticalities are based on a FMECA approach defined in MIL-STD-1629, a commonly used FMECA methodology.

- Risk Priority Number (RPN)

Risk Priority Numbers or RPN are also numerical assessments of risk. RPNs are based on a FMEA such as those defined by SAE, AIAG, and Ford. RPN values range from 1 to 1000. To use RPNs, the analyst evaluates each failure mode and determines the Severity, Occurrence, and Detection level in each case. The calculation of RPN is then defined as: Severity x Occurrence x Detection.

- Criticality Rank

Criticality rank is an approach described in the SAE FMEA 5580 document. The criticality rank is a value based on a multi-criterion, Pareto ranking system. Failure modes are assessed by the analyst in terms of severity and probability of occurrence.

- Risk Level

A risk level assessment technique is introduced in the book FMEA, Failure Modes & Effect Analysis, Predicting & Preventing Problems before they occur by Paul Palady. This approach allows the analyst to group failure modes into established categories to ensure that the most critical items are evaluated. By then graphing each failure mode, they will fall into one of the three graph areas: high, medium, or low. Figure A4 below shows a potential failure mode and effect analysis form used for this purpose.

Process FMEA-Potential Failure Modes and Effects Analysis

Part or Process Name/No	Design/Manufacturing Resp.	Other Areas Involved	Suppliers & Plants Affected
Homogenizer/Piston Head	Processing Department	Production , Maintenance	Production planning,Filling & Deliv.

Series No./Dev.Step	Engineering Release Date	Prepared By	FMEA Date	Key Production Date
20121-10215/010	10.02.95	Carlo Rossi	15.03.97	27.03.98

Process Descrip.	Process Purpose	Potential Failure Mode	Potential Effects of Failure(s)	Severity	Potential Causes of Failure	Occurrence	Current Controls	Detection	RPN	Recomm. Action(s)	Area Individual Respons. & Completit. Date	ACTION RESULTS				
												Actions taken	Severity	Occurrence	Detection	RPN
Mechan. treatm. of milk fat globules	Breaking of milk fat globules	Piston head breaking	No milk treatment leading to: • bad milk quality • milk contamin.	7	• Mechanic. wear • Manufact. problems	4	Preventive actions to check: • teflon seal wear • mechanic. wear	2	56	Preventive checks: • teflon seal wear • mechan. wear • piston stroke	Produc.dep. 5/4/98 Mainten. dep 6/4/98 Mainten. dep 6/4/98	Operator check every 250 work.hours Preven. maint. measur. added	7	3	2	42

Figure A4: FMEA form

The FMEA form identifies potential failures modes and assesses the potential customer effects of the failures.

6. Maintenance history and technical documentation review

In this step we examine the necessary reliability data input. Reliability data is necessary to define the criticality, to mathematically describe the failure process and to optimize the time between PM tasks. Reliability data include a mean time between failures (MTBF), mean time to restore (MTTR), and failure rate function. The failure distributions (Gaussian, Weibull…) are rather flexible, and may be used for detailed modelling of specific failure mechanisms. However, for most applications the class of Weibull distributions is sufficiently flexible to be the preferred distribution. From information gathered during the review of maintenance history and the results of the failure modes and effect analysis, a maintenance approach for each of the failure effects can be determined. The value of MTBF, the failure rate and its distribution will give us an idea of the reliability of the part. More specifically, we can:

- Calculate the failure rate of each failure mode and decide whether a design review is desired on a developmental item, and
- Decide when the part should be replaced if scheduled replacement is required.

7. Determine maintenance approach for each failure effect

There are four major components of the Reliability Centered Maintenance program:

- Reactive Maintenance (Corrective Maintenance),
- Preventive Maintenance,
- Predictive Maintenance (Condition Monitoring), and
- Proactive Maintenance.

The RCM logic tree is to be used to determine the maintenance tasks and to logically work through the tasks likely to be needed to develop RCM program. After creating a logic tree, four distinct types of maintenance tasks usually result in:

- Time Directed Tasks (all preventive maintenance procedures)

This task is generally applied to failure modes that can be restored without the need to replace the part. Examples in this area include; re-machining, cleaning, flushing, sharpening, re-positioning, tightening and adjusting.

- Condition Directed Maintenance (preventive and CBM)

This task aimed at detecting the onset of failure or the potential failure. Often referred to as CBM or On-condition Maintenance, the goal is to ensure that the occurrence of failure modes that have undesirable consequences are predicted so that they can be mitigated through planned activities.

- Failure Finding

This task suggests replacing a physical component in order to restore its function. As with preventive restoration tasks these are also hard time tasks. Common examples of tasks include greasing bearings, changing oil filters and oil (if done on a time basis), and routine light bulb replacement (often but not always).

- Running To Failure (decision to run certain components to failure)

These are tasks that are done to detect whether an item has already failed so that action can be taken. These tasks are only used with items that have hidden functions. Task selection can be supported by the correct application of different “decision logic trees” which provide the pathway to identify the right maintenance approach for each failure pattern. A decision logic tree, for task selection, showed in Figure A5 can be used to identify the criteria needed to apply condition monitoring and time directed task.

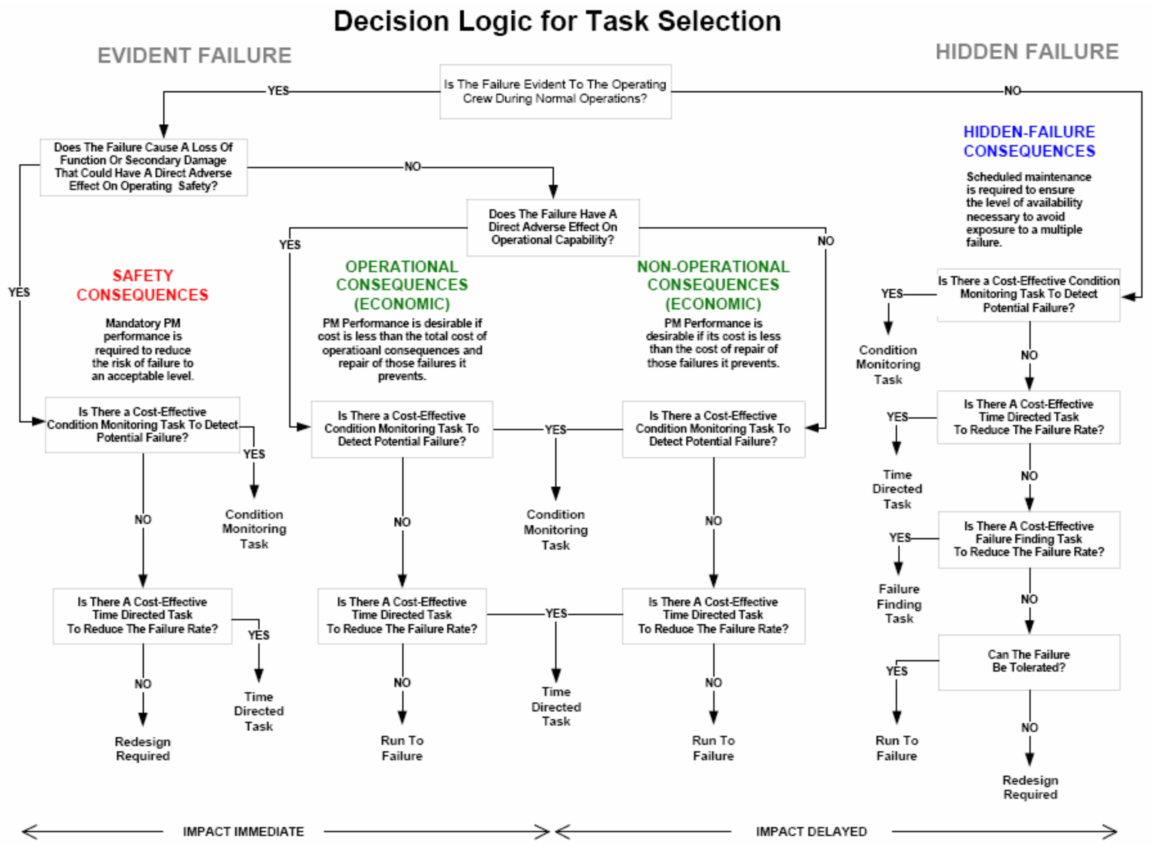

Figure A5: Decision logic for task selection [27]

Many failure modes exhibit signs of warning as they are about to occur. The methodology to estimate the P (Potential) and F (Functional) interval or Failure Detection Threshold (FDT), which are two typical ways to describe the detectability of a failure, is to be introduced. As shown in Figure A6, the time range between P and F, commonly called the P-F interval, is the window of opportunity during which an inspection can possibly detect the imminent failure and address it.

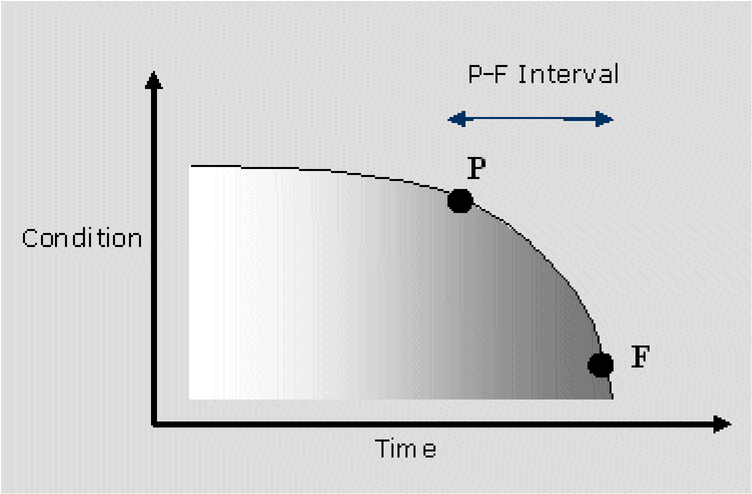

Figure A6: P-F curve [43]

FDT is a number between 0 and 1 that indicates the percentage of an items life that must elapse before an approaching failure can be detected. For example, if the FDT is 0.9 and the item will fail at 1000 days, the approaching failure becomes detectable after 90% of the life has elapsed, which translates to 900 days in this case (0.9x1000=900). This time period is known as time from onset (Tos) that is the time at which potential failure is detectable. Figure A7 shows the beginning of Tos as the point on the slope at which a physical symptom (potential failure) appears. To assure that an inspection to detect impending failure will occur between the appearance of potential and functional failure, inspection intervals must be shorter than Tos.

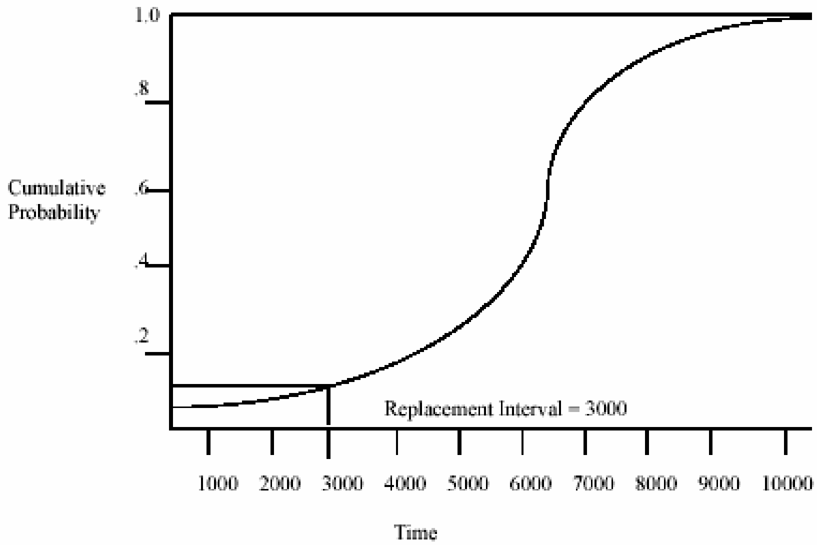

Figure A7: Inspection time interval [15]

Since an inspection could fail to identify and correct the mechanical wear or symptom, there would be at least one more inspection before functional failure occurs. For critical machine parts or components (according to HACCP & reliability analysis), the inspection interval is to be established at 1/3 or 1/4 of Tos. When failures occur in a narrow range, a normal failure distribution curve can be used for task scheduling. Figure A8 shows a curve representing a normal failure distribution.

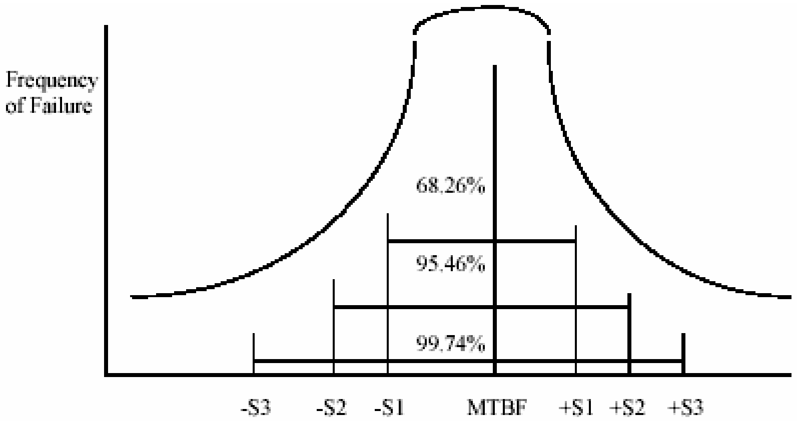

Figure A8: Normal failure distribution [15]

There have been many models, or combination of model, suggested to represent typical failure distributions, as described by the cumulative distribution function. Typical of those most frequently mentioned are the Exponential, Gamma, Erlang and Weibull distributions.

Step Three: Safety & Reliability analysis through HACCP & RCM

The design process started with the application of HACCP to identify the product safety critical issues, then the application of RCM enabled to highlight equipment reliability criticalities, now, at this point of the design process, HACCP and RCM techniques are combined together to carry out safety and reliability analysis. The purpose of this analysis is to identify the whole risk produced by the failure effects on product safety, on equipment reliability and then on production activity. The different risk priority numbers will give us the opportunity to weight the risks regarding to total effects produced by a specific failure mode on:

- Final product (product safety problems)
- Equipment functions

- Production activity (interaction between equipment and packages).

Table A1 shows a form which combines both FMECA (Failure Modes Effect and Critical Analysis) with some of meaningful HACCP and HAZOP criteria. This form has been called FMEHA (Failure Mode Effect and Hazard Analysis) and it provides the opportunity to identify all conceivable problems depending on equipment, on operational reliability and on product safety.

FMEHA - Failure Modes Effect and Hazard Analysis (FMECA + HACCP)

Part or Process name							Design/Manufacturing Resp.						Other Areas Involved			Suppliers & Plants Affected					
Series No./Dev.Step							Engineering Release Date						Prepared By			FMEA Date					
Description of: (1) Part/Process (2) CCP (3) Operational Practice	Process Purpose	Identify the Potential Hazards: (B) Biological (C) Chemical (P) Physical	Critical Limits for each CCP	Deviations	Potential Failure Mode	Potential Effects of Failure(s)	Severity	Potential Causes of Failure	Occurrence	Current Controls	Existing monitoring procedures	Frequency	Detection	RPN	Recommended Action(s)	Area Individual Responsibility & Completion Date	Actions Taken	Severity	Occurrence	Detection	RPN

Table A1: FMEHA form designed for food industry

The purpose of this form is to record both equipment reliability and product safety issues to highlight all the criticalities in place, to gain, as result, a global view and a total Risk Priority Number (RPN) based on CCP and critical reliability issues identified in the design process.

Step Four: List of Priorities (Safety & Reliability analysis)

As result of a combined analysis of product safety and equipment reliability issues, we now obtained a risk priority number which embody both HACCP and RCM criticalities. At this point, as shown in Table A2, we carry out the analysis of different failure modes effects, based on equipment reliability and on product safety, to produce a list of priorities based on RPN scoring.

List of Priorities (Safety and Reliability issues)

Equipment Name (System)						Design/Manufacturing Resp.		Sub-System		Areas Involved		
Series No./Dev.Step						Engineering Release Date		Prepared By		Date		
Part or Process Description	HACCP Hazard (B, C, P) & Reliability Risk	Severity	Occurrence	Detection	RPN	Potential Effects of Failure (to be kept under control)	Condition Monitoring Tools	Tools & Templates	Critical Limits or Warning Limits	Competence Level Required	Time/Cycle Interval	Maintenance Actions (Chk, Adj, Rep)

Table A2: List of Priorities

The form showed in the table above, describes (from the left):

- the part or the process taken under consideration,
- the hazard type (B, C and P),
- the RPN found,
- the potential effects produced by that failure,
- the condition monitoring tools used
- the tools and templates available to carry out maintenance activities (objective tools for measurements)
- the critical or warning limits to be monitored or checked
- the competence level required (operator or technician, electrical, mechanical…)
- the time (working hours) interval or No. of cycles at which a maintenance need to be planned
- the maintenance action devised in the previous section.

Since through RCM analysis we already split the equipment/line or system into different sub-systems, groups, component functions and system boundaries, at this step of the design process, a list of priorities is to be defined for each sub-system. This activity will represent a sort of bridge between step 3 and 5 to enable the designer to move forward in the design process and to display the criticalities in place within the different sub-systems defined in the equipment.

Step Five: Design of Maintenance Tasks

As result of the design activities carried out in the previous steps, we identified the functions that the equipment is intended to perform, the ways that it might fail to perform the intended functions and the evaluation of the consequences of these failures. The next step is to define the appropriate maintenance strategy for the equipment parts and components analyzed in the design process. The RCM guidelines include task selection logic diagrams based on the Failure Effect Categorization, these tools provide a structured framework for analyzing the functions and potential failure modes for the equipment parts under consideration in order to develop a scheduled maintenance plan that will provide an acceptable level of operability, with an acceptable level of risk, in an efficient and cost-effective manner. According to Figure A9 below, from the original RCM report we are provided four basic routine maintenance tasks:

1. On Condition or Condition Based Maintenance task
2. Preventive or Scheduled Restoration
3. Preventive Replacement
4. Detective and Run to Failure Maintenance.

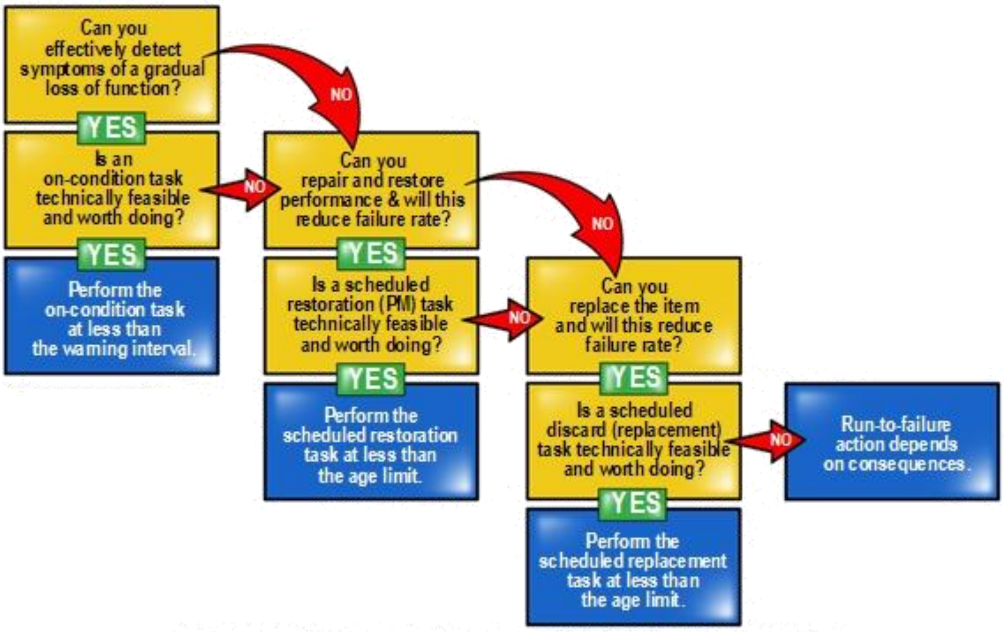

Figure A9: Decision Logic Tree [19]

- Predictive Maintenance

This task aimed at detecting the onset of failure or the potential failure. Often referred to as Condition Based Maintenance (CBM) or On-Condition Maintenance, the goal is to ensure that the occurrence of failure modes that have undesirable consequences are predicted so that they can be mitigated through planned activities. Where applicable, the use of on line and condition monitoring systems will enable to detect the deviation of physical parameters (temperature, vibration, oil residues…) more effectively.

- Preventive Restoration

This is the task necessary to restore a machine original resistance to failure based on some measure of hard time, such as calendar hours, running hours, or litres pumped for example. This task is generally applied to failure modes that can be restored without the need to replace the asset. Examples in this area include: re-machining, cleaning, flushing, sharpening, re-positioning, tightening and adjusting. Often preventive restoration task can include calibration where this is done on a hard time basis.

- Preventive Replacement

This task addresses the replacement of a physical part in order to restore its resistance to failure. As with preventive restoration tasks these are also hard time tasks. Common examples of preventive replacement tasks include greasing bearings, changing oil filters and oil (if done on a time basis), and routine light bulb replacement (often but not always).

- Detective Maintenance or Run To Failure (RTF)

These are tasks that are done to detect whether an item has already failed so that action can be taken. These tasks are only used within the four categories on the hidden side of the RCM decision diagram and are not referred to in the four categories on the evident side at all. Detective tasks include proof testing of critical instrumentation and the occasional running of stand by pumps. Although often associated with safety related failures this is not always the case. Within RCM it provides the last line of defence for routine maintenance when a failure mode cannot be predicted or prevented.

The content of the tasks can be further improved through the continuous improvement activity based on collection of historical figures, to combine quantitative and qualitative analysis necessary to update and upgrade the quality of the designed maintenance tasks. Figure A10 summarizes the described process steps to design maintenance procedures.

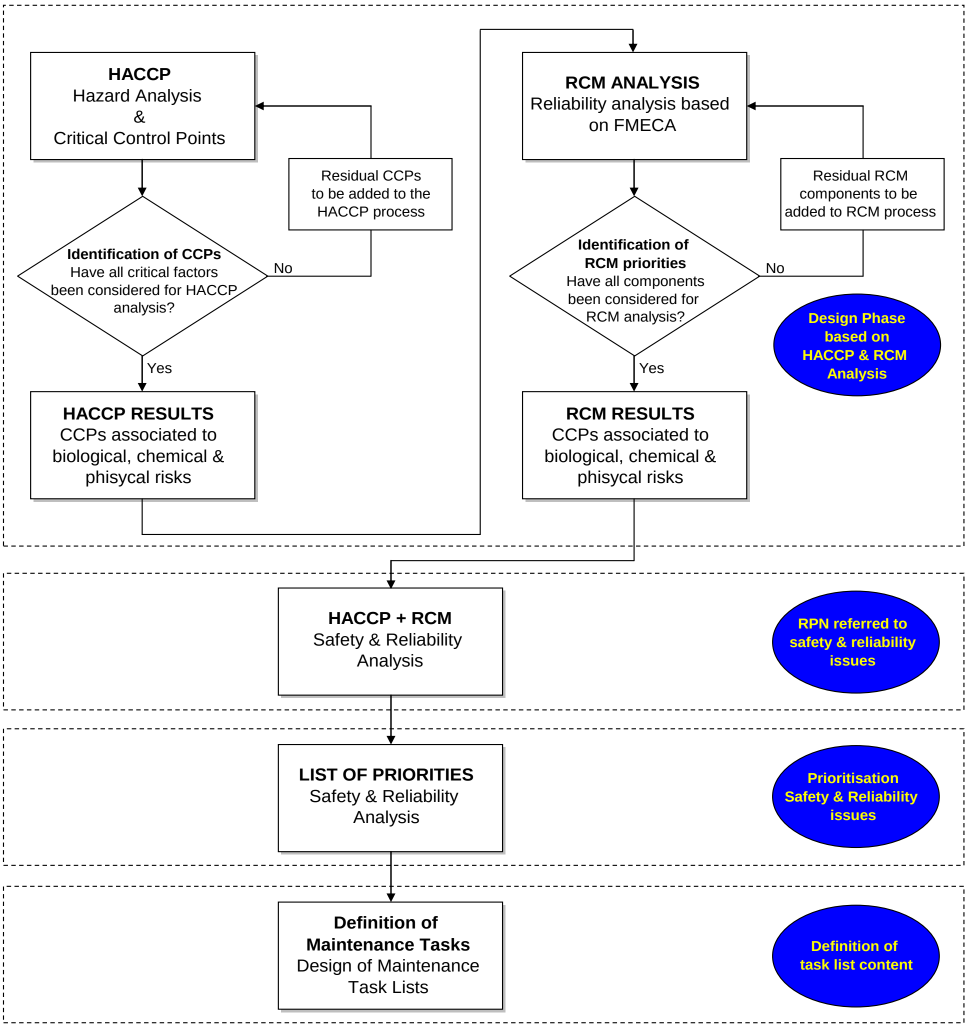

Figure A10: Process to design maintenance task list for food industry