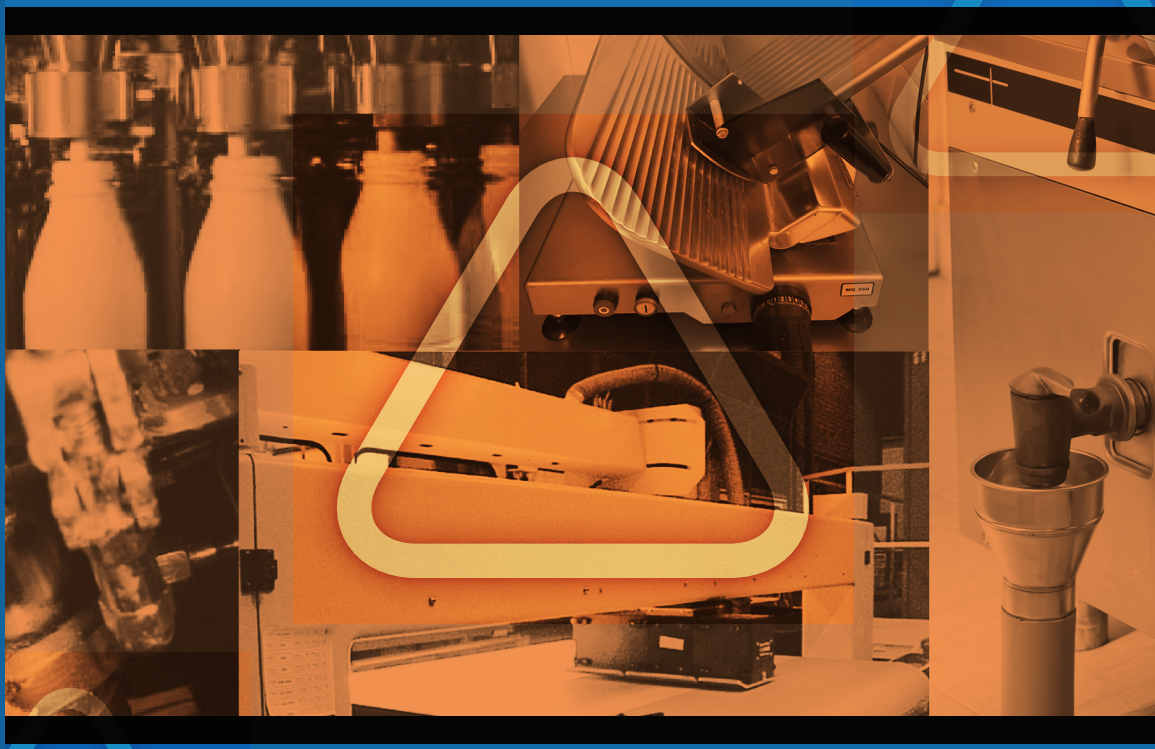
Designing Food Safety and Equipment Reliability Through Maintenance Engineering



SAURO RICCETTI

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Contents

List of Figures

List of Tables

Preface

The organization of maintenance in food industries represents an important management task that enables a company to pursue food product safety, higher manufacturing effectiveness, and improved market share. The original quality of food needs to be maintained during its shelf life; if the process to pasteurize or sterilize a rough product and to pack and transport it is not reliable, food safety can be heavily compromised. A food packaging line can be complex, with many critical control points that need to be monitored. Some of them are constantly monitored through automatic devices, but many need to be put under control through specific maintenance activities. Lack of systematic control of such criticalities may result in a huge food contamination that could be dangerous to public health. This book examines problems existing in this industry sector and proposes, as a solution, a process to design and implement maintenance activities intended to put food and equipment criticalities under control. These two complementary processes (design and implementation) have been conceived and designed to answer the particular needs of the 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 that it can be considered an investment that produces an added value and generates a real company profit. The existing maintenance engineering techniques pursue equipment reliability at minimum cost, but in the food industry, food safety represents the most critical issue to address and solve.

To highlight problems due to low equipment reliability, different case studies have been examined to show the negative effects produced by lack of or poor maintenance design and implementation applied to the food industry. Many case studies show that low maintenance effectiveness could have dramatic effects on final consumers and on the company's image. They underscore the need for a maintenance design and implementation process that takes into consideration all critical factors relevant to the 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 process necessary to address and solve maintenance problems in the food industry. The increasing regulations currently in place in the food industry and the lack of literature available to define a maintenance design and implementation process for food packaging lines represent the stimulus to write this book and attempt to fill this important gap. The findings produced by personal research in this area, and many years of experience on the field, provided a useful guide to identify the process to design maintenance tasks able to put under control food safety and equipment reliability criticalities. On the other side, awareness of a company's restraining forces and cultural inertia that work against the new maintenance approach have been analyzed to design a maintenance implementation process able to avoid losing the benefits produced by the design phase. The analysis of some condition monitoring systems shows tools and techniques useful to improve product safety, equipment reliability, and then maintenance effectiveness.

The scope of this book is to aid food producers and consultants in filling the existing gap between equipment reliability and food product safety by showing important solutions to manage both food safety and manufacturing effectiveness issues in the food industry. This result is achieved through the identification of a maintenance design process able to capture all conceivable critical factors in the food manufacturing lines and to provide a solution to design reliable task lists. Furthermore, the maintenance implementation process shows the way to maximize maintenance design outcome through the empowerment of equipment operators and their close cooperation with maintenance and quality specialists. The maintenance design and implementation process proposed in this book represents an answer for reliable management of food safety and equipment criticalities, to allow the food industry to improve its global production effectiveness.

Abbreviations

ALF	Aseptic liquid food
AM	Autonomous maintenance
BSI	British Standards Institution
CBM	Condition-based maintenance
CCP	Critical control points
CE	Container efficiency
CIM	Computer-integrated manufacturing
CIP	Cleaning in place
CM	Condition monitoring
CU	Container utilization
EEC	European Economic Community
FD	Failure determination
FDT	Failure detection threshold
FFA	Force field analysis
FFT	Fast Fourier transform
FMEA	Failure mode and effect analysis
FMECA	Failure mode effect and critical analysis
FMEHA	Failure mode effect and hazard analysis
FR	Failure rate
FRACAS	Failure reporting, analysis, and corrective action system
FSSC	Food Safety System Certification
FTA	Fault tree analysis
GDP	Gross domestic product
GMP	Good manufacturing practice
GPT	Gross production time
HACCP	Hazard analysis and critical control points
HAZOP	Hazard operability
HRM	Human resource management
IR	Infrared thermography
ISO	International Organization for Standardization
KPI	Key performance indicator
LCC	Life cycle cost
LCL	Lower control limit
LCP	Life cycle profit

LED	Light-emitting diode
JIPM	Japan Institute of Plant Maintenance
JIT	Just in time
MTBF	Mean time between failures
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–act
PDF	Probability density function
PDM	Predictive maintenance
PDT	Planned down time
PGTU	Production gross time utilization
P&L	Profit and loss
PM	Preventive maintenance
PT&I	Predictive testing and inspection
RCA	Root cause analysis
RCM	Reliability-centered maintenance
RMS	Root mean square
RPN	Risk priority number
RTF	Run to failure
SEE	Simple equipment efficiency
SPC	Statistical process control
TEI	Total employee involvement
TEP	Total equipment productivity
TEU	Total equipment utilization
Tos	Time from onset
TPM	Total productive maintenance
TQC	Total quality control
TQMain	Total quality maintenance
TTU	Total time utilization
UCL	Upper control limit
UHT	Ultra-high temperature
WCM	World-class manufacturing

About the Author

Sauro Riccetti, PhD, obtained a graduate diploma in electrical and electronic engineering and membership of the Society of Engineers (London), then a postgraduate diploma and MSc degree in manufacturing engineering at the Open University (UK). He continued his research studies in maintenance and process engineering applied to the food industry, receiving his PhD degree in manufacturing engineering from the School of Engineering and Design at Brunel University (London). He is a member of the Institution of Engineering and Technology (UK) and a chartered engineer of the Engineering Council (UK).

Dr. Riccetti has worked in the food industry for more than 30 years. He has carried out research on maintenance and process engineering applied to the food industry and is actively involved in developing new products and services to improve food safety and equipment reliability in the food industry's packaging lines.

His experience at Tetra Pak Italy and in holding several different positions therein, including training manager, customer service director, and business development director, as well as his involvement in improvement projects for the food industry, have enabled him to gain wide experience on maintenance and process engineering applied to the food industry.

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1

Introduction

In this chapter, the background of the problem existing in the food industry is defined starting from an analysis of packaging systems used to produce long-life products. Food products, existing in nature, distributed, and sold as fresh or long-life foods, need to be pasteurized or sterilized in order to reduce or eliminate the bacterial load existing in the environment. The presence of bacteria in the food product, due to poor sterilization efficiency or to a lack of container integrity, may result in food product spoilage, which can be dangerous for public health.

In this regard, threats, coming from increasing regulations from European legislation, are discussed as the basis, which leads food manufacturing units to look for a reliable design and implementation of maintenance procedures. Since public health can be heavily impacted by the reliability of the equipment used for food packaging, and by the relative food safety, the design and implementation of maintenance procedures represent a fundamental tool to reach product safety and equipment reliability. The scope of this book is to present maintenance as a proactive tool able to identify the food packaging line criticalities and to offer a solution to put these criticalities under reliable control.

This chapter answers the following questions:

- What are the food equipment criticalities?
- What are the potential problems caused by equipment failures and stops?
- What are the mandatory product safety requirements in the food industry?
- How can we reduce uncertainties due to human factors?
- What are the aims and objectives of this book?

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

1.1 FOOD INDUSTRY THREAT AND CHALLENGE: INCREASING REGULATION ON PRODUCT SAFETY

Compliance with product safety European Economic Community (EEC) directives and international standards represents a mandatory requirement for those who operate in the food industry. Current legislation on food packaging calls for the producers to identify the equipment critical control points in order to put them under control during the different production phases.[14]

In aseptic packaging, which is the most critical food sector, the following are some of the functions that can be considered 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[7] specifies food composition, safety, hygiene, and labeling. At the present time, rules, guidelines, and regulations, covering good manufacturing practices (GMPs) for long-life products, are being formulated in an increasing number of countries, either on a voluntary or legislative basis. Furthermore, hazard analysis and critical control points (HACCP) is a production process control methodology introduced at the European Community level (December 1995) through EEC Directive 93/43.[8] Directive 852/04 sets a mandate to incorporate best practices in hygiene, sanitation, health, and product safety through the application of HACCP principles as guidelines. EEC Directives 852, 853, 854, and others, including 1331, set the general guidelines that call food sectors to implement and maintain a fundamental system for hazard analysis, leading to the identification of critical points relevant to food safety.

The mandate set by these directives must be enforced, ensuring compliance by the various food industry sectors, considering the risk factors and implications.

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.[15] 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 FOOD SAFETY PROBLEMS PRODUCED BY LOW EQUIPMENT RELIABILITY

This section introduces, as an example, the production process in place in the aseptic liquid food (ALF) industry (main process): starting from raw liquid product, to ultra-high-temperature (UHT) sterilization and 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 ALF Process and Criticalities

The manufacturing process for an ALF packaging line is based on three main operations.

1.2.1.1 Food Product Processing (UHT Sterilization)

Product processing covers the processes from the raw product inlet tank of the 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 a result, must be free from toxins, pathogenic microorganisms, and microorganisms that can grow under normal storage and distribution conditions.

1.2.1.2 Aseptic Packaging (Aseptic Filling)

Aseptic packaging or aseptic filling 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 or container normally sterilized by the aseptic filler. Package filling, forming, sealing, and cutting are critical operations necessary to produce a hermetic filled package/container ready to be stored and distributed.

1.2.1.3 Container Distribution and Storage

Container distribution covers the processes from the filling machine output to the storage of the container (distribution machines such as straw or spoon applicator, tray packers, and palletizer are normally used for this purpose). Figure 1.1 shows the three main blocks regarding the aseptic liquid food packaging process.

An ALF process must satisfy four main requirements:

1. Raw liquid product sterilization
2. Aseptic packaging
3. Production of hermetic sealed packages or containers
4. Package/container 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 container can be contaminated at any time if container integrity is lost. A small hole, of the dimension of 1 μm, produced by a scratch or due to bad container sealing, may produce product contamination. Some critical functions might cause food product contamination if an appropriate maintenance activity is not carried out on the line equipments, for example:

- Equipment sterilization
- Packaging material or container sterilization

FIGURE 1.1
Aseptic liquid food (ALF) process.

- Container filling with food product
- Container forming, sealing, and cutting
- Container handling

Product contamination can be dangerous to public health, and the production unit responsible for such a problem can be forced to close down its activity.

1.2.2 Main Problem to Be Addressed

A maintenance process, intended to maintain the equipment criticalities under control, represents a mandatory requisite to ensure equipment reliability, necessary to avoid negative interactions between equipment and food 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 poor product safety and quality. In spite of these requirements and stringent health and safety regulations, many companies operating in food processing show appalling complacency when it comes to investigating the reasons behind low food process safety and equipment reliability. In this book we are going to investigate the effects produced by equipment failure and downtime on product safety to highlight the importance of a maintenance design and implementation process specifically designed for the food industry. Lack of literature to define a reliable maintenance design and implementation process for the food industry may represent an important gap to be filled to avoid poor manufacturing effectiveness, which produces a serious risk for the final consumer's health. Moreover, a manufacturing company responsible for such events may also experience a big market share and huge economical losses.

1.2.3 Effects of Equipment Stop in the Food Industry

While in the mechanical industry a machine stop could have a low economical impact on production cost, in the ALF industry, for instance, an equipment stop must often be followed by equipment cleaning and sterilization before a new production start. Product and container waste, together with other raw material waste, creates a strong impact on total production costs.

Moreover, the downtime necessary to clean and 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 primary conditions need to be satisfied:

1. Equipment cleaning. Surfaces in tanks, pipes, and other process equipment that come into contact with the food product have to be properly cleaned to avoid formation of dirt and growth of bacteria. A cleaning procedure normally involves a prerinsing with water, cleaning with detergents and chemical agents, and postrinsing with clean water.
2. Equipment sterilization. For aseptic products, sterilization by means of heating or with chemicals is necessary to render the equipment 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 2 to 4 h. Both these operations must be carried out every time that the equipment is stopped down to zero position and sterilization is lost for whatever reason. Sometimes the filling equipment 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 program. 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 to 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 food safety legislation and by good manufacturing practices (GMPs), the maintenance design and implementation process must address and solve the problems linked to food

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 International Organization for Standardization (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 book is to define a maintenance design process able to identify the equipment critical control points (CCPs) in the production line and the relevant maintenance procedures to put under control food safety risks. Moreover, we are going to identify an implementation process to ensure an effective implementation of maintenance procedures through the integration of different company 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 represents a necessary tool to reduce the risks associated with human factors. 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 establish automatic monitoring of critical parameters, therefore improving 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 food 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 SCOPE OF THIS BOOK

Every person working on a food industry packaging line is aware that many product safety and equipment criticalities need to be put under control through a reliable maintenance process. Too often, this activity is only based on reactive actions intended to fix specific problems or failures happening during the daily operations.

Every food packaging line is designed to maintain the original quality of food products that need to be sterilized, packed, and conserved during their whole shelf life. If the process functions to sterilize, pack, and transport the final food product are not reliable, food safety can be heavily compromised. A food packaging line is often complex, with many critical control points that need to be put under control through specific maintenance activities. Automatic monitoring devices represent a mandatory solution to monitor critical variables, but lack of a systematic maintenance control of such criticalities may result in a huge food contamination that can be dangerous for public health. The process to design and implement maintenance procedures must acknowledge and address the following critical variables that arise in the case studies described in Chapter 2:

- Food product safety
- Equipment reliability
- 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 achievement of this objective starts with the identification of CCPs in place in a food packaging line to design and implement a maintenance process that allows product safety and equipment reliability

to be reached at a reasonable cost. Maintenance is to be considered not a cost, but an investment that produces a company's competitive advantage through reliable control of all product and equipment criticalities. Maintenance processes implemented in other industrial fields normally pursue quality, reliability, efficiency, and cost-driven issues. Lack of literature on a maintenance process able to manage food product safety critical issues represents one of the reasons that promote the production of this book.

The analysis of case studies examined will clearly address the following:

- The necessity of a maintenance process specifically designed for food packaging lines
- The heavy losses produced by poor product quality and safety, higher operational cost, and low customer satisfaction

It is not my intention to write a scientific summary of some of the main modern maintenance engineering techniques, but to provide, instead, a useful and practical tool to address and solve food safety and quality problems. This can be achieved through the identification of equipment problems existing in the food industry and establishing the highest production line reliability. During my last 30 years spent in the food industry, I realized that reliable solutions depend not only on knowledge of maintenance engineering and quality techniques, but also on the ability to get people's commitment, and this is the reason why an extensive part of this book is spent examining problems related to maintenance implementation.

1.6 CONCLUSION

The food product safety EEC directives and standards introduced represent a mandatory requirement that calls the food industry to identify the packaging line CCPs and the relative solutions to put them under control. Examination of a food packaging line process shows criticalities that link equipment reliability to product safety: poor equipment reliability, dependent on lack of an effective maintenance process, could produce, as a result, heavy consequences on product safety and then on public health. The demands placed by the legislation, compared with the complexities existing in the food industry, lead to the necessity to study this subject to

identify reliable solutions. The effects produced by lack of control of food packaging line CCPs on product safety and on company costs represent the leverage to identify the equipment criticalities together with the solutions to put them under control.

The benefits coming from the use of condition monitoring devices can improve the inherent equipment reliability through the automatic monitoring of CCPs and the possibility to be less dependent on the quality of subjective checks and manual control.

2

Link between Food Safety and Equipment Criticalities to Address Maintenance Needs

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.

This chapter shows the following:

- Problems and threats, but also opportunities available in the food industry
- Equipment complexities and criticalities
- Five case studies that show the criticalities of the food packaging lines and the effects produced by lack of a maintenance process to design and implement maintenance tasks

Food market problems dealing with increased competition, cost pressures, and downsizing call food industry managers to consider maintenance as an important weapon to improve product quality and safety, to reduce costs, to establish compliance with food safety legislation, and to improve the company's competitive advantage. The different

case studies underline the effects produced by lack of control of some equipment critical control points (CCPs), the economical losses produced by product contamination, and the need of a maintenance process to put food safety criticalities under control.

2.2 PROBLEMS, THREATS, AND OPPORTUNITIES IN THE FOOD INDUSTRY

The competition in the food 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 a positive result on costs.

2.2.1 Increasing Competition

The market for aseptic liquid food companies 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 constantly identify possible sources of cost reduction.

2.2.2 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 occurs. An extreme reaction to increased competition is shown by those companies that postpone investments and refuse to pursue any kind of production efficiency methodology. The economic crisis is leading to a state of inertia with regard to major investments in technology needed to improve both the reliability of systems and the safety of food products packed.

2.2.3 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 or to gain access to new markets and new technologies.

According to Morris,[36] 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 panelists 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 to work on long-life liquid food packaging lines requires a specific knowledge and experience over many different areas. The outsourced personnel have, in most cases, general electrical or mechanical competency, but lack the experience necessary to deal with equipment and food 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. Quite often 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 food packaging line 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 food product quality.

2.2.4 New Approaches to Maintenance

The external pressures on food processors, from increasing health and safety legislation and regulation to increasing competition, continue to focus attention on the company's maintenance function. This function has to be seen not simply in terms of compliance to directives or

the avoidance of a problem, but as a potential contributor to creating competitive advantage. While the state-of-the-art 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 EQUIPMENT CRITICALITIES IN THE FOOD INDUSTRY

When we consider the process to transfer, pasteurize, and sterilize a liquid food such as milk, we know and have learned from experience that bacterial infection of milk is often caused by the equipment used. Any surface coming in contact with milk is a potential source of infection. It is therefore very important to clean and sanitize the equipment in a reliable way, through automatic systems able to put under control all critical parameters. The state-of-the-art cleaning equipment used to clean packaging line equipment, such as cleaning in place (CIP) sensors used to monitor critical parameters such as temperature, flow rate, concentration of fluids, and automation, represents an important factor in determining cleaning effectiveness. Figure 2.1 shows bacterial growth following a contamination in raw milk; the graph indicates the rate of bacterial development at different temperatures.

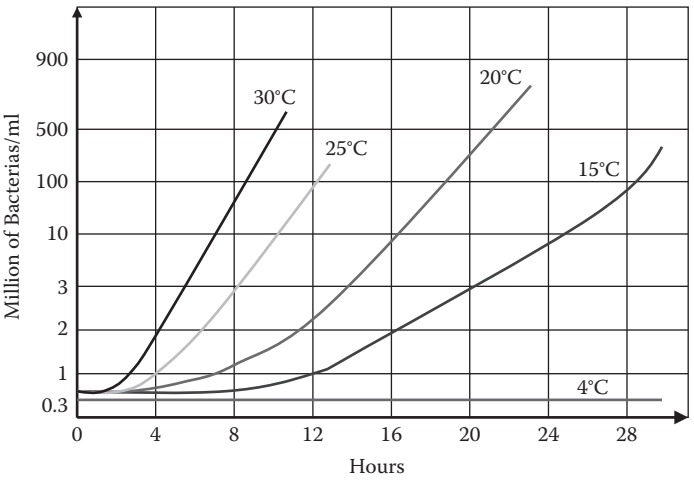


FIGURE 2.1
Bacterial growth in raw milk.

2.3.1 Heat Treatment of Milk

Since milk represents a perfect growth medium for microorganisms, heat treatment has been introduced to prevent milk from being a source of infection. Diseases such as tuberculosis and typhus were sometimes spread through milk. The term *pasteurization* remembers the name of Louis Pasteur, who discovered the killing effects of heat treatment on microorganisms and the use of heat treatment as a technique of conservation. The pasteurization of milk has been defined as "any heat-treatment that ensures the certain destruction of the bacillus of tuberculosis (TB) without affecting significantly the physical and chemical properties of milk."[19] All common pathogenic organisms that may be present in milk are killed by relatively soft heat treatments, which only have a very slight effect on the physical and chemical properties of milk. The tubercle bacillus is normally killed by heating milk to 63°C, for 10 min, but complete safety can be ensured by way of heating milk to 63°C for 30 min. In addition to pathogenic microorganisms, milk also contains other microorganisms that can spoil the taste and reduce the shelf life of various dairy products. Then a secondary purpose of the heat treatment is to destroy the greatest possible number of these other organisms. The combination of temperature and holding time is very important, since it determines the intensity of the heat treatment. Figure 2.2 shows lethal effect curves for Coliform bacteria, typhus bacteria, and tubercle bacilli.

Intense heat treatment of milk is effective from a microbiological point of view, but such treatment produces adverse effects on taste, on nutritional value of milk, and on its appearance. Since heat treatment is the most important and critical part of milk processing, its influence on milk needs to be better understood. The various heat treatment processes are shown in Table 2.1.

2.3.1.1 Thermization

This process is used to temporarily inhibit bacterial growth by preheating milk to a temperature just below the pasteurization temperature. In this process, called thermization, milk is heated to 63–65°C for about 15 s.

2.3.1.2 LTLT Pasteurization

In the original heat treatment, based on a batch process, milk was heated to 63°C in an open container and held at that temperature for 30 min. This method is called low-temperature, long-time (LTLT) pasteurization.

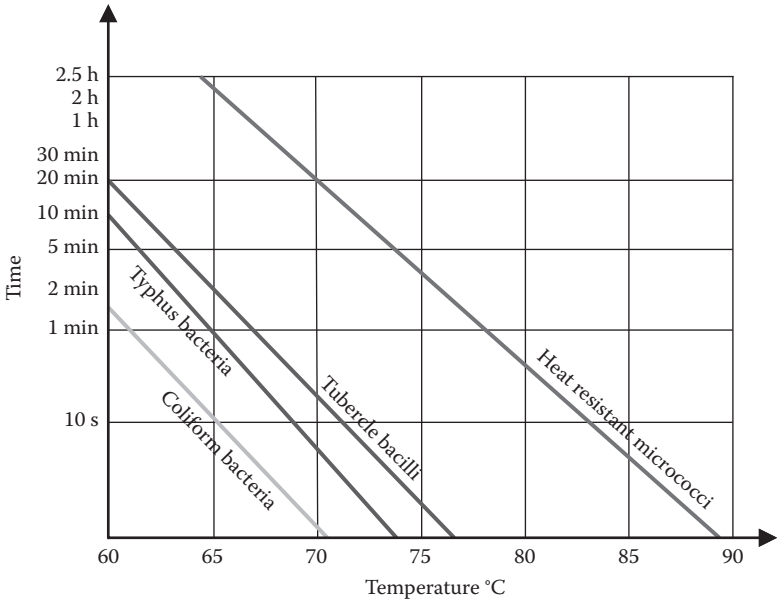


FIGURE 2.2
Killing effect of heat on bacteria.

TABLE 2.1

Main Categories of Heat Treatment in Dairy Industries

Process	Temperature	Time
Thermization	63–65°C	15 s
LTLT milk pasteurization	63°C	30 min
HTST milk pasteurization	72–75°C	15–20 s
HTST cream pasteurization	>80°C	1–5 s
Ultra-pasteurization	125–138°C	2–4 s
UHT flow sterilization	135–150°C	Few seconds
Sterilization in container	115–120°C	20–30 min

2.3.1.3 HTST Pasteurization

HTST is the acronym for high temperature, short time. The time-temperature combination applied to a food product varies according to the following factors:

- Quality of raw milk
- Characteristics of product treated
- Required keeping properties

For milk, the HTST process involves heating the product to 72–75°C with a holding time of 15–20 s before it is cooled.

2.3.1.4 Ultra-Pasteurization

For particular pasteurized products a shelf life of 30–60 days can be required; in these cases milk is to be heated to 125–138°C for 2–4 s and then cooled to a temperature of <7°C. This process is well known as extended shelf life (ESL). This term is normally used to identify heat-treated food products that have been given improved keeping qualities. To avoid losing the effects of this heat treatment, ESL products must normally be kept refrigerated during distribution and in retail stores.

2.3.1.5 UHT Treatment

UHT stands for ultra-high temperature. This treatment refers to a high-temperature heat treatment process, typically a short heating shock, commonly applied to milk, which is directed at extending shelf life to around 6 months without refrigeration, achieving commercial sterility and reducing food spoilage organisms. This exposition to heat kills microorganisms that would otherwise spoil the products. UHT treatment is a continuous process that takes place in a closed system that prevents the product from being contaminated by airborne microorganisms. Liquid food product is pumped into different heating and cooling stages, and then into the aseptic filling to avoid reinfection of product.

Two main alternative techniques are used for UHT treatment:

- Indirect heating and cooling in heat exchangers
- Direct heating, by steam injection or infusion

2.3.1.6 Sterilization in Container

In the in-container sterilization, the product is sterilized after the container has been filled and hermetically sealed. The peculiarity of this treatment is that food product is sterilized inside the container. This method eliminates the need for aseptic packaging, and the product is packed in rigid, semi-flexible, or flexible packaging as long as the package can withstand thermal treatment. In-container sterilization usually takes place at temperatures that range between 115 and 120°C, for 20–30 min. After fat standardization,

homogenization, and heating to about 80°C, milk is packed in clean containers, usually glass or plastic bottles for milk and cans for evaporated milk. The product, still hot, is transferred into autoclaves in batch production or to a hydrostatic tower in continuous production.

2.3.2 Pasteurization of Milk Products

The design of a packaging line for pasteurized milk products depends on many factors:

- Legislation and regulations in place in the country
- Quality level to be achieved
- Technical solutions adopted by the management

The basic process used to pasteurize and pack the raw milk may be built up with a pasteurizer, a buffer tank, and a filling machine. The process could become more complex if it has to be designed to produce several types of milk products.

Figure 2.3 shows a typical process flow for a pasteurized milk line. Milk enters in the balance tank (1) and is pumped (2) through a flow controller, to a plate heat exchanger (4), where it is preheated before it continues to the separator (5), which produces skim milk and cream. Milk continues its path toward the heating section (4) and (6), where is treated at pasteurization temperature. The holding tube (7) allows milk to be maintained at

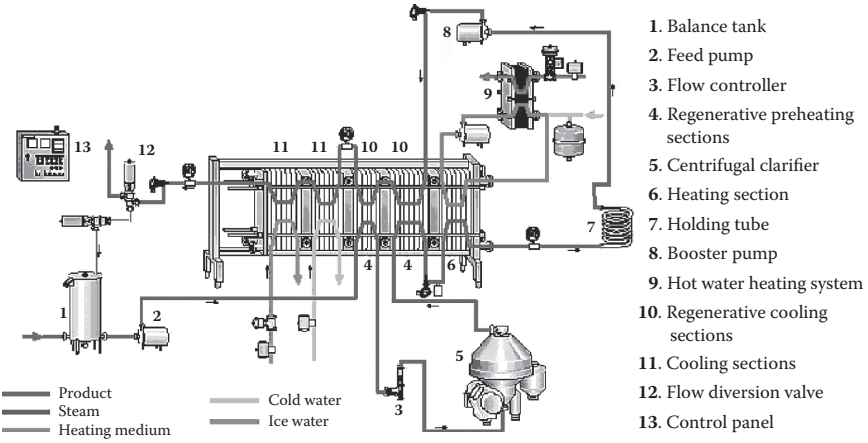


FIGURE 2.3
Process line for milk pasteurization. (From Bylund, G., *Dairy Processing Handbook*, Tetra Pak Processing Systems, Lund, Sweden, 1995.)

the pasteurization temperature for the stated holding time. The product is pumped through a booster pump to the regenerative cooling section (10) and (11) and, at the end, to the flow diversion valve.

The shelf life of pasteurized milk is basically dependent on the quality of raw milk; ordinary pasteurized milk should have a shelf life of 5–10 days, distributed at a temperature of 5–7°C in a closed container. To improve the quality of pasteurized milk and prolong its shelf life, the pasteurization process can include a bactofugation or microfiltration equipment. The bactofugation is based on centrifugal separation of microorganisms. The two-stage centrifugation on bacteria spores produces a reduction of up to >99%, but this is not good enough for extended shelf life milk distributed at a temperature up to 7°C. Reduction up to 99.5–99.99% of bacteria and spores can be achieved with microfilter membranes of pore sizes of 1.4 mm or less. A flowchart showing milk treatment with microfiltration is illustrated in Figure 2.4.

If milk processed by this plant is kept at a temperature lower than 7°C during the whole chain, from dairy to the final consumer, it is possible to attain a shelf life of up to 40–45 days in a closed container.

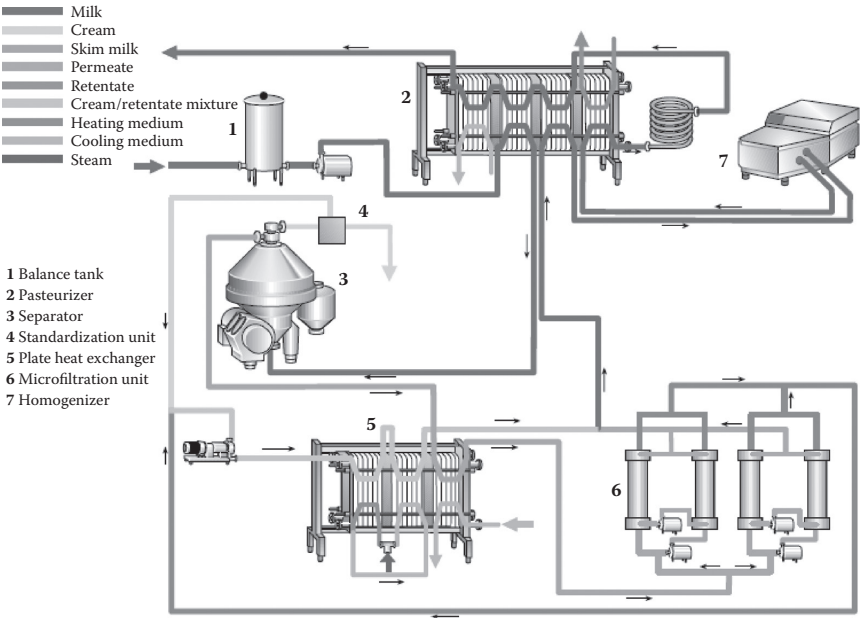


FIGURE 2.4
Milk processing including microfiltration (MF). (From Bylund, G., *Dairy Processing Handbook*, Tetra Pak Processing Systems, Lund, Sweden, 1995.)

2.3.3 Sterilization of Milk Products

Sterilization is a process based on a heat treatment such that all microorganisms and heat-resistant enzymes are inactivated. Sterilized products have excellent keeping qualities and can be stored for long periods of time at ambient temperatures.

The killing effect of sterilization on microorganisms can be mathematically expressed as the following logarithmic function:

$$K \times t = \log N/Nt$$

where N = number of microorganisms (spores) originally present in the product, Nt = number of microorganisms (spores) present after a given time of treatment (t), K = a constant, and t = time of treatment.

A logarithmic function can never reach zero! This means that sterility, defined as the absence of living bacterial spores in a food product, is impossible to achieve. The expression "commercial sterility" is commonly used to identify UHT food products. A commercially sterile product is a food product that is free from microorganisms that grow under the prevailing conditions. The graphs shown in Figure 2.5 show the temperature-time curves concerning the two heat sterilization

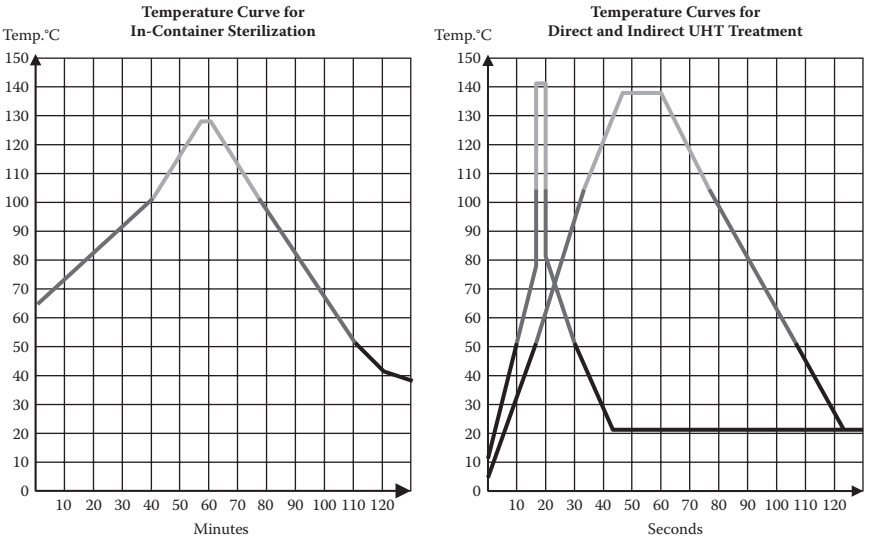


FIGURE 2.5
Temperature curves for in-container and UHT sterilization.

systems most frequently used. From these figures we can see that while the time for sterilization of containers with nonsterile product requires minutes, the corresponding time for UHT treatment is just a matter of seconds.

The two methods used for production of long-life milk are shown:

1. In-container sterilization, with product and container heated at about 116°C for about 20 min
2. Ultra-high-temperature (UHT) treatment with the product heated at 135–150°C for 4–15 s, followed by aseptic packaging in packages protecting the product against light and atmospheric oxygen

Both filled containers can be stored at ambient temperature.

2.3.3.1 In-Container Sterilization

The two processes used for product sterilization in bottles or cans are shown in Figure 2.6, and they are the following:

- Batch processing in autoclaves
- Continuous processing systems carried out by:
  - Vertical hydrostatic towers
  - Horizontal sterilizers

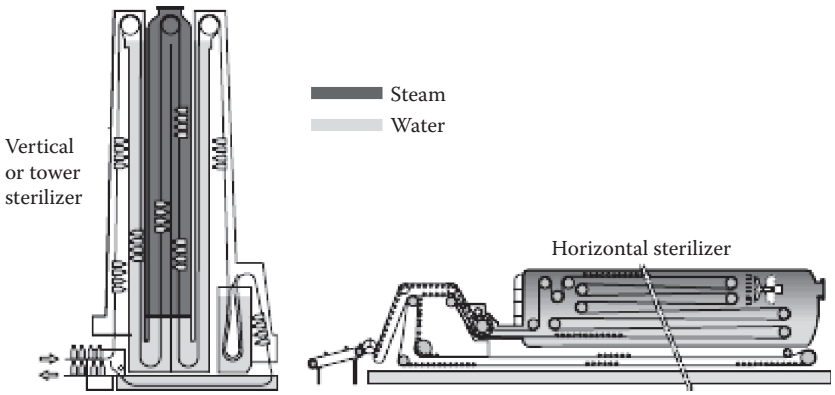


FIGURE 2.6
Vertical and horizontal sterilizers. (From Bylund, G., *Dairy Processing Handbook*, Tetra Pak Processing Systems, Lund, Sweden, 1995.)

2.3.3.1.1 Batch Processing

The batch system can be performed by three different methods:

1. In stacks of crates in a static pressure vessel (autoclave)
2. In a cage that can be rotated in a static autoclave
3. In a rotary autoclave

In the sterilization through autoclave, milk is preheated to about 80°C and then transferred to bottles previously cleaned and heated. Bottles are capped and placed in a steam chamber to be sterilized, normally at 110–120°C, for 15–40 min. The batch is then cooled and the autoclave can be filled with a new batch. The same principle is normally used for cans. There are different quality advantages that make rotary autoclave more desirable than the static autoclave. Batch sterilization in autoclaves is a technique more often used for canned solid foods. Since sterilization takes place after bottling or canning, aseptic handling criticalities are completely avoided, but on the other hand, heat-resistant packaging materials or containers must be used for this purpose.

2.3.3.1.2 Continuous Processing

Continuous processing systems are normally used for mass production. For continuous sterilization, there are two main types of equipment:

1. The hydrostatic vertical bottle sterilizer
2. The horizontal rotary valve-sealed sterilizer

The hydrostatic vertical sterilizer (tower) consists of a central chamber maintained at sterilizing temperature by steam under pressure, counterbalanced on the inlet and discharge sides by columns of water producing an equivalent pressure. With this equipment a capacity of 20,000 containers/h can be achieved to sterilize plastic and glass bottles as well as flexible containers with plastic films.

2.3.3.2 UHT Treatment

UHT treatment is a continuous process used for products that can be pumped. It can be applied to a wide range of liquid food products. Milk is pumped in a closed system to be preheated, heat treated, homogenized, cooled, and packed in aseptic conditions. Low-acid (with pH above 4.5)

liquid products are usually heated to 135–150°C for a few seconds, by either indirect heating, direct steam injection, or infusion. High-acid (with pH below 4.5) liquid products such as juice or tomato soup are normally heated at 90–95°C for 15–30 s. Compared with traditional sterilization in hydrostatic towers, UHT treatment saves time, labor, energy, and space. Moreover, UHT is a high-speed process that has much less effect on the flavor of the milk. There are two main types of UHT systems widely used on the market:

1. Direct systems
2. Indirect systems

2.3.3.2.1 Direct Systems

In the direct systems products come in direct contact with the heating medium, followed by flash cooling in a vacuum vessel. Figure 2.7 shows the two techniques used in direct systems: steam injection and steam infusion.

The direct systems are divided into:

- Steam injection systems, with steam injected into the product
- Steam infusion systems, with product introduced into a steam-filled vessel

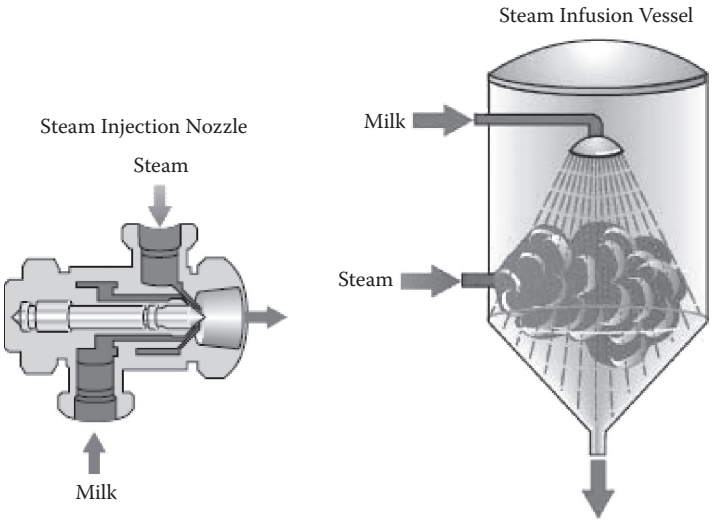


FIGURE 2.7
Direct sterilization by steam injection and steam infusion. (From Bylund, G., *Dairy Processing Handbook*, Tetra Pak Processing Systems, Lund, Sweden, 1995.)

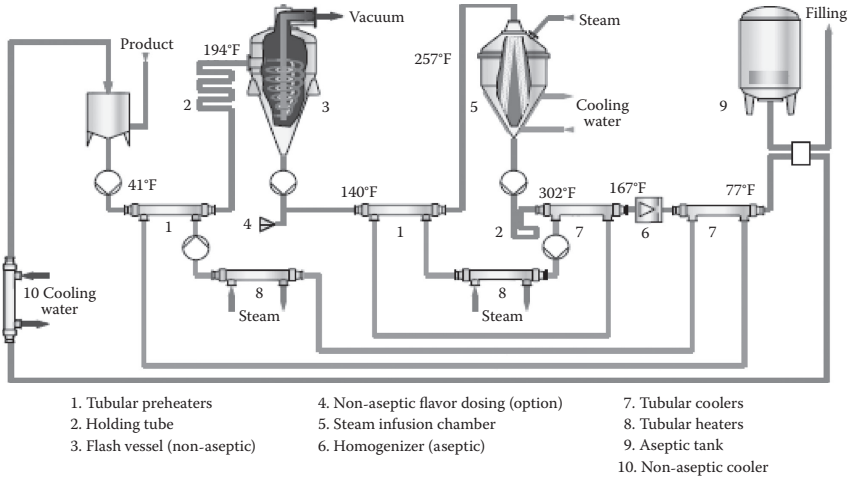


FIGURE 2.8
High heat infusion sterilizer.

A direct UHT plant is based on steam infusion.

The flow diagram in Figure 2.8 illustrates the principal design of a heat infusion sterilizer. UHT systems, based on infusion heating, are used where the manufacturer wants to produce a high-quality product with as little heat degradation as possible. Also, flexibility in throughput and variety in product range call for an infusion-based system. The vacuum chamber has been installed prior to the infusion chamber. This design facilitates improvement in energy recovery, and it is possible to achieve 75% regeneration compared to 40% with conventional infusion systems and 80–85% with indirect tubular systems. The growing incidents of heat-resistant spores (HRSs) are challenging traditional UHT technologies and setting new targets. The HRSs are extremely heat resistant and require a minimum of 145–150°C for 3–10 s to achieve commercial sterility. If the temperature is increased to this level in a traditional indirect UHT plant, it would have an adverse effect on the product quality and the overall running time of the plant. Furthermore, it would result in higher product losses during start and stop, and more frequent CIP cycles would have to be applied.

2.3.3.2.2 Indirect Systems

Indirect heating UHT plants are normally built for production capacities up to 30,000 L/h. A typical flowchart is shown in Figure 2.9.

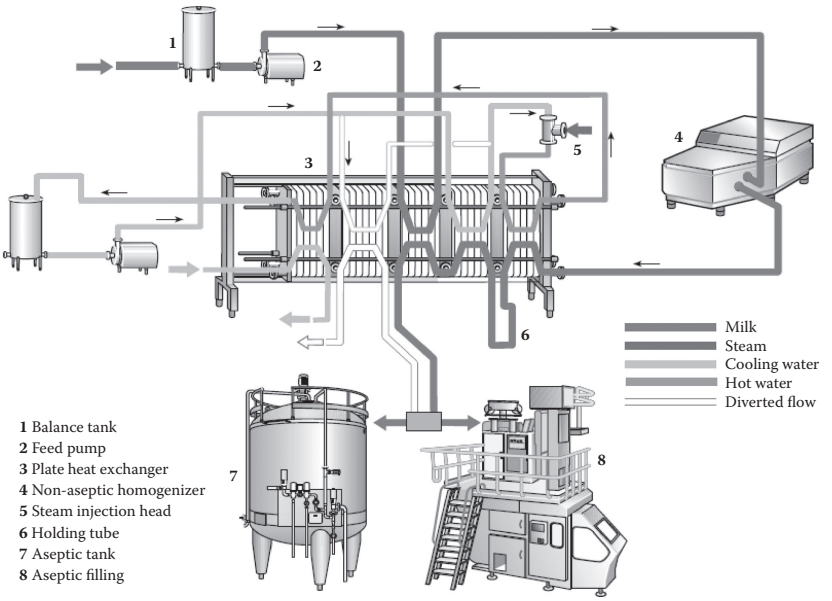


FIGURE 2.9
Indirect UHT system based on plate heat exchanger. (From Bylund, G., *Dairy Processing Handbook*, Tetra Pak Processing Systems, Lund, Sweden, 1995.)

In the indirect systems heat is transferred from the heating media to the product through plate or tubular wall, heated by hot water or steam. As shown in Figure 2.10, the indirect systems can be based on the following:

- Plate heat exchangers
- Tubular heat exchangers
- Scraped surface heat exchangers, used to transfer heat to liquid products

Looking at the indirect heating plant shown in Figure 2.9, the product is pumped at about 4°C from the storage tank to the balance tank (1), and from there by the feed pump (2) to the regenerative section of the plate heat exchanger (3). In this section the product is heated to about 75°C by UHT-treated milk, which is cooled at the same time. The preheated product is then homogenized (4) at a pressure of 18–25 MPa (180–250 bar). The preheated, homogenized product continues to the heating section of the plate heat exchanger, where it is heated to about 137°C. The heating medium is a closed hot water circuit with the temperature regulated by steam injection (5) into the water. After heating, the product passes

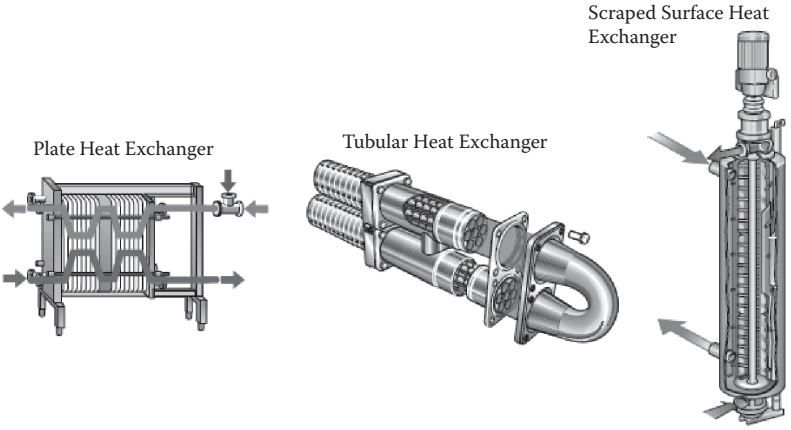


FIGURE 2.10
Plate, tubular, and scraped surface heat exchangers. (From Bylund, G., *Dairy Processing Handbook*, Tetra Pak Processing Systems, Lund, Sweden, 1995.)

through the holding tube (6), dimensioned for about 4 s. Finally, cooling is performed in two sequences:

1. Against the cool end of the hot water circuit
2. Against the cold incoming product

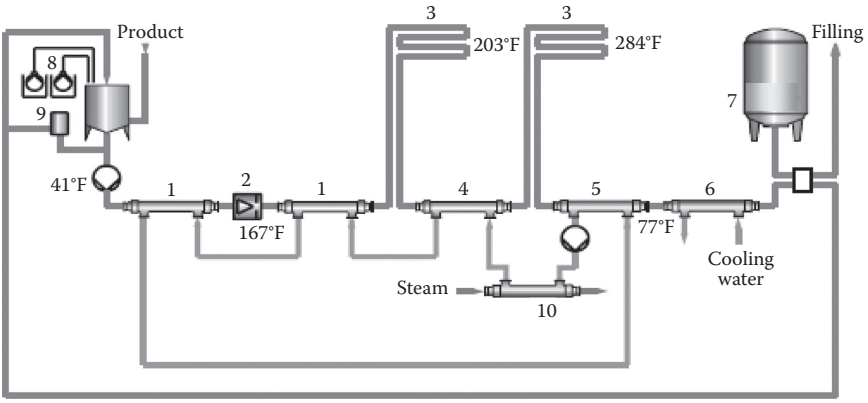
The product that leaves the regenerative cooler continues directly to the aseptic packaging (8) or to an aseptic tank (7) for intermediate storage.

UHT systems based on tubular heat exchangers have become popular in many countries and are typically chosen where large volumes of liquid food products have to be processed at the lowest possible costs. In Figure 2.11, a flow diagram illustrates the design principle, including some of the processing parameters.

Figure 2.12 shows how the pressure drop affects the maximum running hours. In a plate-based sterilizer, the increase in pressure drop is limited to 30–40%. This is not a limiting factor in tubular systems, and 16–20 h operating time between cleaning (CIP) is possible. It is also possible to operate with an intermediate cleaning each 20 h and reduce the full CIP cycles to once a week. Exact times will depend on particular food products and microbiological considerations.

2.3.3.2.3 Aseptic Tanks

The aseptic tank shown in Figure 2.13 is normally used as an intermediate storage of UHT liquid dairy foods.



1. Tubular regenerative preheaters
2. Homogenizer
3. Holding tubes
4. Tubular final heater
5. Tubular regenerative cooler
6. Final cooler
7. Sterile tank
8. CIP unit
9. Sterilizing loop
10. Water heater

FIGURE 2.11
Flow diagram of a tubular sterilizer.

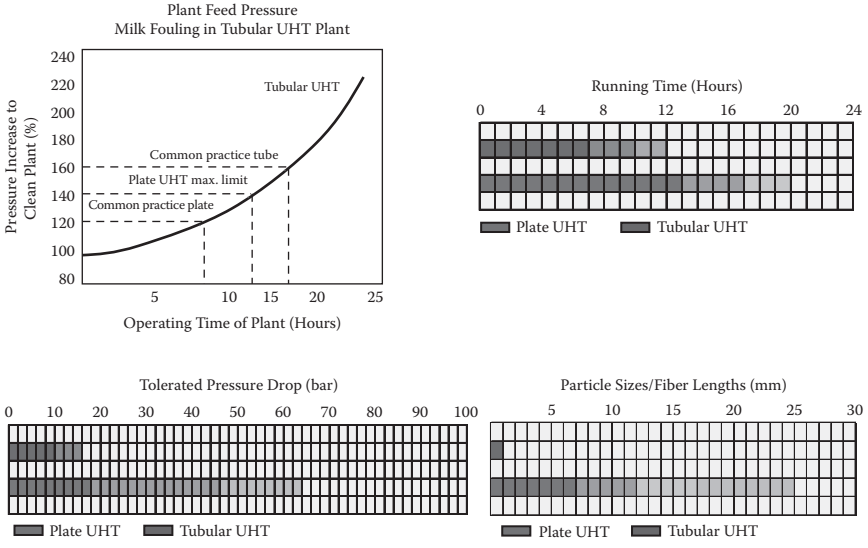


FIGURE 2.12
Comparison of data for tubular and plate sterilizers.

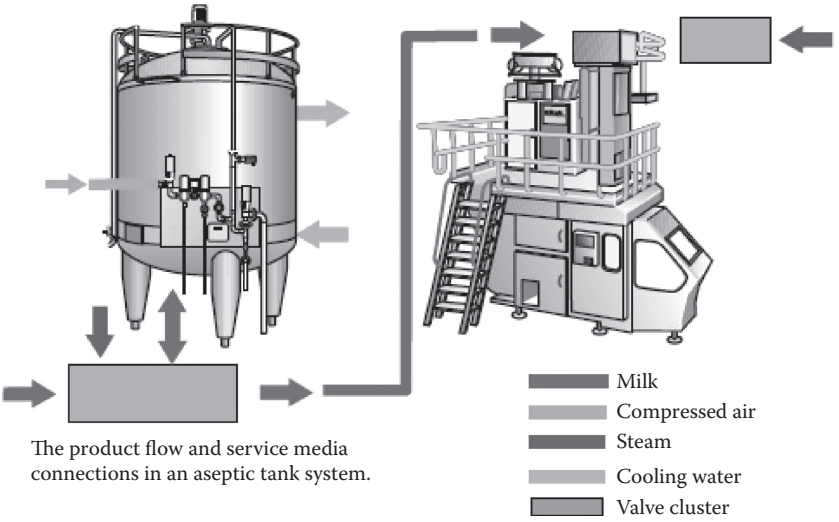


FIGURE 2.13
Aseptic tank connected to the aseptic filler. (From Bylund, G., *Dairy Processing Handbook*, Tetra Pak Processing Systems, Lund, Sweden, 1995.)

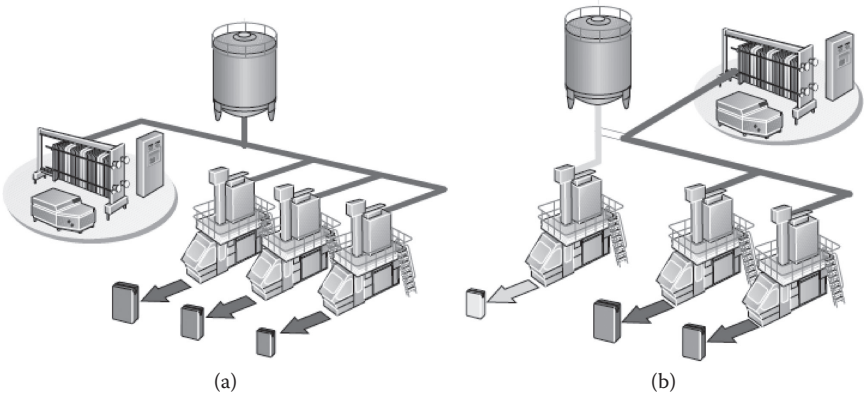


FIGURE 2.14
Aseptic tank used (a) as a buffer and (b) as an intermediate storage tank. (From Bylund, G., *Dairy Processing Handbook*, Tetra Pak Processing Systems, Lund, Sweden, 1995.)

Figure 2.14 shows two different applications that represent the most common use of an aseptic tank, and food product flows in UHT lines.

1. In the application (a), if one filling equipment incidentally stops, the aseptic tank takes in product surplus during the stop time. Processing equipment is not stopped, sterility of product is not lost,

and as soon as filling machines are still available, production will restart without losing time and money to clean and sterilize processing equipment.
2. Application (b) shows a simultaneous packaging of two different products. The aseptic tank is first filled with one product, in quantity necessary to supply a filler for a full production shift. Then the UHT plant is switched over to another product that is packed directly in the line of the packaging machines.

One or more aseptic tanks included in the production layout offer flexibility in planning production of different food products.

As we see, this equipment contains a lot of critical components that control critical parameters and that need to be put under regular maintenance control; among them we find the following:

- Aseptic valves. Parts such as gasket, O-rings, seals (used to make a tight seal between sterile and nonsterile areas), and steam barrier chambers have to be regularly checked through maintenance. Biological and chemical hazards might be produced by lack of insulation between sterile and nonsterile areas and between food product and cleaning circuits.
- Sterile and microfiltered air circuits. Circuits to generate sterile air, by heat or microfiltration, make use of critical components such as microfilters, air pressure regulators, thermoregulators, thermocouples, and sensors that need to be regularly checked through maintenance. Biological hazards may be dependent on anomalous behavior of sensors or on wrong air pressure or flow caused by dirty microfilters.
- Heat exchangers. These components exchange heat between two different sterile and nonsterile media. Pipes and plates used as separator means, gaskets, and silicon rubber seals need to be regularly checked through maintenance. Biological hazards may be produced by small mechanical microcracks in plates or microholes in pipes.
- Food product pumps. Product pumps, with moving parts, seals, and sterile and nonsterile areas, represent critical components for which a reliable maintenance design must identify tasks useful to put these components under control. Biological and physical hazards may be produced by anomalous wear-out of rotor blades.

Biological, chemical, and physical food safety hazards need to be identified at the maintenance design stage through quality and reliability techniques that enable food companies to design maintenance programs able to produce safe foods with reliable equipment.

2.3.4 Aseptic Filling Equipment

Equipment and technologies used to pack aseptic liquid foods are rather complex; since packaging of fresh foods has a lower complexity, this section will mainly show technical criticalities of aseptic packaging systems. Aseptic packaging can be defined as the filling of a commercially sterile food product into a sterile container under aseptic conditions and hermetically sealed so that reinfection is prevented. Aseptic packaging technology is fundamentally different from that of conventional food processing by canning. As shown in Figure 2.15, in canning the process begins with treating the food prior to filling, and food product is introduced into the package, usually hot (hot filling). The container

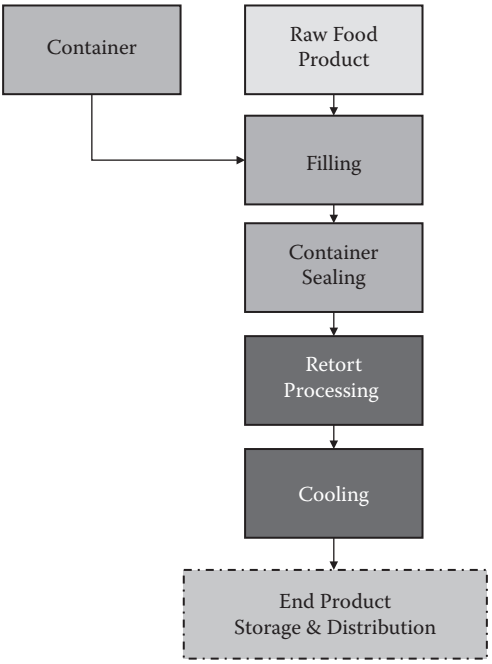


FIGURE 2.15
Process flow for canning.

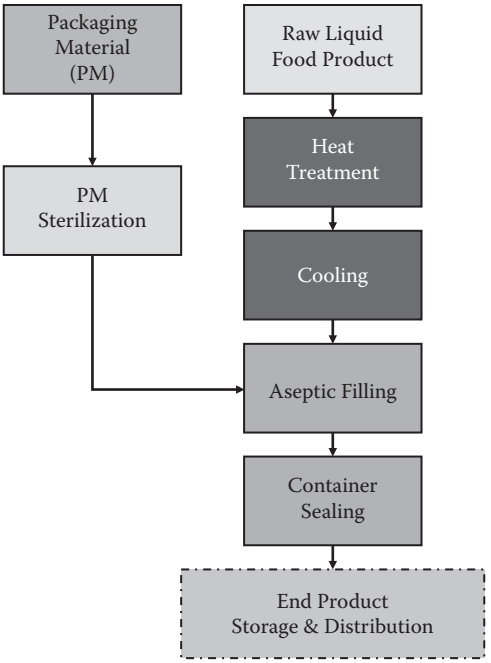


FIGURE 2.16
Process flow for aseptic processing and packaging.

is hermetically sealed and then subjected to heating (retort processing). The saturated steam process is the oldest method of in-container sterilization: the retort vessel is saturated with steam and all air is evacuated from the retort. There is no overpressure during the sterilization phases of this process; however, there may be air overpressure applied during the cooling steps to avoid or prevent container deformation. The container must be able to withstand heat to about 100°C for high-acid products (pH lower than 4.5) and up to 127°C for low-acid products (pH higher than 4.5), which must receive added heat to destroy heat-resistant microbial spores.

As shown in Figure 2.16, aseptic processing and packaging comprise the following phases:

- Sterilization (normally direct or indirect heating) of products before filling
- Sterilization of packaging materials or containers
- Aseptic filling:

  - Sterilization of the aseptic filler before operation
  - Maintaining of sterility during production
  - Package forming
- Package sealing before filling
- Production of hermetic containers

Some of the main criticalities of the aseptic packaging phases are described below.

2.3.4.1 Packaging Material (PM) Sterilization

In the aseptic packaging systems, packaging material is sterilized by different methods. Hydrogen peroxide (H_2O_2), with concentrations up to 35%, temperatures up to 80°C, and contact times with PM up to 15 s, with or without wetting agent (used to improve adhesion with PM), has been found to be successful for inline and continuous aseptic packaging. For legal restrictions, the end food product must not contain H_2O_2 in quantities greater than 0.5 parts per million (ppm). This is the reason why a PM sterilization system must provide not only an effective sterilization circuit, but also a drying circuit able to remove, mechanically or by heat, the H_2O_2 residues on surfaces in contact with food product. Different methods of packaging material sterilization are currently used, but sterilization efficiency should be established in terms of numbers of log (logarithmic) cycle reductions of the most resistant microorganisms. Packaging material is usually sterilized either:

- Inside the filling equipment
- Externally, and then introduced aseptically into the aseptic zone of the aseptic filler

Microorganism inactivation has traditionally been carried out by heating. Microorganisms, especially spores, show greater thermal resistance when exposed to dry heat than moist heat. When heat is used, the nature of the packaging material surface must be carefully considered. Plastics or carton packaging, with their low conductivity, are more difficult to thermally sterilize than metal or glass containers. In addition, plastic materials generally have a low thermal stability and can be permanently deformed by the time-temperature sequences necessary to achieve sterilization. Thermal processes do not deposit any hazardous or undesirable

residues on the surface being treated and do not present environmental hazards.

Chemical methods use a wide variety of chemicals in the form of liquids and gases to disinfect and sterilize equipment and packaging materials. Hydrogen peroxide is one of the most widely used chemicals for sterilizing packaging materials. To sterilize packaging material surfaces (in contact with food), the first successful aseptic filling system used a combination of hydrogen peroxide and heat. Many aseptic packaging systems use hydrogen peroxide at concentrations varying from 30 to 35%, followed by hot air (60–125°C) to increase the sterilizing effect and dry hydrogen peroxide residues from packaging materials and other food contact surfaces. Sterilization performance increases with both peroxide concentration and temperature.

Figure 2.17 shows that the packaging material reel is unwound and guided to be dipped into a hydrogen peroxide bath where it is sterilized (sterilization by immersion). Hydrogen peroxide is indirectly heated through an inner deionized hot water bath to a temperature up to 80°C. At the hydrogen peroxide bath outfeed, a dry hot air station produces

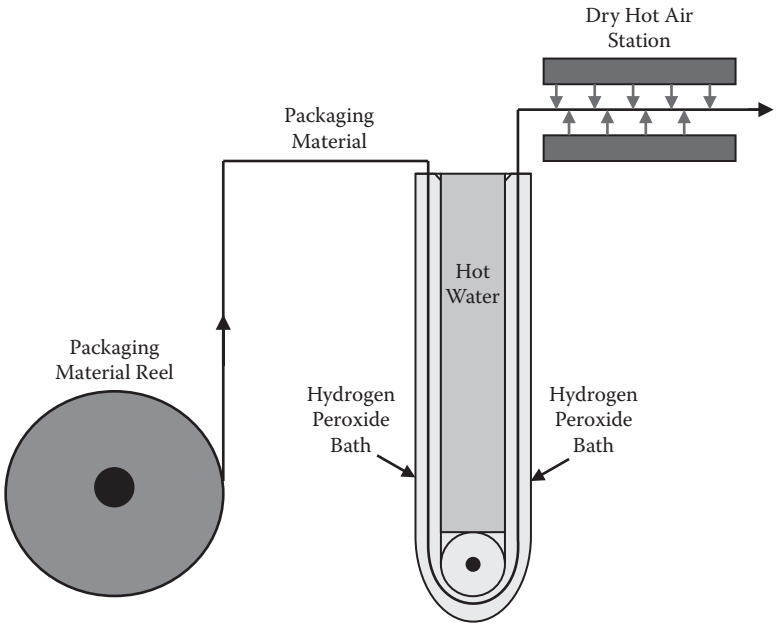


FIGURE 2.17
Packaging material sterilization through immersion of an H_2O_2 bath.

air knives, at a temperature of 100–130°C, able to dry H_2O_2 residues and improve PM sterilization efficiency. In this type of system, PM sterilization efficiency depends on:

- Immersion time of PM into the H_2O_2 bath. In this system this is normally a fixed parameter dependent on the following:
  - Length of hydrogen peroxide bath
  - Equipment speed
  - Volume of package
- Hydrogen peroxide temperature and concentration. H_2O_2 temperature and concentration are normally established by the equipment supplier.
- Hot air (to dry H_2O_2 residues on packaging material) temperature and flow.

Hot air temperature and flow are established by the equipment supplier.

In this equipment unit, we have several critical components and parameters:

1. Packaging material guides. Different drive rollers and guides enable PM to be guided both outside and inside of hydrogen peroxide bath to avoid friction with metallic parts and contact with hot surfaces. Smooth and constant packaging material running or sliding within these units is important for its sterilization and to avoid damage on the internal and external surfaces (caused by scratches and pinches).
2. Hydrogen peroxide temperature and concentration. A preset temperature of hydrogen peroxide is indirectly achieved through heat generated and irradiated by an inner water bath heated by a group of heating elements. Hydrogen peroxide concentration can be automatically monitored through instruments able to measure its density variation or manually through the equipment operator.
3. Hot air station to dry and sterilize packaging material. Airflow and temperature represent two critical parameters that ensure PM sterilization efficiency. Other criticalities may be introduced by burnt PM and polyethylene residues that can produce scratches on the side of packaging materials that come in contact with food product.

Maintenance and cleaning on drive rollers, guides, and thermoregulators on mechanical components represent the tool to avoid biological

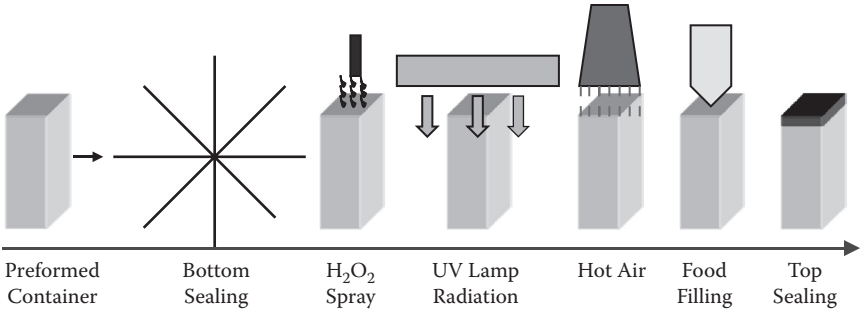


FIGURE 2.18
Preformed container sterilization.

hazards produced by a poor PM sterilization, and by scratches and pinches on PM.

Other packaging material sterilization processes that start from a preformed container instead of a PM reel make use of the technology shown in Figure 2.18.

After a container's bottom sealing, a spray nozzle injects a 2% concentration of H_2O_2 into the package. At the next station, UV lamp radiation is used to reduce microbial contamination inside the package. Vegetative cells are significantly more susceptible to UV light exposure than bacterial spores. The synergy established by a combination of hydrogen peroxide, UV light, and hot air blown into the package at the next stage of the process allows us to sterilize and dry package material for product filling. After final top sealing, the container is conveyed to the filler outfeed and downstream equipment.

With this technology we still have some other different criticalities that need to be put under control through a reliable maintenance design program (continued from list on previous page):

4. Hydrogen peroxide spray. H_2O_2 concentration, air pressure used to spray sterilization solution into the package, and microfiltration of pressurized air are some of the criticalities that need to be monitored through regular maintenance.
5. UV lamp radiation. Electrical parameters of UV lamp power supply and feedback signals from UV light radiated into the package need to be monitored to avoid low sterilization efficiency.
6. Hot air to dry and sterilize the package. Sterile air pressure/flow and temperature are some of the critical parameters that need to be

monitored to avoid low sterilization efficiency and anomalous H_2O_2 residues.

7. Filling station. There are different systems available to realize a smooth and precise filling, but in any case, to avoid package integrity problems, it is mandatory to avoid product residues on the top sealing area of the package. Also in this case, maintenance design will play an important role in ensuring quality and reliability.
8. Package sealing. The technology used to realize package bottom and top sealing makes use of heating bars, ultrasonic, or induction heating elements.

Criticalities are dependent on package position and stability, pressure of sealing jaws, heat generation, and transfer to the package sealing area.

Nowadays, many critical parameters have been put under constant control through sensors and transducers that connect to automatic control systems that allow us to carry out reliable monitoring activity. Despite the use of modern technologies, maintenance continues to play a fundamental role in maintaining food criticalities under control. Mechanical wear, adjustment, and calibration of physical parameters can be done only through a reliable maintenance design program.

2.3.4.2 Package Filling, Forming, and Sealing

In systems where packages are realized through a process starting from a packaging material reel, PM is first longitudinally sealed, and as soon as bottom transversal sealing is realized, food product is introduced into the package and package forming and sealing can finally take place. Filling systems are normally realized by aseptic valves with a steam barrier to avoid contact between cleaning solutions (alkali and acid) flowing in one pipe and food product flowing in another communicating pipe, but insulated by an aseptic valve. As shown by Figure 2.19, steam barrier valve, pistons, and gaskets represent sure critical components that need to be regularly inspected through maintenance.

Constant flow valves illustrated in Figure 2.20 are used to control flow or volume of product flowing or dropping into the container. These valves are driven by a feedback signal coming from a product probe that feels the level of food product in the container. Mechanical components such as springs, O-rings, gaskets, and seals, used in the aseptic valves, together with conductivity probes, represent some of the components that need to be put

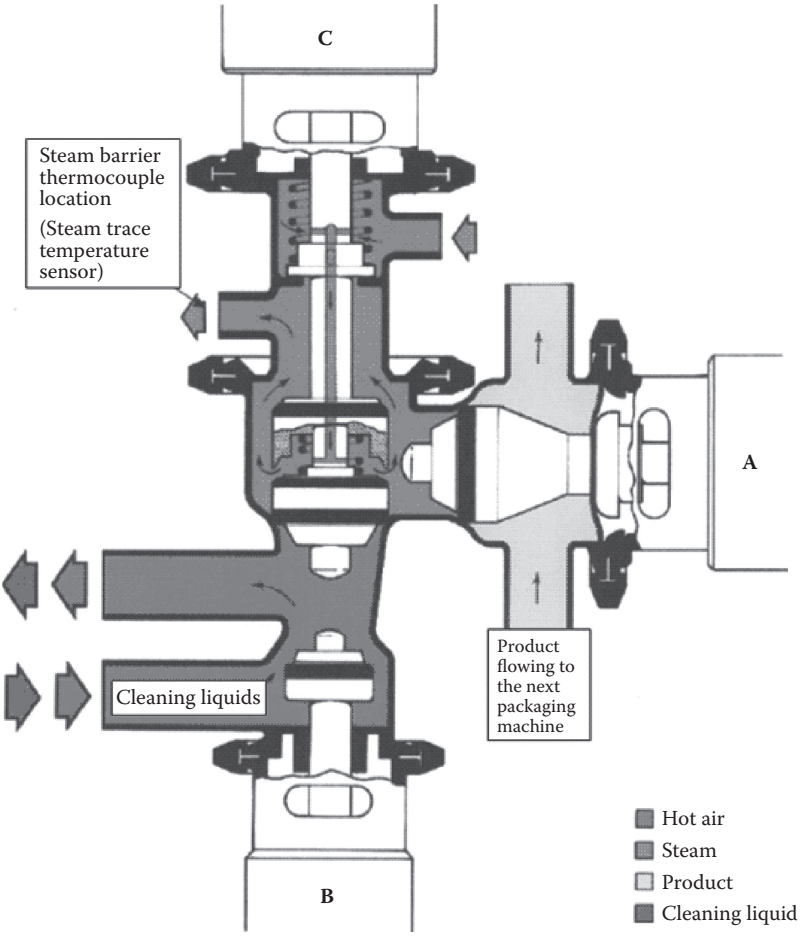


FIGURE 2.19
Aseptic valve with steam barrier. (From Tetra Pak Training Department, Training material on equipment, 1996.)

under maintenance control. The forming section is made up of different types of jaws or heads that form the container through mechanical pressure or through various forms of heating. Figure 2.21 shows a system that makes use of forming and pressure jaws that, through longitudinal and transversal movements, determine the length and width of the package.

The forming process is rather complex and involves a lot of different critical functions and conditions, many of which can be controlled only through maintenance. Surfaces of mechanical parts used to form packages must be smooth, free from crevices or scratches that can pinch the package

FIGURE 2.20
Constant flow valves used to fill containers.

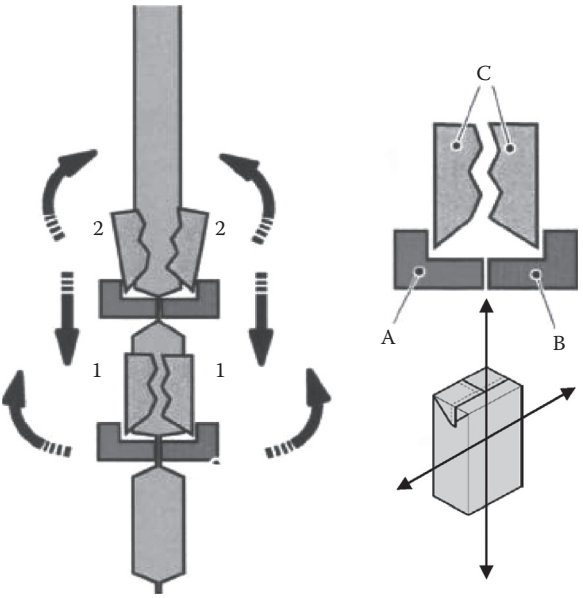


FIGURE 2.21
Package filling, forming, and sealing process. (From Tetra Pak Training Department, Training material on equipment, 1996.)

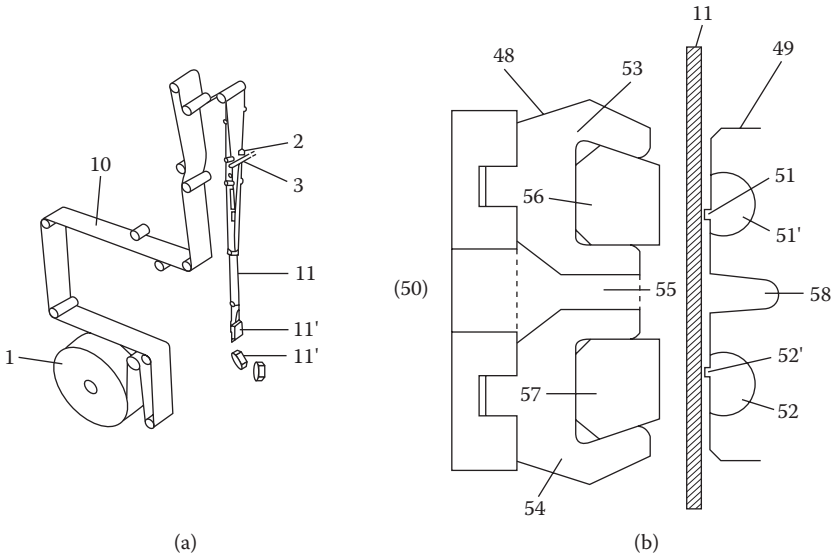


FIGURE 2.22
Packaging material web: From reel to forming and sealing section. (From Tetra Pak Training Department, Training material on equipment, 1996.)

and produce biological hazards. Often, electrical servo-motors are widely used to move pressure and sealing jaws, both longitudinally and transversally, to form and seal packages according to their printing design.

Food packaging processes, for many solid and liquid foods, such as juices, milk, pastes, and soups, are often of the type "form, fill, and seal" and may be carried out by shaping a packaging material web moving continuously toward the form, seal, and fill unit. Figure 2.22(a) shows an example of tube forming from a continuous web of packaging material to supply the unit used to form, seal, and cut the package. Packaging material is made up of materials comprising a core layer of paperboard, an outer heat sealing layer of polyethylene, and where necessary, an aluminum foil as a gas barrier layer used to realize induction heating for longitudinal and transversal sealing of the package.

Packaging material web is progressively shaped to form a tube and sealed in the longitudinal direction within the filling equipment. While the packaging material tube is moving downward, liquid food is supplied from the filling pipe inside of the tubular packaging material. As shown in Figure 2.23, the longitudinal sealing necessary to close the ends of this tube is carried out by heat sealing of outer polyethylene surfaces.

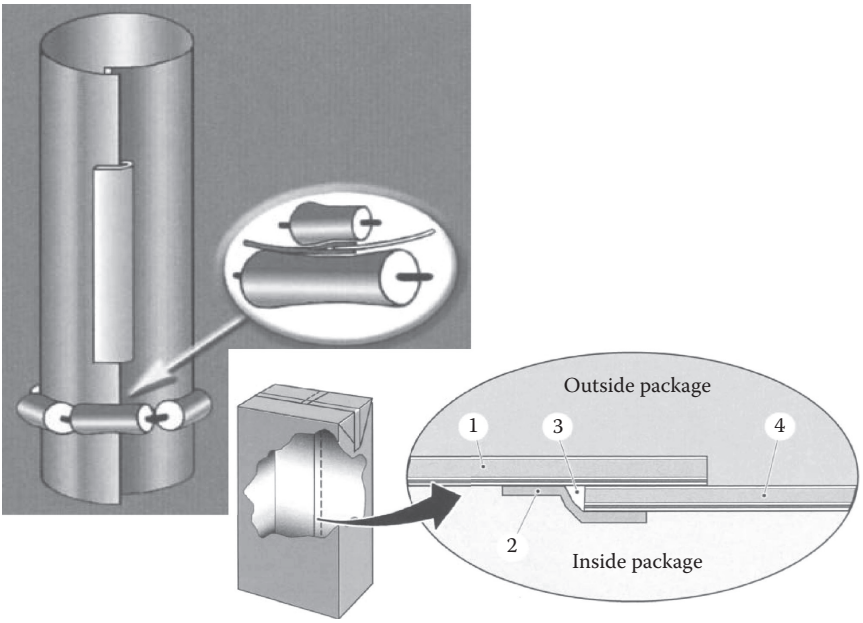


FIGURE 2.23
Longitudinal sealing. (From Tetra Pak, *Quality Control Manual*, Issue 8605, 1986.)

This heat sealing may be performed by techniques such as the following:

- Induction heating
- Radio frequency (RF)
- Microwaves
- Hot air sealing
- Ultra-sonic heat sealing

A widely used heat sealing technique for longitudinal and transversal sealing is induction heating. Aluminum foil, as a packaging material core layer, acts as an electrical secondary element in which an induced electrical current generates heat. The contiguous polyethylene layers are melted together by simultaneous application of induction current and mechanical pressure. As shown in Figure 2.22(b), the transversal sealing system is built up by counter jaws and heat sealing jaws.

Figure 2.24 shows that each counter jaw is provided with a pair of cutting rails, and each heat seal jaw is provided with a sealing inductor. Each sealing inductor is electrically supplied with medium- or high-frequency

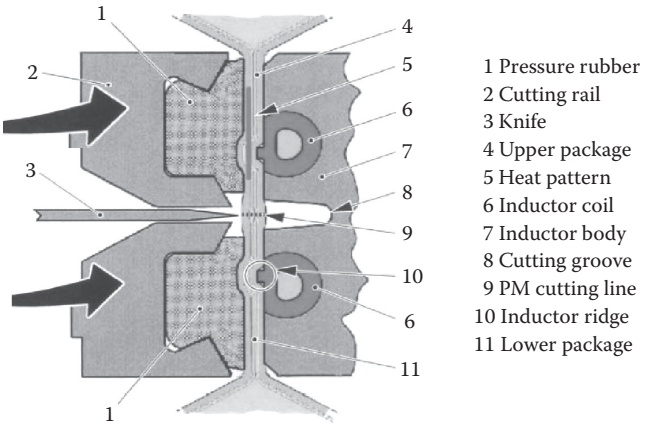


FIGURE 2.24
Cutting rails and sealing inductors. (From Tetra Pak, *Quality Control Manual*, Issue 8605, 1986.)

voltage to generate induced current on aluminum foil, and then the transversal heat necessary to seal the packaging material. A cutting knife, used to cut packages, is moved into the gap realized between the two inductor coils. Each sealing inductor has a counter element, named pressure pad or rubber, that extends along the cutting rail.

Critical components and parameters of this section are the following:

- Sealing elements (with inductor coils). Because of pressure generated by a pair of jaws (sealing and counter pressure) linked together with a double layer of packaging material placed just in between, sealing elements tend to progressively become concaves. These elements need to be regularly checked on a daily basis by equipment operators. If they become concaves, or if they present an irregular profile, the sealing quality and package integrity can be heavily compromised, generating a food biological hazard. If inductor surfaces are irregular with sharp edges, as a result of being cleaned with wrong materials (hard or abrasive), the transversal sealing quality can be compromised.
- Electrical cables (that supply electrical power to sealing inductors). Cables are often subjected to mechanical stress and interested by vapors generated from hydrogen peroxide and cleaning solutions. A short circuit can be experienced if the integrity of the cables is not checked to verify the quality of external cladding. Insulation between

electrical cables must be verified periodically to avoid power losses and short circuits.
- Cutting system. The cutting function, activated by hydraulic and mechanical power, needs to be regularly checked by the equipment operator to avoid low transversal sealing quality and then biological hazard.
- Servo-motors and kinematic mechanisms used to move pressure and sealing jaws need to be checked by maintenance specialists to ensure the right transversal sealing pressure necessary to seal and cut the package and avoid quality transversal sealing problems.

In roll-feed fillers the operations to form, seal, fill, and cut packages are more complex than those of the systems that process preformed packages. To avoid biological, physical, and chemical hazards, a reliable maintenance design should define what, when, and how critical components need to be maintained.

2.4 ANALYSIS OF CASE STUDIES TO ADDRESS THE NEED OF A MAINTENANCE PROCESS FOR FOOD INDUSTRY PACKAGING LINES

Under this heading, the analysis of some case studies will underline the need for a maintenance process specifically designed for the food 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 good manufacturing practices (GMPs) applied to this industrial sector.

2.4.1 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.

1. Equipment setup. Two different sterilizers supply the aseptic liquid 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 L. Four different filling machines are used to pack white milk and chocolate milk.

2. Problem description. The company experienced an unsterility problem on one production line that caused a direct economic loss higher than 400,000 euro.

   The production manager claimed that this economic loss was due to costs arising from the following:

   - Packaging material waste
   - Product waste
   - Equipment 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 4 days, by means of product pH measurement, confirmed with plating, identified product contamination. After further investigation, carried out through destructive testing on packages produced, some micro-holes with plastic lumps were found on the longitudinal sealing of the package.

3. Troubleshooting. To identify the potential causes behind this phenomenon, a troubleshooting activity was carried out in 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.

4. 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. Poor knowledge of critical control points existing in the filling equipment and the potential effects produced by lack of control determined a superficial approach in defining a reliable maintenance program. This experience shows the importance of getting good knowledge of all critical variables that can affect package integrity and their effect on biological risk. All maintenance activities must be a result of a design and implementation process able to control biological risk and prevent package integrity problems that produce product contamination.

2.4.2 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.

1. Equipment setup. One product sterilizer supplies an aseptic filler packing cream and fruit juice at a capacity of 20,000 packs/h. 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.
2. Problem description. The company claimed a product contamination, due to the sporadic presence of nonhermetic 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 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.

3. Troubleshooting. The troubleshooting activity started on jaw (package forming) and sealing systems to verify if mechanical and electrical operations were correctly performed. The different destructive tests, carried out 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 troubleshooting 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 as counter-pressure devices) were completely worn out.
   - Some inductor profiles were out of tolerance (concave instead of straight).
   - The electromechanical power transfer system (based on bar and slider) was 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.
4. 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 simple daily and weekly maintenance procedures.
   - The wrong power transfer could have been detected by the machine operator if further training had enabled him to regularly check some electrical parameters.
   - The company's management understood that the intention to save money had 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 with the production of hermetic sealed packages containing

liquid food products. Because of criticalities involved in the packaging forming and sealing section, the equipment functions and parts that form, fill, and seal the packages needed to be put under systematic maintenance control. In this regard, the company was not aware of

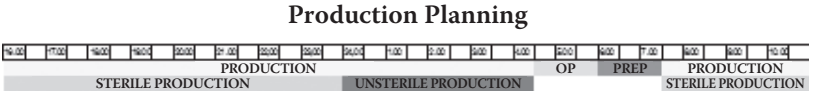
- The effects produced by a failure on the sealing system
- The importance of maintenance control through procedures able to manage the biological and physical risks depending on equipment reliability

This case underlines the importance to identify the critical control points existing in the forming and sealing section of equipment used to pack liquid or solid foods. Longitudinal and transversal sealing of food containers is normally realized through a close interaction between electrical and mechanical devices that use parts subject to wear that are not automatically monitored. Lack of knowledge of criticalities and their effect on product safety may result, as we saw in this case, in a wide product unsterility dangerous to public health.

2.4.3 Third Case Study: Product Contamination due to Mineral Oil Leakage

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

1. Equipment setup. Two product sterilizers supply an aseptic filler packing cooking cream with a capacity of 7500 packs/h. The downstream equipment is quite simple and made by one cardboard packer and a final palletizer.
2. Problem description. The company claimed a sporadic product contamination, concentrated on a specific time interval, which disappeared after a final 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 to both production planning and 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.

3. Troubleshooting. The troubleshooting 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 careful monitoring activity, an oil leakage was noticed coming from a hydraulic piston that was working on a cylinder that fed 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).
4. 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 the machine.
   - While the preventive maintenance checklists 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 hazard analysis and critical control points (HACCP) analysis was applied on this filler section, there was not a clear awareness of the criticality associated with 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 a HACCP plan and relative maintenance procedures, designed to put under control the equipment critical control points, determined a higher risk of chemical contamination of product packed.

All potential sources that could cause chemical food contamination must be identified and reliable maintenance tasks designed to avoid food product safety risks dangerous to public health.

2.4.4 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.

1. Equipment setup. Two different product sterilizers supply the aseptic fillers of two packaging lines with a capacity of 12,000 packs/h each. The downstream equipment is made up by one cap applicator, one cardboard packer, and a final palletizer, all installed in the same line.
2. Problem description. This producer claimed the finding of a few unsterile packages, randomly distributed, over five different production runs, produced by two different packaging lines.

   Despite only one or two unsterile packages being found on each pallet produced, the company was forced to withdraw from the market the pallets containing a single defective pack. 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.
3. Troubleshooting. Because of the different types 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 the cleaning phase. Moreover, because of the diversity and complexity of problems found, special attention was placed on examining the training

and skillfulness of people involved in operating and maintaining the equipment.

The investigation done covered the following critical areas:

- Pre- and postproduction practices
- Production practices
- Quality control practices during production
- Cleaning procedures (pre- and postproduction)
- Preventive maintenance program

Below are the findings gathered according to the type of defect found:

Compliance to standards and specification. The production monitoring showed a general noncompliance to 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 represented a risk of an uneven pressure and then a lack of a hermetic seal. The status of transversal sealing inductors and pressure rubbers was not carefully checked by the operators. Packaging material residues have been found trapped in the transversal sealing inductors (see the arrow in Figure 2.25), and this led to their break. As a result, some unsterility packages were found with nonhermetic longitudinal and transversal sealing.

FIGURE 2.25
Transversal sealing inductor.

The visual checks and cleaning practices, normally executed on a daily basis, are particularly important in the filling equipment; the inability of the operator to carry out these practices was one reason for this failure.

Cleaning procedures. Cleaning of the filling system for equipment used to pack liquid food is a particularly important activity; it represents a fundamental prerequisite to be carried out before equipment sterilization. The sterilization process may be ineffective if food product residues are not completely removed through cleansing energy (mechanical or kinetic energy produced by liquid pressure). Sanitization or sterilization can be effective only on surfaces that are free from food product residues. GMPs, normally identified through a HACCP plan, must enable equipment operators to remove any source of dirt and ensure a proper sterilization phase. Cleaning of product filling pipe is a critical operation that can produce product contamination if product residues, splashed on its surface (see Figure 2.26), are not properly removed through manual cleaning. A different way of cleaning this part had been noticed: by using either different detergents or different materials. Big quantities of packaging material dust were found spread all over the internal sterility environment of the filling machine.

FIGURE 2.26
Product residues on filling pipe.

Aseptic piping: connection 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 2.27). These leakages were mainly due to connections not being properly tight and to gaskets completely worn. This phenomenon could be the cause of some unsterile packages found without integrity problems, but with coagulated milk inside.

This is another critical area normally underestimated; lack of systematic maintenance could produce dangerous product leakages that are critical sources of food contamination.

Quality control of filled containers. The quality control procedures intended to check the integrity of the packages produced were not carried out according to the standards described in the operational manual.

Interviews with the equipment operators have shown deep knowledge gaps due to the lack of a basic training program: it was discovered that the only training received consisted of a coaching activity created by an expert colleague.

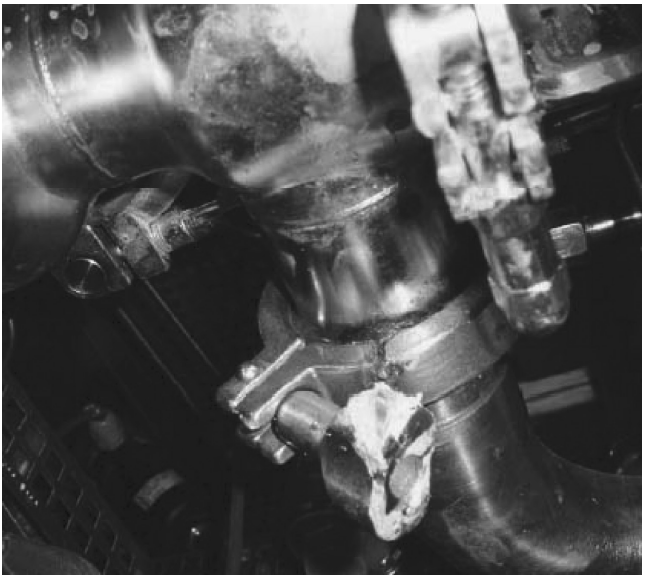


FIGURE 2.27
Milk leakages on pipe connection.

4. 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.
   - The lack of an operator training program produced, as a 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 were not regularly executed, and this was most likely the reason for some unsterility cases.
   - Lack of cleaning and maintenance on longitudinal and transversal sealing inductors was the reason for some not hermetic seals found on blown packages.
   - Caramelized milk residue enabled us to discover leakages of milk on product piping due to weak connection tightness and worn gaskets.

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

2.4.5 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, producing peanut butter. A problem emerged in 2004, in Georgia's peanut country, when it 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 its 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, after hundreds of people were sickened by salmonella-contaminated peanut butter produced at the plant, demanded the records in 2007, 3 years later, and verified the contamination claims. The consequences of this huge contamination include the following:

- Half of the salmonella children illnesses were traced back to the Blakely plant.
- A worldwide recall included peanut butter shipped to schools, military bases, and nursing homes.
- The safety issues raised by this outbreak drew comparisons to those in China's contaminated milk scandal.

Robert Tauxe, a disease prevention expert from the Centers 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:

1. Raw product contamination. Unsatisfied workers on minimum wage, supplied by temporary agencies, put on their uniforms at home, potentially dragging contaminants into the plant, which also had rodents.
2. 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 the thermoregulator system. As result, the equipment designed to pasteurize the product was nonworking at the right temperature, and no alarm or corrective action was able to switch a mandatory production stop.
3. Product quality control. The quality control procedures to detect potential product contaminations at the source were not implemented correctly by the operational staff involved.

In conclusion, this case shows important points of discussion, to be held in great consideration, that support the cases previously analyzed, and the

problem existing in food packaging lines. Below are few questions and reflections about this case:

- Why didn't a critical failure of the product pasteurization system produce any equipment alarm or corrective action? Beyond the possible obsolescence of the equipment used to pasteurize 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, the lack of a HACCP plan produced a lack of maintenance procedures intended to put under control the critical technical parameters of the thermoregulator system.
- Why didn't product quality control and equipment inspection allow detection of the problem? This case emphasizes how important is the quality control of the product during the different phases of the process. If an inline 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 thermoregulator failure, lack of maintenance checks of critical parameters put the system completely out of control.
- Why weren't equipment operators trained and empowered to take full responsibility of the process through autonomous maintenance? Production of fresh, medium-life, 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 equipment and production criticalities, together with an implementation model that defines roles and tasks for an effective implementation.

2.4.6 Analysis of Case Studies and Lessons Learned

The analysis of different case studies showed that one of the common reasons behind unsterility cases and food product contamination is lack of preventive maintenance procedures. The different equipment CCPs that caused food contamination can be put under control only if the different

machine critical functions are properly identified and preventive maintenance actions implemented.

In the first case, the integrity of packages was lost and product contaminated because of the wrong maintenance activity implemented by a person not trained for such a maintenance task. Sometimes a filled container, made by different flexible materials, may hit against a mechanical part that can produce a small hole, which becomes a channel of communication between the external environment and food product sterilized. The analysis of this case study showed a lack of regular maintenance inspection of a critical device (package dumper), and the reason was the unavailability of a HACCP plan intended to identify CCPs and the 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 to the company's image, was not quantifiable.

The second case study has shown that due to economic pressures, the maintenance approach chosen was corrective only, and 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 has shown 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 underlined how important maintenance is in determining whole control over the different critical process elements that produce, as a result, product quality and safety.

The fifth case has shown the dramatic effects of a food process out of control: lack of a HACCP plan and a reliable quality control

and maintenance process produced heavy problems for public health. At the end of this section some common conclusions and suggestions can be drawn:

1. 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.
2. The design and 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.
3. 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.
4. An effective maintenance design process allows the identification of equipment reliability weakness areas where improvements can be achieved through condition monitoring systems, structural modifications, or reliable maintenance procedures.

The process to design and implement maintenance procedures for fresh and long-life food packaging lines must be able to identify the equipment criticalities that can produce food contamination and put them under control through maintenance tasks effectively implemented.

2.5 CONCLUSION

In this chapter food criticalities have been considered with regard to problems placed by threats coming from mandatory legislation, higher competition due to globalization, and cost reduction, which often produces 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 show 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. These cases emphasize 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 show that the economical loss produced by some unsterility cases was very high, but reduction of market share, resulting from damage to a company's image, was definitely higher and difficult to quantify.

The nature of failures that produced food product safety noncompliances drew the attention of food manufacturing companies to identify the relationship existing between equipment reliability and product safety. If critical equipment functions, linked to biological, chemical, and physical hazards of food products, are not effectively put under control through maintenance, the company's image can be compromised and public health too. In conclusion, the scope of this chapter is to make food manufacturers aware of the necessity to

1. Identify the CCPs in the packaging line
2. Define the effects of equipment failures produced on food
3. Establish the maintenance tasks to put the CCPs under control

These requirements cannot be simply satisfied through a reactive approach, but with a maintenance design process able to identify and address the criticalities existing in the packaging line.

3

Potential Contribution Given by Food Safety Certifications and GMPs

There are many food safety certifications (FSCs) and good manufacturing practices (GMPs) adopted in many countries; the scope of this chapter is to examine some of them and identify their contribution to the maintenance design and implementation process. A food safety certification scheme can help the food producer to provide a clear path to have a global view of the whole food chain; it is of no help to use it as a tool to display a formal compliance to a mandatory certification. The GMPs represent another important medium to establish standards concerning manufacturing practices. These standard practices are the base for inspections, training, and future improvements promoted by those who operate the equipment.

3.1 FOOD SAFETY SYSTEM CERTIFICATION (FSSC) 22000

Food safety represents a global problem, not only because of its importance to public health, but also because of its impact on international trade and society. The globalization of food production and its supply make food chain wider more critical and increase the risk of accidents linked to food safety. Food safety certification represents a mandatory step for a food 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 hazards.[16] Effective food safety systems shall manage and ensure the safety and suitability of

food in each link of the supply chain. For this reason, the International Organization for Standardization (ISO) has developed a standard for food safety management systems, called ISO 22000, which is applicable to all organizations in the food chain, ensuring complete integrity of the whole chain.

3.1.1 Global View of the Whole Food Chain Criticalities

FSSC 22000 is specifically developed to audit and certify food safety systems of food manufacturers that process or manufacture products with a long shelf life at ambient temperature. The certification scheme FSSC 22000 establishes requirements to develop, implement, and manage a certification system capable of ensuring the effectiveness of the system and the competence of the personnel involved. FSSC 22000 establishes the requirements for the assessment of the food safety system of food production organizations.

The added value of an organization with certified food safety is

- The capacity acquired by the organization in the identification of the critical issues and control measures in the whole food chain
- The continued effort put in place to keep the system through the continuous involvement of all the people who work in the various sectors involved
- The management commitment to pursue the continuous improvement of its performance

According to the provisions of the law, food safety is defined with the general concept that food composition does not damage the health of the final consumer. Organizations in the chain are therefore required to take seriously all the safety risks that exist in the food department where they are responsible. The final product's quality and safety when HACCP (ISO 22000, clauses 3.1 and 3.3, note 4) is implemented depends on the ability to satisfy the prerequisite programs.

As 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 whole food chain prior and subsequent to its operations when developing and implementing its food safety management system.

3.1.2 Primary and Secondary Sources of Contaminations

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

- Shall have specified requirements
- Shall be described in documents to the extent needed to conduct hazard analysis
- Shall be managed in conformance with the requirements of BSI-PAS 220, clause 9 (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 linked to their activity (ISO 22000, clause 6.2.2). In the requirements and regulations for providing certification (Appendix IIB) important technical issues are taken into consideration:

- Layout of premises workspace:
  - Location of equipment
  - Laboratory facilities
  - Storage of food, packaging materials, ingredients, and nonfood chemicals
- Utilities—air, water, and 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

A food safety certification helps to identify critical issues owing to the different parts of the process regarding hazards coming from primary and secondary sources of contamination. Too often criticalities linked to air condition systems or utilities, completely neglected, have been the hidden cause of sporadic contamination of fresh and, in some cases, long-life food products. Potential primary sources of contamination regarding equipment in direct contact with food products can be influenced by secondary sources of contamination dealing with production environment, services to equipment, and other interacting issues. A global view of the production process allows us to identify cross-contamination areas and interacting elements with different degrees of risk severity that supply a complete picture of the existing hazards. The certification process represents a tool to verify if the characteristics of the internal and external environments in which food production takes place allow food quality and safety, and if all conceivable sources of contamination are under control. Quality audits, from internal and external auditors, have to be seen not as a threatening experience that lead to a negative judgment, but as an opportunity to compare and contrast technical and organizational solutions to identify possible room for further improvements.

3.2 GOOD MANUFACTURING PRACTICES (GMPs)

Good manufacturing practices represent a guidance document for the quality assurance audit to implement and maintain GMPs and fulfill their role in assuring the quality of operational processes. GMPs are ongoing practices designed to ensure an effective overall approach to product quality control and risk management. They do so by setting appropriate standards and practices for product testing, manufacturing, storage, handling, and distribution. The definition of GMPs given by the Institute of Food Science and Technology (UK)[13] in the *Guide to Its Responsible Management* is: "The combination of manufacturing and quality control procedures aimed at ensuring that food products are consistently manufactured to their specifications." GMPs represent a fundamental prerequisite to an effective maintenance design and implementation process since they avoid

equipment stop times or failures simply dependent on lack of standards and provide clarity on how to operate and manage the equipment. Operational, maintenance, cleaning, and quality control practices need to be effectively defined and implemented as a standard by all people to avoid tailor-made behaviors that are often the reason for equipment failures and food safety problems. GMPs are normally divided into four categories:

1. Buildings/facilities and equipment
2. Personnel and quality assurance
3. Processes
4. Products

3.2.1 Buildings/Facilities and Equipment

3.2.1.1 Buildings/Facilities

This section sets out the requirements for the physical premises in which food products are manufactured and stored, and for the equipment used to pack food products. Every food product shall be manufactured, packed, and stored in premises that are designed, constructed, and maintained in a manner that permits the activity to be carried out under sanitary conditions. In particular, these conditions are such that they:

1. Permit the premises to be kept clean
2. Permit the effective cleaning of all surfaces in the premises
3. Permit the food product to be stored or processed appropriately
4. Prevent the contamination of the food product
5. Prevent the addition of extraneous substances to food products

Every food product shall be stored under conditions that will maintain the quality and safety of that product. Manufacturers should ensure that

- Buildings are designed and built to carry out maintenance, cleaning, and sanitary operations; prevent entry of insects and other animals; and prevent cross-contamination of raw, packaging, and product materials
- During production, doors giving direct access to manufacturing and packaging areas to the outdoors are adequately sealed to prevent pests from entering
- Seal surfaces and joints are preventing contamination from extraneous materials and permitting effective cleaning

- They provide adequate ventilation, filtration, and lighting
- Humidity and temperature are controlled, where required, to protect materials and products
- Supply water of potable quality for processing and cleaning meets the Guidelines for Drinking Water Quality
- Floor drains are screened and trapped
- Raw and packaging materials and in-process and finished products are protected against physical, chemical, and microbial contamination, as well as deterioration of the products and the container during storage and temporary storage while in transit

Often, lack of standards regarding production room or service specifications is the cause of food product quality problems and equipment failures with critical safety problems on the food product packed. The interaction existing between equipment used to pack food and the surrounding environment where production takes place must be clearly identified to avoid unknown variables that can negatively affect food product safety and equipment reliability. When the performance of the equipment used and the food product safety are strictly dependent on production room air quality, it is mandatory to define and bring under control air classification. It is important for classification of the production area to place most emphasis on data generated under dynamic conditions, with personnel present, equipment in place, and operations ongoing. For an aseptic processing facility, a monitoring program will assess conformance with specified clean area classifications under dynamic conditions on a regular basis. Table 3.1 summarizes clean area air classifications and recommended action levels of microbiological quality.[23]

3.2.1.2 Equipment

GMPs set out the requirements for the equipment used to manufacture, pack, label, and store food products during operation. Every food product shall be manufactured, packed, labeled, and stored using equipment that is designed, constructed, maintained, operated, and arranged in a manner that

1. Permits the effective cleaning of its surfaces
2. Permits it to function in accordance with its intended use (specifications)

TABLE 3.1

Air Classifications[a]

Clean Area Classification (0.5 µm particles/ft³)	ISO Designation[b]	≥0.5 µm Particles/m³	Microbiological Active Air Action Levels (cfu/m³)[c]	Microbiological Settling Plate Action Levels[c,d] (diameter 90 mm: cfu/4 h)
100	5	3520	1[e]	1[e]
1000	6	35,200	7	3
10,000	7	352,000	10	5
100,000	8	3,520,000	10	50

[a] All classifications based on data measured in the vicinity of exposed materials/articles during period of activity.

[b] ISO 14644-1 designations provide uniform particle concentration values for clean rooms in multiple industries. An ISO 5 particle concentration is equal to Class 100 and approximately equals EU Grade A.

[c] Values represent recommended levels of environmental quality. You may find it appropriate to establish alternate microbiological action levels due to the nature of the operation or method of analysis.

[d] The additional use of settling plates is optional.

[e] Samples from Class 100 (ISO 5) environments should normally yield no microbiological contaminants.

3. Prevents it from contaminating the food product
4. Prevents it from adding an extraneous substance to the food product

To meet the GMP requirements,[13] manufacturers must ensure what follows:

- The equipment used for production is designed, constructed, installed, and maintained to facilitate cleaning, sanitizing (where appropriate), and inspection of the equipment and the surrounding areas.
- The procedures for cleaning and maintaining equipment and tools used must be established to manufacture food products.
- The prevention procedures are established for avoiding equipment stops and temporary repairs.
- The analytical instruments and associated control systems are protected from vibration, electrical interference, and contact with excessive moisture or other external factors.
- The production equipment and tools that come in direct contact with materials and products are constructed of smooth, nonreactive, and nontoxic materials, and are designed to withstand to repeated cleaning.
- A proper equipment design is done to avoid the possibility of lubricants or other maintenance materials to contaminate the food products.
- The instruments and controls, including laboratory equipment, are properly maintained to ensure that they remain accurate and retain records.
- A calibration program for critical manufacturing, packaging, and testing equipment is developed and records maintained.
- The records of equipment maintenance and facility cleaning are maintained.
- The equipment usage records are accurately maintained.

For aseptic processes, container closures represent one of the most critical issues to control. The process used to seal the package will depend on the nature of the container or closure materials. Presterilization preparation of glass containers usually involves a series of wash and rinse cycles. These cycles play an important role in removing foreign substances. To avoid contaminating containers, rinse water of high purity should

be used. Plastic containers used for food products can be sterilized with an appropriate gas, irradiation, or other suitable means. Critical parameters must be automatically monitored to avoid loss of control. A container closure system that permits penetration of microorganisms is unsuitable for sterile products. Safeguards should be implemented to strictly preclude shipment of product that may lack container closure integrity and lead to unsterility or to product quality spoilage. Equipment suitability problems or incoming container or closure deficiencies can cause loss of container closure integrity. Finished food's recall can, for example, be caused by failure to detect vials fractured by faulty equipment as well as by mishandling of bulk finished stock. If damage that is not readily detected leads to loss of container closure integrity, improved procedures should be quickly implemented to prevent and detect such defects. Lack of clear definition of equipment specifications, according to the type of production carried out (fresh, extended shelf life (ESL), aseptic, or sterile) associated with solid, liquid, and liquid with particulates food products, can be the cause of hidden quality or sterility problems. Some of the critical processes and practices that need to be accurately defined are microbial load of production room, water and steam quality, production room air quality, and overpressure.

3.2.2 Personnel and Quality Assurance

This section covers the education, training, and experience requirements for personnel working in manufacturing, packaging, labeling, and storing food products.

In general, every food product shall be manufactured, packed, labeled, and stored by personnel who are qualified through education, training, and experience to perform their respective tasks. To meet the requirements, manufacturers must ensure that:

- Individuals in charge of manufacturing and quality assurance have adequate education, training, and practical experience to control and supervise the activities.
- All personnel have appropriate education (including ongoing updates on GMPs or other continuous training) and have the practical experience necessary to perform their assigned tasks. Records of education and training have to be maintained and updated.

Too often food product quality and safety problems have been caused by personnel who were not trained at the level required for the tasks to be carried out under their responsibility. To avoid this hazard, GMPs must define manufacturing tasks and the relative knowledge and experience necessary to perform each task.

Quality assurance practices set out the requirements and responsibilities of the quality assurance department. Every manufacturer shall have a quality assurance specialist who

1. Is responsible for ensuring the quality of the food product before it is made available for sale, and has the training, experience, and technical knowledge relating to the activity conducted and the requirements of this part
2. Investigates and records every complaint received with respect to the quality of the food product and, if necessary, takes corrective action
3. Ensures that every food product is manufactured, packed, and labeled using only material that, prior to its use in the activity, has been approved for that use by a quality assurance department
4. Ensures that every lot or batch of food product is approved by the quality assurance department before it is made available for sale
5. Ensures that every food product that is sold and subsequently returned to its manufacturer, as the case may be, is approved by the quality assurance department before that food product is made available for resale

To meet the requirements, manufacturers must have a quality assurance function that is responsible to do the following:

- Establish and follow written procedures to ensure that food products conform to specifications and regulatory requirements.
- Establish and follow written procedures for sampling, inspecting, and testing raw and packaging materials, in-process, and finished products.
- Approve or reject all formulations, procedures, specifications, test methods, controls, and results that affect the purity, quality, and composition of each ingredient and product. Written procedures shall be established and implemented.
- Approve or reject all raw materials, packaging materials, and finished products, including products manufactured by contractors, based

upon conformance/nonconformance to respective specifications. Written procedures shall be established and implemented.
- Review and maintain completed batch records.
- Approve or reject the product for distribution against the completed batch record.
- Approve or reject product quality deviations and product reprocessing in the manufacture of a food product. Written procedures shall be established and implemented.
- Destroy returned products unless a quality expert determines, by assessment or other investigation, that they may be released for resale. Written procedures shall be established and implemented.
- Maintain records with respect to returned, reprocessed, and redistributed products and include the name and description of the product, lot number, reason for return, quantity returned, and date and means of final disposition.
- Ensure that laboratories (in-house and contract) are capable of performing all of the tasks and responsibilities assigned to them.
- Maintain laboratory records of tests and investigations.
- Set up and follow written procedures for handling product complaints. These procedures must include determining whether further investigation and corrective action are required.
- Document all complaints with the following information:
  - Name and description of the product
  - Lot number
  - Source and nature of the complaint
- Any response
  When an investigation is conducted, include in the written record the findings and any follow-up action taken.

It is good practice for manufacturers to provide a written job description to their quality assurance roles to help protect them from conflicts of interest that may arise when duties conflict with those outlined in the quality procedures.

The production of quality assurance (QA) practices represents a mandatory prerequisite in food manufacturing to define quality procedures concerning the organization and practices necessary to carry out quality control of the product packed. Reliable GMPs implemented by the equipment operator, regarding quality control of the food product packed, preproduction practices, cleaning procedures and practices, and

daily and weekly cleaning and maintenance can avoid nonconformity products sold to retailers and production activity to rework food products with quality problems. Quality procedures and practices regularly implemented and updated by the people involved avoid unconformity behaviors and define a common strategy that allows the company to effectively manage food safety hazards.

3.2.3 Processes

Every food company must set out processes and procedures for sanitation and hygiene to avoid possible sources of contamination coming from premises, equipment, and people. A sanitation program sets out the sanitation requirements for the premises and the health and hygiene of personnel. Every food product shall be manufactured in accordance with a sanitation program that defines the following:

1. Procedures for an effective cleaning of the premises in which the activity is carried out
2. Procedures for an effective cleaning of the equipment used in the packaging line
3. Procedures for handling any substance used in the activity
4. All requirements, with respect to the health, hygienic behavior, and clothing of the personnel who are involved in the activity, that are necessary to ensure that the activity is carried out in sanitary conditions

To meet the requirements, food manufacturers shall have a facility sanitation program and a health and hygiene program in place as detailed below:

- Cleaning procedures for facilities and processing equipment
- A list of cleaning/sanitizing agents and pesticide chemicals that shall be identified, used, and stored in such a manner to prevent the contamination of raw materials and packaging and process equipment
- Identification, use, and storage of pesticide chemicals in such a manner to prevent the contamination of raw and packaging materials and process equipment
- Procedures for cleaning frequencies and cleaning lines between the production of different products

- Provisions for storing cleaned equipment to avoid recontamination
- Procedures for the destruction and disposal of waste materials and debris

The food company must ensure that all personnel that come in direct contact with raw and packaging materials, in-process materials, and any unpacked products, as well as personnel who use processing equipment, follow appropriate practices to protect products against contamination. This health and hygiene program must be in writing and should include the following requirements:

- Wearing outer garments, including shoe coverings, that protect against contamination of products and equipment, when applicable
- Removing all unsecured jewelry and hand jewelry, or covering hand jewelry that cannot be removed, when applicable
- Using intact, clean, and sanitary gloves
- Wearing hairnets, caps, beard covers, or other effective hair restraints
- Maintaining personal cleanliness
- Washing hands thoroughly before starting work and at any other time when hands may have become soiled or contaminated
- Storing clothing or other personal effects outside of processing areas
- Refraining from consuming food and drink, as well as chewing products or smoking in manufacturing, packaging, and testing areas
- Respecting quarantine times imposed by public health authorities
- Removing from the manufacturing facility any person who has, or appears to have, an illness that could be a possible source of product contamination, until the disease or hygienic condition is no longer a risk for possible product contamination

To ensure the sterility of food products, sterilization, aseptic filling, and closing operations must be adequately validated. The goal of the most effective sterilization processes can fail if the sterilized elements of a product (the food formulation, the container, and the closure) are brought together under conditions that contaminate any of those elements. An aseptic processing operation should be validated using a microbiological growth medium in place of the product. This process simulation normally includes exposing the microbiological growth medium to product contact surfaces of equipment, container closure systems, critical environments,

and process manipulations to closely simulate the same exposure that the product itself will undergo. The purpose of this test, often called killing test, is to verify the equipment or line sterilization effectiveness before commercial production starts. The sealed containers filled with the medium are then incubated to detect microbial contamination. Results are interpreted to assess the potential for a unit of food product to become contaminated during actual operations (e.g., start-up, sterile ingredient additions, aseptic connections, filling, closing). Environmental monitoring data from the process simulation can also provide useful information for the processing line evaluation.

Whenever contamination exists in a production run, it should be considered indicative of a potential sterility assurance problem, regardless of run size. The number of contaminated units should not be expected to increase in a directly proportional manner with the number of containers produced in the run. Test results should reliably show that the units produced by an aseptic processing operation are sterile. Modern aseptic processing operations in suitably designed facilities have demonstrated a capability of meeting contamination levels approaching zero.[47,52]

Recommended criteria for assessing the state (compliance to specifications) of aseptic line control are as follows:

- When filling fewer than 5000 units, no contaminated units should be detected: one contaminated unit is considered cause for revalidation, following an investigation.
- When filling from 5000 to 10,000 units:
  1. One contaminated unit should result in an investigation, including consideration of repeating a test run.
  2. Two contaminated units are considered cause for revalidation, following investigation.
- When filling more than 10,000 units:
  1. One contaminated unit should result in an investigation.
  2. Two contaminated units are considered cause for revalidation, following investigation.

For any run size, the intermittent presence of microbial contamination in filled containers can be indicative of a persistent low-level contamination problem that should be investigated.

Manufacturers shall ensure that practices and procedures are in place for material control, process control, the inspection program for contractors,

and product recall, where applicable. Some of the main material control practices are as follows:

- Set up and follow written procedures for the transportation, receipt, identification, examination, handling, sampling, testing, and approval or rejection of raw and packaging materials. Update the procedures as required.
- Identify each lot of raw and packaging materials with a distinctive lot number.
- Inspect containers of raw and packaging materials upon receipt for closure and physical integrity.
- Assess each lot of raw and packaging materials against specifications, such as plant identity, detectable foreign matter, and the integrity (appropriate characteristics) and quality of plant material or extracts.
- Test raw and packaging materials after any exposure to conditions likely to adversely affect their purity, quality, or composition.
- Identify and control each lot of raw and packaging materials according to its quality status (e.g., quarantined, approved, or rejected).
- Store raw materials, in-process materials, and reprocessed materials in appropriate conditions, including temperature and humidity, to protect against quality deterioration and contamination.
- Set a time limit beyond which raw materials that are subject to deterioration may not be used in production without additional testing. When appropriate, use the oldest approved stock of raw and packaging materials first. Follow the first in first out (FIFO) system.
- Establish appropriate systems and controls to ensure that water used to produce products is of potable quality and meets the Guidelines for Drinking Water Quality.
- Destroy outdated or obsolete printed packaging materials and record their disposal.

Some of the main process control practices are

- Formulate the product to ensure that it adheres to regulatory requirements and claims stated on the label.
- Identify all materials, products, samples, containers, processing lines, and major equipment at all times to indicate their contents or status.

- Ensure procedures are in place to prevent extraneous materials from being included in the products and finished package.
- Establish written procedures for reprocessing batches that do not conform to finished product specifications.
- Set up and follow written procedures to ensure the correct labels and packaging materials are issued and used.
- Identify each package with a lot number and expiry date that permits determination of the history of the manufacture and control of the lot.

3.2.4 Products

Food products must be identified by the following specifications:

1. Every food product available for sale shall comply with the specifications submitted with respect to what is specified by law.
2. The specifications shall contain the information with respect to the purity of the product, on each medicinal ingredient, and a description of the methods used for testing or examining the food product.

To meet the requirements, manufacturers must do the following for finished products, where applicable:

- Develop and implement written specifications for all finished products
- Ensure that specifications are maintained and every change is approved by the quality assurance department prior to use
- Set up and follow written procedures that describe tests to be conducted to ensure the identity, purity, and quantity of finished products
- Confirm that all test methods provide accurate and consistent results
- Assess each lot for compliance with specifications prior to release

Every manufacturer and every importer shall determine the period of time that, after being packed for sale, the food product will continue to comply with its specifications when:

1. It is stored under its recommended storage conditions
2. If it does not have recommended storage conditions, it is stored at room temperature (e.g., aseptic or sterile products)

To meet the requirements, manufacturers must ensure the following for lot or batch samples, where applicable:

1. If the competent authority has reasonable grounds to believe that a lot or batch of a food product made available for sale may result in injury to the health of a purchaser or consumer, the authority may require the manufacturer, importer, or distributor to provide a sample of that lot or batch.
2. The sample shall be of sufficient quantity to enable a determination of whether the lot or batch of the natural health product complies with the specifications for that food product.

Manufacturers must do the following:

- Retain an adequate number of samples of each lot of a finished product.
- Retain samples in their final trade packages or in containers of the same material and construction.
- Store samples in the environmental conditions listed on the label.
- Ensure that samples are of sufficient size to permit complete testing according to specifications.
- Maintain samples for at least 1 year after the expiry date. Shorter retention times may be approved by the quality assurance department.

3.3 CONCLUSION

At the conclusion of this section, we understand that any maintenance design and implementation process could fail in achieving food product safety and equipment reliability if standard practices and procedures to be applied to the following are not effectively designed and implemented:

- Building and facilities
- Equipment
- Personnel
- Quality assurance
- Processes
- Products

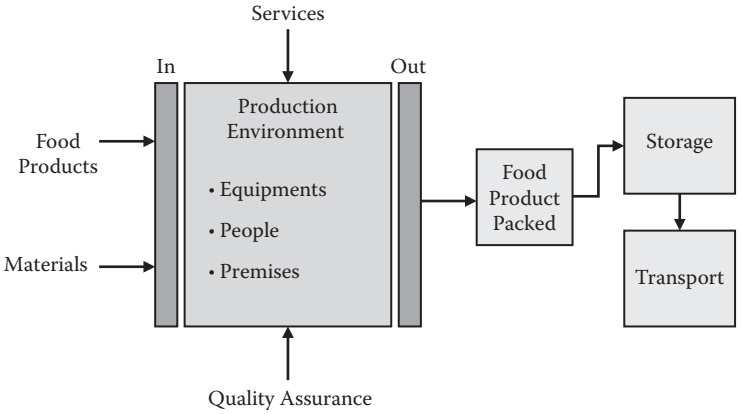


FIGURE 3.1
Manufacturing context for GMPs.

Reliable GMPs represent the platform over which maintenance design and implementation process is built; if this platform is not strong and stable, the maintenance effectiveness could stagger and collapse.

Figure 3.1 shows the main components that are part of the manufacturing environment and that need to be investigated to define reliable GMPs. In the food industry, an effective quality assurance and quality control system requires that acceptance specifications are drawn up (acceptable quality levels (AQLs)) for

1. Product quality levels (standards, AQLs) for raw materials and semi-finished and finished products
2. The maximum acceptable defective rate (AQLs for finished product)
3. The sampling methods (random, concentrated, etc.) of finished product
4. The methodology, tools, and templates used to perform quality control on finished products

If the food manufacturing company under examination lacks a reliable definition of its standards, the production of quality and manufacturing practices is to be seen as a complementary activity to be integrated with a maintenance design and implementation process.

4

Critical Study of Quality and Maintenance Engineering Techniques

4.1 INTRODUCTION

To be able to answer the main food industry request, regarding product safety and equipment reliability, a literature search is necessary to identify the key maintenance engineering techniques to be selected to develop the maintenance design and implementation process. The scope of this chapter is to present a short highlight of some of the product safety techniques, equipment reliability principles, and maintenance engineering techniques chosen to support the maintenance design and implementation process. The questions to answer while different techniques are examined are as follows:

- Why is a literature review necessary to define a maintenance design and implementation process?
- What type of literature has to be searched?
- What criteria should be used to select product safety and equipment reliability techniques?
- How should food product safety and maintenance engineering techniques be integrated to attain, as a result, an effective tool able to manage product safety and equipment reliability criticalities through maintenance tasks?
- How can the selected techniques contribute to the maintenance design and implementation process?

This chapter will not only answer these questions, but also display the main characteristics of the safety, reliability, and maintenance engineering techniques used in the maintenance design and implementation process.

4.2 EQUIPMENT AVAILABILITY THROUGH RELIABILITY, MAINTAINABILITY, AND SUPPORTABILITY (ARMS)

The equipment availability represents one of the most important factors to be used to measure production and maintenance effectiveness: the line equipment 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 food industry.

4.2.1 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" (BS 4778). In other words, availability is a measure of how big a part of total production time the machine is available for production.[32] Availability then depends upon reliability, maintainability, and supportability. A system may possess excellent reliability, i.e., have a low chance of failure during operation, but if and when a failure does occur, the repair time, or downtime, must be short. In the food industry no customer wishes to wait days or weeks for the repair to be carried out, and in some cases, for some liquid products, such as fresh milk, even a few hours can be costly. Availability can be calculated using the formula

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

where MTBF stands for mean time between failures and MTTR for mean time to restore. In order to keep availability high, the MTTR must be as short as possible. According to Figure 4.1, given a machine with a good standard of design and reliability, with high maintainability, much depends upon the skill of the operator and service technician in effecting a rapid return to operation. However, there are other factors that can reduce MTTR that are concerned with the diagnostic instruments necessary to find faults, spare parts availability, and the maintenance policy adopted.

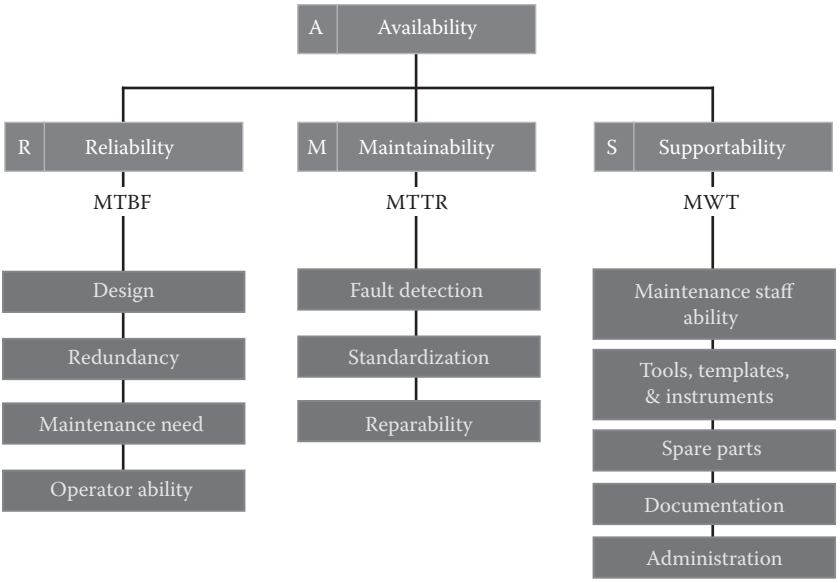


FIGURE 4.1
Packaging line availability.

4.2.2 Reliability

The definition of reliability given by the British Standards, BS 4200, part 2, 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 h 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 h. Since reliability is concerned with probability, what we actually get is a prediction of the likely success of operation. To complete the picture, since reliability is concerned with failure, this also needs to be defined. According to BS 5760, failure is "the termination of the ability of an item to perform a required function." Benefits of higher reliability will not only be an increased line availability through downtime reduction, but also better quality, less use of raw materials, and spare part stock optimization.

4.2.2.1 Reliability Maintenance Techniques and Failure Curves

Each maintenance task needs to be designed to cope with different failure modes found for each equipment component. For the different component

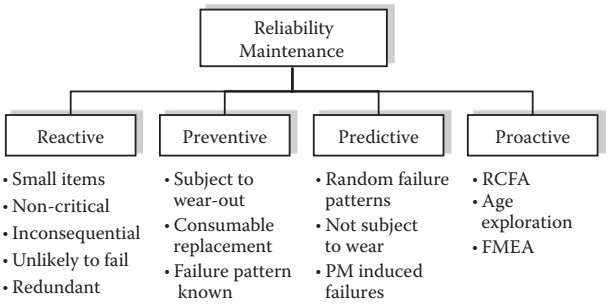


FIGURE 4.2
Reliability maintenance techniques.

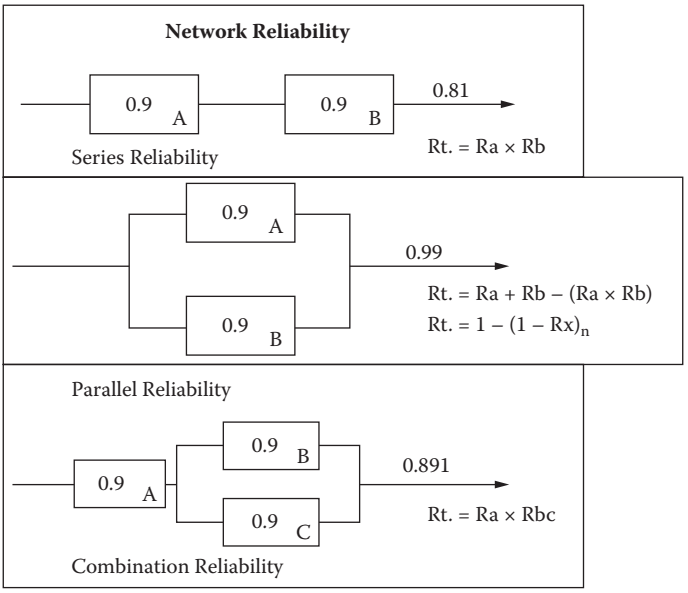
failure modes, the specific reliability maintenance techniques listed in Figure 4.2 will be applied.

4.2.2.2 Product Law of Reliability

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

$$Rs = R1 \times R2 \times R3 \times Rn$$

Below are some possible circuit configurations.[39]



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

4.2.2.3 Failure Rate, MTTF, and MTBF

Since reliability describes how often a machine is stopped due to failures, MTBF or mean time to failure (MTTF) is used to describe the reliability as the average time between failures. The failure rate of a component can be found by operating large numbers of the component for a long period and noting the number of failures that occur. The variation of failure rate (FR) with time is shown graphically in Figure 4.3.

If a test is realized upon 200 light-emitting diodes (LEDs), suppose that after early failure phase, 5 fail over a 1000 h period; then the average failure rate is

$$\text{FR} = \frac{5}{200} \times 100\% \text{ per } 1000 \text{ h} = 2.5\% \text{ per } 1000 \text{ h}$$

Often failure rate is written as a percentage as above, but it could also be expressed as failures per hour:

$$\text{FR} = \frac{5}{200} \times \frac{1}{1000} \text{failures per hour}$$

$$= 2.5 \times 10^{-5} \text{ per hour or } 0.025 \text{ per } 1000 \text{ h.}$$

Failure rate is defined, over the useful life, as the number of failures per number of component hours. In the example done, FR is 2.5×10^{-5}/h

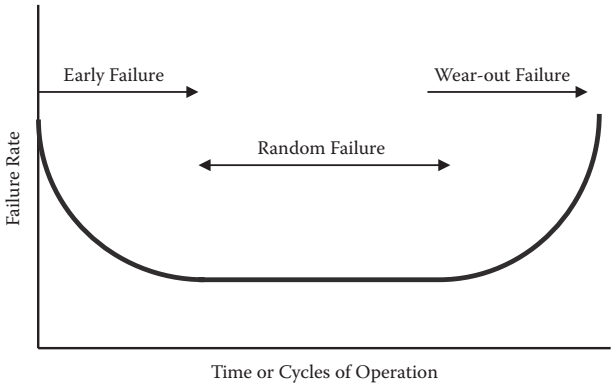


FIGURE 4.3
Failure rate variation on time.

(best estimate). At first glance, this appears to be a low figure, and in fact, if one LED is used, its mean time to failure will be

$$\text{MTTF} = \frac{1}{2.5 \times 10^{-5}} = 40{,}000 \text{ h}$$

indicating a fairly long time.

However, consider the case where 100 LEDs are used in the control panel of a filling machine, and the failure of 1 LED constitutes a panel failure. Since each LED has a chance of failure = 2.5×10^{-5} in every hour, the chance of the panel failing is 100 times greater, i.e., 250×10^{-5} in every hour. Therefore, the mean time between failures of the panel is

$$\text{MTBF} = \frac{1}{250 \times 10^{-5}} = 400 \text{ h}$$

What MTBF gives as a result is a prediction of the average time that a system will run before failing. The term *MTTF* is normally applied to items that cannot be repaired, while *MTBF* is used for repairable items such as mechanical and electromechanical components. The MTBF of a complete system, like the machine under examination, can be calculated by first finding the sum of the failure rates of all subsystems.

Consider, as an example, the main subsystems of a filling machine for liquid food:

A: Filling system
B: Forming unit
C: Sealing unit
D: Cutting unit

Then the total failure rate is *FR*(system) = *FR*(A) + *FR*(B) + *FR*(C) + *FR*(D). The system failure rate is usually quoted as λ. Therefore,

$$\text{MTBF (system)} = \frac{1}{\lambda}$$

4.2.2.4 Exponential Law of Reliability

If a constant failure rate applies, that is, when failure is due to chance alone, a plot of reliability against time produces an exponential curve similar to that shown in Figure 4.4.

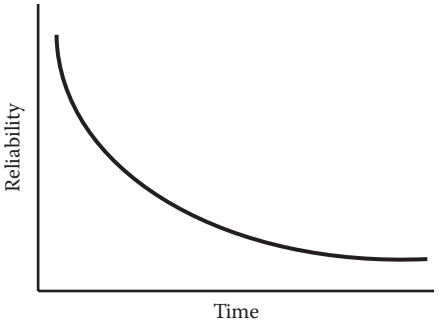


FIGURE 4.4
Exponential curve variation.

The relationship between reliability (R) and system failure rate (λ) is given by the exponential law of reliability formula:

$$R_t = e^{-\lambda t}$$

where t is the operating time, e the base of natural logarithms, that is, 2.7183, and R the reliability or probability of zero failures in time t. The probability of one failure in time t will be $\lambda e^{-\lambda t}$, of two failures, $(\lambda^2/2!)e^{-\lambda t}$, and so on. If Rt represents the probability that failure will not occur in time t, the probability that failure will occur, Ft, will be given by $(1 - Rt)$. Thus, $F_t = 1 - e^{-\lambda t}$ (unreliability). Now since MTBF or $\mu = 1/\lambda$, then $\lambda = 1/\mu$, and therefore $R_t = e^{-t/\mu}$.

According to Figure 4.5, it is useful to show the graph of R against t, with time marked off in intervals of μ. The graph shows that when $t = \mu$, the probability of successful operation has fallen to approximately 0.37, or 37%.

Only when the operating time is shorter than μ (MTBF) does the reliability become high.

4.2.2.5 Factors That Affect Reliability

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

- Capital cost (the purchase price)
- Operation cost
- Maintenance cost

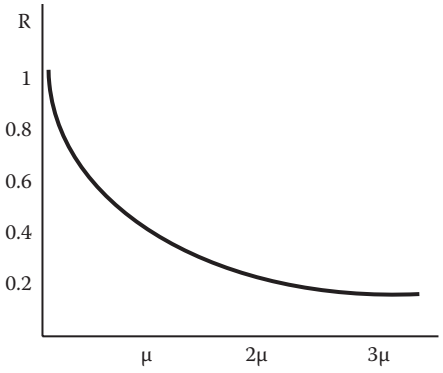


FIGURE 4.5
Reliability against time intervals μ.

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 and the use of high-quality devices and materials that result in higher safety, the machine reliability is improved. In purchasing machinery, the attempt to save money by just looking at the machine price, without considering the machine quality design, might produce a savings in the short term, but heavy losses in the medium to long term.

4.2.3 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 restore and the repair rate (μ) are measures of maintainability:

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

and maintainability $M(t) = 1 - e^{-\mu t} = 1 - e^{-t/\text{MTTR}}$, where t is the time allowed for the maintenance action. If, for example, the average time to repair any fault in a filling machine is MTTR = 2 h, the value of maintainability for a time of 4 h is

$$M(t) = 1 - e^{-t/\text{MTTR}} = 1 - e^{-4/2} = 1 - 0.135 = 0.865$$

Therefore, the probability *M* of the filling machine being returned to a working state within 4 h is 0.865 (86.5%). The time *t* for reliability represents the filling machine operational period, while *t* for maintainability is the allowed maintenance time. Prediction of maintainability involves establishing a value for the system MTTR.

4.2.3.1 Factors That 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 food industries, because of use of perishable products, 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.

4.2.4 Supportability

The effectiveness of a support system around the machine is measured by the mean waiting time (MWT). This can be defined as the time that elapses from occurrence of a fault until the repair is started. The support system within a food company is made up of the following factors:

1. Maintenance staff ability. Development of the necessary abilities for maintenance technicians and equipment operators to carry out maintenance activities represents a real opportunity to reduce MTTR and improve a company's competitive advantage. Development of skillfulness 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. Equipment operator empowerment, through different types of training, represents one of the best investments to improve the effectiveness of a company's support system.
2. Equipment needed. Different diagnostic tools are often necessary to carry out maintenance activities; they are as follows:
   - Templates for mechanical measurements
   - Temperature measurement instruments
   - Oscilloscope and electronic multimeter
   - Notebook computer with diagnostic software

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

3. 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 while waiting for the parts and due to the unavailability of machinery for production activity. A spare parts supply agreement could also be established with a local supplier, instead of having an internal warehouse, to the benefit of a good level of service at reduced cost.
4. Technical data. In order to benefit from 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.
5. Administration. Administration refers to the activities concerning the 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. These figures are normally only partially available, and that is the reason why analytical and objective assessment of line operation and maintenance effectiveness is difficult. Moreover, spare parts availability analysis, to continuously assess the level of service, is necessary to avoid lack of useful spare parts.

4.3 FOOD PRODUCT SAFETY TECHNIQUES

Product safety techniques play a very important role in managing the critical factors that could produce nonconformities to product quality and safety. The maintenance design process for the food 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 also to the ability to integrate safety, reliability, and maintenance engineering techniques.

4.3.1 Product Safety through the Application of HACCP Methodology

Hazard analysis and critical control points (HACCP) is a production process control methodology introduced at the European Community level through ECC Directive 93/43. HACCP identifies and assesses 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. 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.[58] Machine parts or components whose fault may produce biological, chemical, or physical hazards are examined to devise critical control limits and preventive maintenance countermeasures. The use of HACCP methodology leads to the identification of CCPs of the process, and to the design of new maintenance tasks to establish process, product safety, and reliability. 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 a HACCP plan requires seven principal activities whose implementation can ensure the goal of safer food.[58] 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 of all hazards and considerations of any control measures to eliminate or minimize hazards. As the first step, all hazards that may be expected to occur in the production line under consideration are identified. The hazards considered are the following:

- Biological hazards. Biological hazards include toxigenic agents that could contaminate the product. This can, in many cases, be due to the lack of package or container integrity. Food product is biologically contaminated as soon as it (chilled or sterilized) comes in contact with bacteria living in the external environment. This could happen because of a simple micro-hole realized during package forming or package sealing in the container.
- Chemical hazards. Chemical hazards include, among others, cleaning compounds and sterilization agents. Chemicals normally used to clean equipment and pipe surfaces and sterilize packaging materials or containers could come in contact with the product if predictive and preventive maintenance activities are not regularly implemented on critical components.
- Physical hazards. Physical hazards include objects, such as metal fragments and glass, that can be found in the container together with the product, and that may cut the mouth, break teeth, or perforate the package. This could normally happen in the filling section of the equipment and can be caused by the separation of solid parts from devices such as rollers, gaskets, bearings, and guides that drop in the food product. 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 that 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 the hazard is eliminated or reduced to acceptable or minimal levels. The module shown in Figure 4.6 is a HACCP decision tree used for establishing CCPs for all line equipment.

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. And 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 automatic or 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.

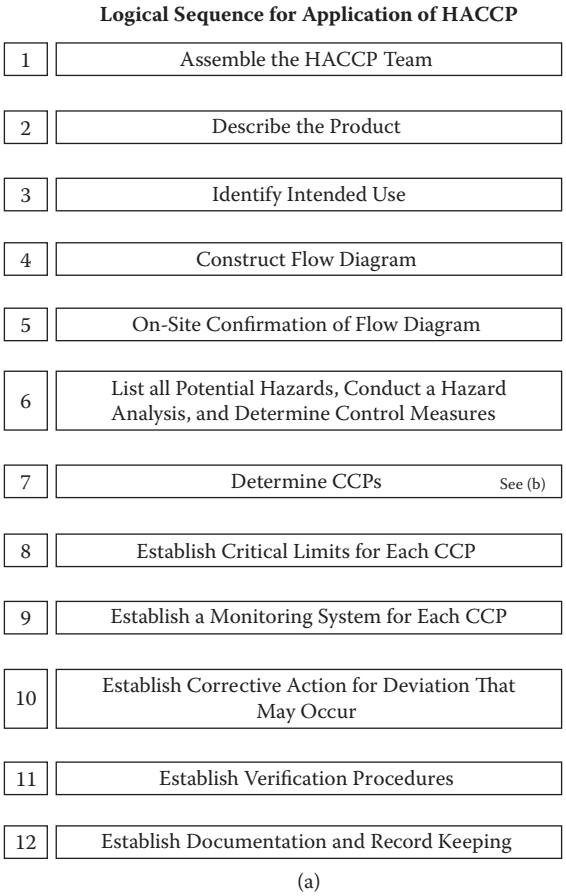


FIGURE 4.6
HACCP decision tree to identify CCPs. (From World Health Organization, Training Considerations for the Application of the Hazard Analysis Critical Control Point System to Food Processing and Manufacturing, 1993.)

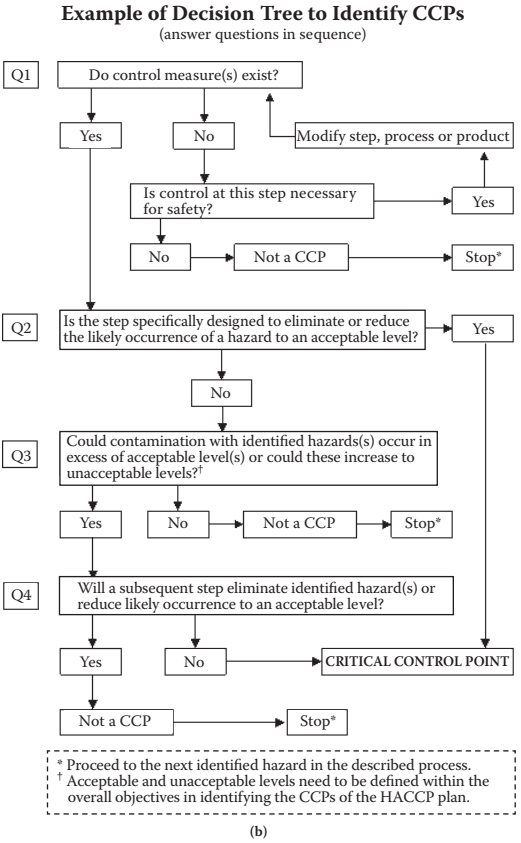


FIGURE 4.6 (*Continued*)

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 a 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 the HACCP plan, CCP monitoring records, deviations file, and preventive maintenance procedures, included in the checklists and checklist review.

HACCP methodology is to 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 CCP identification, a deeper reliability analysis of critical components and parts will be necessary to design maintenance task lists that enable reliable maintenance control of each critical point.

4.3.2 Application of Hazard Operability (HAZOP)

HAZOP reviews have been arising from the chemical industry in Britain during the 1960s. Imperial Chemical Industries developed a standardized method of analyzing processing hazards based on the basic operation conditions. The individual parameters regarding each node of the process are changed, one at a time, to foresee the likely subsequent consequences.[4] This became a standard practice within this company and soon found its way into the general chemical industry. This technique has been selected because it can be easily applied to a food production process to examine the critical factors, depending on equipment, food product, and human behavior.

4.3.2.1 Definitions

Hazard: Any operation that could possibly cause a catastrophic release of toxic, flammable, or explosive substances or any action that could result in injury to personnel.

Operability: Any operation inside the design envelope that would cause a shutdown that could possibly lead to a violation of environmental, health, or safety regulations or negatively impact profitability.

4.3.2.2 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 technique is based on the principle that a team approach to hazard analysis will identify more problems than individuals working alone. The HAZOP team is made up of people with different backgrounds and expertise. The expertise is brought together through a collective brainstorming effort that stimulates creativity and new ideas, and a complete review of the process under consideration. The ability of the team leaders to establish the right working atmosphere to benefit from the contributions given by each member of the team represents a critical weakness of this technique.

4.3.2.3 HAZOP Process

The HAZOP team focuses on specific portions of the process called nodes. For each process parameter identified, say temperature, an action is generated for the node under consideration. Then a series of guidewords are combined with the parameter *temperature* to create a deviation. For example, the guideword *no* is combined with the parameter *temperature* to give the deviation *no temperature*. The team then focuses on listing all the credible causes of a *no temperature* deviation beginning with the cause that can result in the worst possible consequence the team can think of at the time.[4] Once the causes are recorded, the team lists the consequences, safeguards, and any recommendations deemed appropriate. The process is to be repeated for all the guidewords that produce a deviation until completion of the node. The team moves on to the next node and repeats the process.

The primary objective of HAZOP is to ensure that catastrophic incidents will be avoided during the lifetime of the equipment from the processes under review. Safety reviews are primarily looking at the possibilities where human error may occur. Human error is commonly thought of as mainly occurring during the operational phase of the system, but human error can also be the cause of defects in the

- Design
- Material
- Workmanship

Since most dairy equipment is not designed for mass production, but individually designed, there is a large potential for human errors to occur

during design, procurement, and construction. 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 introduced into the sequence that 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, equipment operators, and managers. Studies have shown that up to 90% of accidents are attributable to some degree to human failures.

4.3.2.4 Guidewords, Selection of Parameters, and Deviations

The HAZOP process creates deviations from the process design specifications by combining guidewords (*no*, *more*, *less*, etc.) with process parameters, resulting in a possible deviation from design purpose. A sample list of guidewords is given below:

No
More
Less
As well as
Reverse
Other than

It should be pointed out that not all guideword-parameter combinations will be meaningful. The application of parameters will depend on the type of process being considered, the equipment in the process, and the process intent. The HAZOP software normally includes menus that list both specific parameters and general parameters. The most common specific parameters that should be considered are flow, temperature, pressure, level, and so on. In almost all cases, these parameters should be evaluated for every node in the process. The report produced by the team shall document the team's comments concerning the behavior of these parameters.

Additionally, the node should be screened for application of the remaining specific parameters (see list below) and for the list of applicable general parameters. A sample set of parameters includes the following:

Flow
Temperature
Pressure
Composition
Phase
Level
Relief
Instrumentation
Sampling
Corrosion/erosion
Services/utilities
Maintenance
Addition
Safety
Reaction
Inserting/purging
Contamination

Specific parameters should be identified and considered by the team when evaluating each node. If a particular parameter does not change from one node to the next, then it is not necessary to repeat all of the deviations that were considered in the previous node.

4.3.2.5 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 that the node consists of a valve with liquid product piping up to the flange on a product storage tank. If the deviation *no flow* is applied, then a problem becomes apparent when the team starts talking about the causes of no flow.[4] If a cause of no flow is pipe rupture and the pipe ruptures at the flange connection on the valve, the term *no flow* is ambiguous since there is flow out of the valve but not through the piping to the storage tank. To avoid unreliable evaluation, a POR should therefore be clearly established at the time

the node is defined. It is recommended to always establish the POR at the downstream terminal point of the node.

4.3.2.6 Screening for Causes of Deviations

It is necessary to be thorough in listing causes of deviations: a deviation is to be considered realistic if there are sufficient causes to believe the deviation can occur. Team judgment is used to decide whether to include events with a very low probability of occurring. However, good judgment must be made by the team in determining that events have a low probability of occurrence so that credible causes are not overlooked. There are three basic types of causes:

1. Human errors. These are acts of omission or commission by an equipment operator, designer, constructor, or other person creating a hazard that could possibly result in a release of hazardous or flammable material.
2. Equipment failures. These can be caused by a mechanical, structural, or operating failure, and can result in the release of hazardous events.
3. External events. The items outside the unit being reviewed affect the operation of the unit to the extent that the release of hazardous conditions is possible. External events include upsets on adjacent units affecting the safe operation of the unit (or node) being studied, loss of utilities, and exposure from weather and seismic activity.

The level of detail required in describing causes of a deviation depends on whether or not the cause of the problem occurs inside or outside the node. When the team reaches the node in which the problem is located, then more details can be listed for the various causes; causes external to the node will be considered separately and not as part of the node.

4.3.2.7 Consequences and Safeguards

The primary purpose of the HAZOP is the identification of scenarios that would lead to the release of a hazardous condition, thus exposing workers to injury or food product to safety hazard. In order to make this

determination, it is always necessary to determine, as exactly as possible, all consequences of any credible causes of a release that are identified by the group. This will serve a twofold purpose:

1. It will help to determine a risk ranking in HAZOPs where multiple hazards are uncovered by the group, so that priority can be established in addressing the hazard.
2. It will help make the determination as to whether a particular deviation results in an operability problem or hazard.

If the team concludes from the consequences that a particular cause of a deviation results in an operability problem only, then the discussion should end and the team should move on to the next cause, deviation, or node. Safeguards should be included whenever the team determines that a combination of cause and consequence presents a credible process hazard. A safeguard can be summarized based on the following general criteria:

1. Those systems, engineered designs, and written procedures that are designed to prevent a catastrophic release of hazardous or flammable material
2. Those systems that are designed to detect and give early warning following the initiating cause of a release of hazardous or flammable material
3. Those systems or written procedures that mitigate the consequences of a release of hazardous or flammable material

The team should use care when listing safeguards. Hazards analysis requires an evaluation of the consequences of failure of engineering and administrative controls. In addition, the team should consider realistic multiple failures and simultaneous events, so a careful determination of whether or not these items can actually be considered safeguards must be made.

4.3.2.8 Deriving Recommendations (Closure)

Recommendations are made when safeguards for a given hazard scenario are inadequate to protect against the hazard. Action items are recommendations to be carried out by an individual or a department. Information needs are identified as recommendations for follow-up by one of the team

members. The following guidelines are suggested for the implementation of hazard analysis recommendations:

1. High-priority action items should be resolved within 4 months.
2. Medium-priority action items should be resolved within 4–6 months.
3. Lower-priority action items should be resolved following medium-priority items.

It is recommended that the equipment's safety coordinator review all recommendations to determine priorities and a time schedule for implementation. Recommendations include design, operation, or maintenance changes that reduce or eliminate deviations, causes, and consequences.

A HAZOP table applied to a node called "analysis of flow pressure" can present the following voices:

- Guideword: This is the list of critical words related to the node.
- Deviation: This identifies the deviation from the standard or from a safe condition.
- Possible causes: These show all potential causes.
- Coeffectors: These highlight the consequences of deviation.
- Detection/protection: Here we find a list of solutions based on protection or detection systems available to avoid or detect the deviation.
- Effects: These are effects produced by the deviation.
- Hazard (H): This simply lists yes or no as a rough indication of the presence of hazard.
- Justification/design recommendations: These show indications on solutions coming from protections used or actions suggested to ensure a complete control of the deviation.

4.3.2.9 Conclusions

HAZOP is born to put under control critical working conditions and processing hazards. This technique has been conceived to examine the interactions existing among different critical process parameters and their consequences on people and equipment. Analysis of operating conditions, and individual parameters involved at each node, allows us to progressively highlight hazards that depend on design, operations, or equipment functions. The use of simple guidewords enables us to monitor the causes of deviations from standards to identify human errors, equipment failures,

and anomalous external events. Among the limitations we find that this tends to be a process design approach, which could result in a large number of hazards being identified. Many of these hazards may have low probability or consequences. However, with some experience the method can be used effectively. Since the methodology is heavily dependent on team effectiveness, one of the most important and critical success factors is the quality of the team called to implement this technique. HAZOP cannot detect every weakness in design; in particular, it cannot draw attention to weaknesses in layout. HAZOP assumes that the design assumptions are followed during construction and operation; if, for instance, wrong material of construction is used or equipment is not tested as assumed, then problems may result. But some of the HAZOP features can be effectively used in the maintenance design process for the food industry to identify critical interactions among equipment, human factors, and external events in determining, as a result, a hazard condition for food, human health, or equipment functions.

4.4 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 analyses of failures allow us to gain a deeper knowledge on each failure type, and on the effects produced on the equipment. This analyis leads us to the identification of maintenance activities to be designed for each failure type.

4.4.1 Reliability-Centered Maintenance (RCM) Technique

In 1976, *Reliability Centered Maintenance*, a report by Stanley Nowlan and Howard Heap, described the RCM methodology developed for the Boeing 747, Douglas DC-10, and Lockheed 1011.[41] The key to RCM was abandoning the philosophy of preserve equipment in favor 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 that has no wear-out pattern was

of no help. 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[41] also concluded the following:

- 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 nonintrusive 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.
- Nonintrusive maintenance tasks should be used instead of intrusive maintenance whenever possible. In other words, do not do any maintenance, except monitoring and nonintrusive sustaining actions, until a condition directs intrusive corrective action.

Four statistically significant studies have confirmed the validity of RCM.

When it comes to understanding 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.[24] 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 food 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.[18] For example, if a food 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 analyzes failure modes and 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.[28] Based on the results of this process, optimized maintenance task lists (task schedules) can be defined to address the following:

- Inspection or monitoring/measurement for parts that are more likely to fail
- Rework or rebuild to "like new" condition
- Removal/replacement with new parts/assemblies
- Inspection for undetected failures

Development of such a program depends on the following:

- A determination of how a component/system can fail
- The consequences of failure
- 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. Reliability-centered maintenance is a systematic approach to maintenance that consists of a complete analysis of all the equipment within a system; then it is decided which pieces are the most critical, and a prudent schedule of tasks is created. This methodology makes use of the failure modes and effects analysis (FMEA) technique to identify the root cause of failures and design preventive maintenance procedures. Preventive maintenance (PM) tasks are performed on the most crucial machine parts, while other pieces get as much attention as necessary to provide smooth cost-efficient operations. 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.[44] 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 one system is done 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 to the next.

The classic approach includes the following:

1. System selection
2. Boundary definition and 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

1. System selection. The first step in the RCM process determines which system/part to examine. According to HACCP results, safety and health issues should influence the priorities in the selection of systems and subsystems.
2. Boundary definition and operational mode summary. Once a machine system has been identified, components or parts directly linked to the group under examination should be listed to define both component functions and system boundaries. Looking at the system 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. These data are used to establish the reliability and maintainability (R&M) characteristics of the system. In other words, it gives us a baseline our maintenance program must support.
3. Functional and potential failure determination. To better understand maintenance and subsequently RCM, acknowledgment of failure is required. A failure is an unsatisfactory condition. Any identifiable deviation from the original condition, which is unsatisfactory to a particular user, is a failure. The exact division between satisfactory and unsatisfactory conditions depends upon the function of the system. The technical specifications, defined by the equipment

designer and adjusted by the field service engineer (FSE) during machine field test, can in many cases be taken as a reference point in the failure definition. 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 or potential.

- 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 that 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 4.7 illustrates these relationships.

Prior to performing an RCM 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

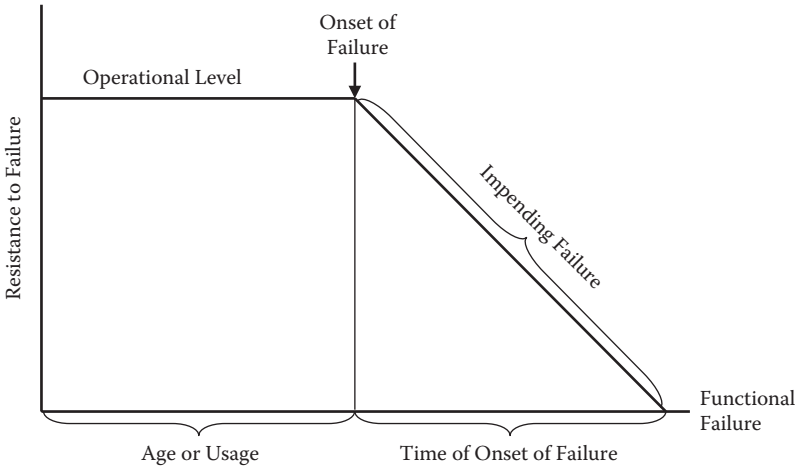


FIGURE 4.7
Functional and potential failures.

breakdown structure (WBS). When performing an RCM analysis on a fielded system, we can use a maintenance allocation chart (MAC) in lieu of generating a separate WBS.

4. Failure modes and effects analysis (FMEA). Performing a FMEA is next in the process. Failure modes include likely causes of breakdown for each of the functional failures. There are several different standards available for FMEAs. Some examples are the military standard (MIL-STD-1629A), the Society of Automotive Engineers Ground Vehicle Recommended Practice (SAE J1739), and the Society of Automotive Engineers Aerospace Recommended Practice (ARP 5580). All three of the above standards provide general FMEA forms and documents, identify criteria for the quantification of risk associated with potential failures, and offer general guidelines on the mechanics of completing FMEAs. There are four basic types of FMEAs:
   - System FMEAs. System FMEAs can be used to analyze a system at any level, from the piece-part level up to the system level. At the lowest level, a FMEA can be performed by looking at each component in the system to determine the ways in which it can fail and how these failures affect the system.
   - Design FMEAs. Design FMEAs are performed on a product or service at the design level, during the design phase. The purpose is to analyze a system design and determine how failure modes affect the system operation. Once the anticipated design deficiencies have been uncovered, solutions can be considered to correct the design or reduce the impact of failure modes. This FMEA is generally used before the product is released to manufacturing operation.
   - Process FMEAs. Process FMEAs are performed on the manufacturing processes. They highlight possible failure modes in the manufacturing process, limitations in equipment, tooling gauges, operator training, or potential sources of error. This information can then be used to determine the corrective actions that need to be taken.
   - Functional FMEAs. Functional FMEAs are also known as "black box" FMEAs. This type of FMEA focuses on the intended function, or use, of a component or subsystem. As an example, a functional FMEA would consider that a regulating valve is intended to regulate the liquid food flow and then

analyze the effect of the valve not regulating the flow, rather than considering what occurs if the regulating valve fails in its operation.

Figure 4.8 shows a potential failure modes and effects analysis form used as an example.

The process FMEA identifies potential product-related process failure modes and assesses the potential customer effects of the failures. As shown in Figure 4.9, it develops a list of potential failure modes ranked according to their effect on the manufacturer, thus establishing a priority system for corrective action considerations.

This exercise is a combination of three separate efforts:

a. Failure mode (the manner by which a failure is observed). It generally 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 (the consequences). It is the effect that a failure mode has on the operation, function, or status of the specific item being analyzed. Failure effects are classified as local effect, next higher level, and end effect.
c. Criticality analysis (a procedure by which each potential failure mode is ranked). This is done according to the combined influence of (i) severity and (ii) probability of occurrence. Since the criticality numbers are established based upon subjective judgments, they should only be used as indicators of relative priorities.
    i. Severity. Classified as follows:

        Catastrophic. A failure that may cause death or equipment system loss, e.g., disintegration of the machine drive system.

        Critical. A failure that may cause severe injury, major property damage, or major system damage that will result in operation loss, e.g., a loss of brakes or stripped transmission gears.

        Marginal. A failure that may cause minor injury, minor property damage, or minor system damage that will result in delay or loss of availability, e.g., loss of hydraulic system or loss of motor drive capability.

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

Part or Process Name/No.				Design/Manufacturing Resp.			
Homogenizer/Piston Head				Processing Department			
Series No./Dev. Step				Engineering Release Date			
20121-3055							
Part/Process Description	**Process Purpose**	**Potential Failure Mode**	**Potential Effects of Failure(s)**	**Severity**	**Potential Causes of Failure**	**Occurrence**	**Current Controls**
Mechanical treatment of milk fat globules	Breaking of milk fat globules	Piston head breaking	No milk treatment leading to - Bad milk quality - Milk contamination	7	Mechanical wear Manufacturing problems	4	Preventive checks: - Teflon seal wear - Mechanical wear

Other Areas Involved			Suppliers & Plants Affected					
Production, Quality			Production Planning, Operations					
Prepared By			FMEA Date					
Carlo Rossi			27.03.1997					
Detection	**RPN**	**Recommended Action(s)**	**Area Individual Responsibility & Completion Date**	**Actions Taken**	**Severity**	**Occurrence**	**Detection**	**RPN**
2	56	Preventive checks: - Teflon seal wear - Mechanical wear - Piston stroke measurement	Production Dep. 05.04.1998 Maintenance Dep. 06/04/1998 Maintenance Dep. 06/04/1998	Operator check every 250 working hours Preventive Maintenance Preventive Maintenance	7	3	2	42

FIGURE 4.8
Process FMEA form.

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 4.9
Example of a risk evaluation form. (From NASA, *Reliability Centered Maintenance: Guide for Facilities and Collateral Equipment*, 2000.)

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

Frequent. A high probability of occurrence during the item operating time interval. 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. A moderate probability of occurrence during the item operating time interval. Reasonably probable is a single failure mode probability of occurrence that 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. A single failure mode probability of occurrence that 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 that is more than 0.001 but less than 0.01 of the overall probability of failure during the item operating time.

Extremely unlikely. A failure whose probability of occurrence is essentially zero during the 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 that will indicate a priority of failure modes. During research and development, those failure modes possessing the highest priority should be redesigned if possible.

Furthermore, the consequences that a failure mode had on operation or machine function were analyzed. Then for each failure, a critical analysis was done to identify a critical number that is derived by the failure severity, occurrence, and detection classification.

Figure 4.10 shows how failure severity, occurrence, and detection have been classified.

By combining the severity of failure and the probability of occurrence. The matrix shown in Figure 4.11 indicates a priority of failure modes.

MTBF was a basic data element needed for RCM analysis. This number is derived from the following formula:

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

5. Review of maintenance history. This step is necessary to determine the equipment stops that have occurred, the causes, and MTBF. From information gathered during the review of maintenance history and the results of the failure modes and effects analysis, a maintenance approach for each of the failure effects can be determined. The value of MTBF and the failure rate will give us an idea of the reliability of the equipment/part. More specifically, we can:
   a. Calculate the failure rate of each failure mode and decide whether a design review is desired on a developmental item

SEVERITY

Score No.	Severity Classif.	Failure Severity Assessment Criteria
1	I	No damages to product packed or to people. Customer will not realize any failure effect.
2–3	II	Failure effects are not serious.
4–6	III	Failure effects are serious enough. There could be problems on product and the event will be noted by the customer.
7–8	IV	Failure effects are serious. Production must be stopped.
9–10	V	Failure effects are very serious. Failure effects infringe national laws on product safety.

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 occur
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 events happen very frequently

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

FIGURE 4.10
Failure severity, occurrence, and detection classification tables. (From NASA, *Reliability Centered Maintenance: Guide for Facilities and Collateral Equipment*, 2000.)

b. Decide when the part should be replaced if scheduled replacement is required

Moreover failure 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

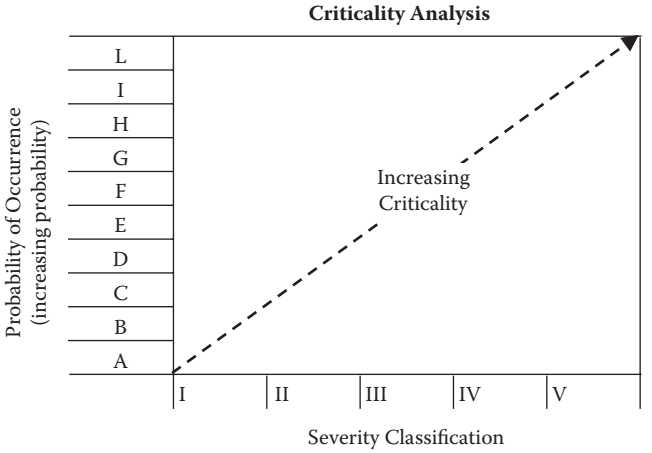


FIGURE 4.11
Criticality analysis matrix. (From NASA, *Reliability Centered Maintenance: Guide for Facilities and Collateral Equipment*, 2000.)

pursues the elimination of chronic failures through the following activities:

- Problem definition
- Physical analysis of the problem
- Identification of the likely causes of the problem
- Equipment, materials, and methods assessment
- Development of techniques for analysis and inspection
- Elimination of disturbing factors
- Devising of proposals and improvements

6. Determine maintenance approach for each failure effect. The RCM logic tree has been used to determine the maintenance tasks and to logically work through the tasks likely to be needed to develop an RCM program. After creating a logic tree, four distinct types of maintenance tasks usually result in
   - Time-directed tasks (all preventive maintenance procedures)
   - Condition-directed maintenance (preventive and CBM)
   - Failure finding
   - Running to failure (decision to run certain components to failure)

   Putting these four tasks together in a meaningful order and incorporating them into daily maintenance operations is the actual RCM practice.

4.4.1.1 RCM Logic Tree

Decision logic for task selection, shown in Figure 4.12, provided some useful guidelines that enable us to identify the criteria needed to apply condition monitoring and time-directed tasks. Basic questions on cost-effective tasks and on failure finding tasks are provided, together with questions on safety that guide to PM or redesign activities.

The decision logic tree shown in Figure 4.13 was used to define predictive testing and inspection (PT&I) activities to reinforce the condition-based maintenance (CBM) approach in case of lack of correlation between age and component failure. The logic tree shown in Figure 4.14 was used to define types of maintenance task, identify run-to-failure issues, CBM, and time interval-based tasks, and redesign activities to reduce failure risk.

To define if a maintenance task is cost-effective or not, the logic tree shown in Figure 4.15 was used to provide an easy path for task selection.

4.4.1.2 Determining the Task Interval

Since, as shown in Figure 4.16, 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).

Figure 4.17 provides an example, and the point on the slope at which a physical symptom (potential failure) appears is the beginning of Tos. The maximum inspection interval time is Tos. To ensure that an inspection to detect impending failure will occur between the appearance of potential and functional failure, inspection intervals must be shorter than Tos.

If an inspection fails to identify and correct the mechanical wear or symptom, there would be at least one more inspection before functional failure occurs. For that reason, for critical machine parts or components (HACCP and reliability issues), the inspection interval was established at 1/3 or 1/4 of Tos. Scheduling a replacement or overhaul task was an exercise based upon the curve shown in Figure 4.6, which indicates the cumulative probability of failure for a specific component at different lifetimes. Since probability of failure increases as the component's age increases, the task interval was selected to provide an acceptable probability of failure. In this case, the decision for replacement of the component occurs at 3000 operating hours, where the probability of failure exceeds 0.15. When data available show that failures are evenly distributed around the mean,

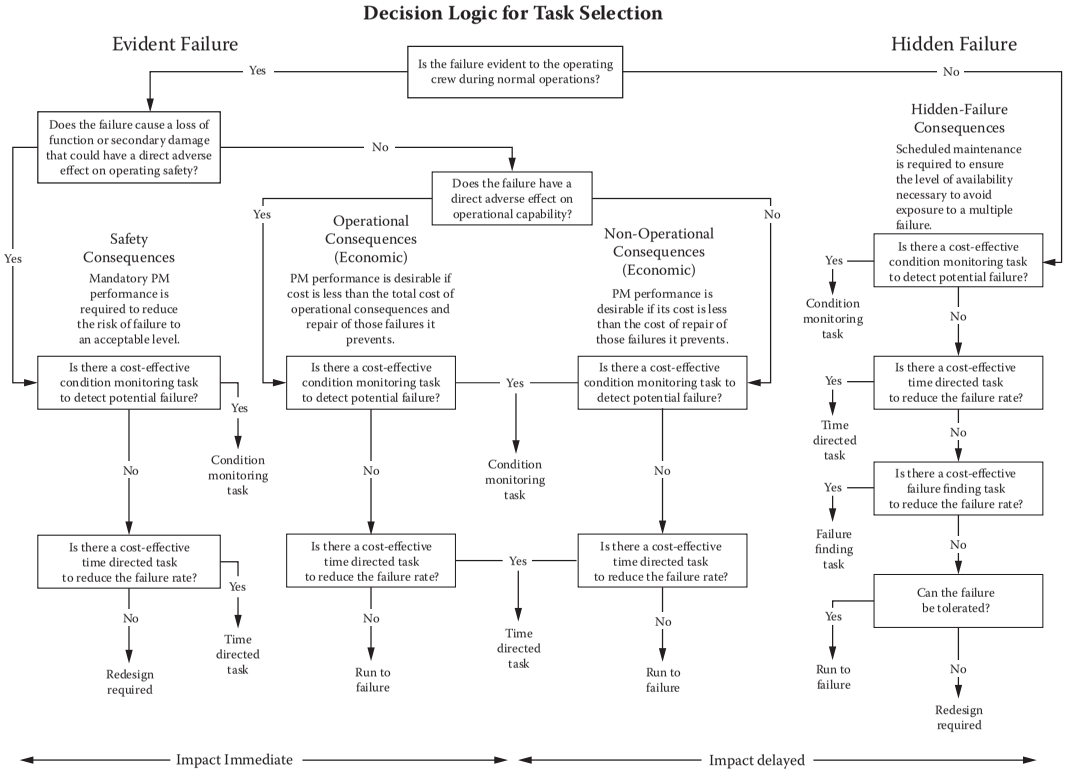


FIGURE 4.12
Decision logic for task selection. (From Tetra Pak Training Department, Training material on TPMS, 1999.)

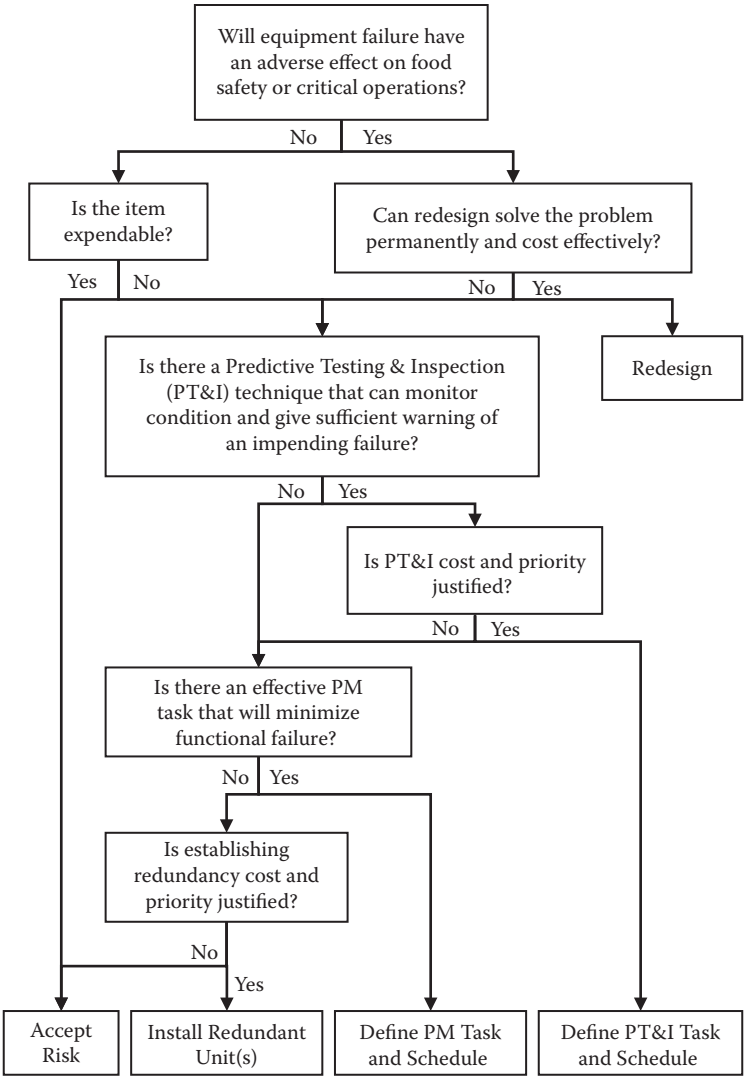


FIGURE 4.13
Decision logic tree.

the MTBF could be used to schedule maintenance intervals. Figure 4.18 shows a curve representing a normal failure distribution.

When the failures occurred in a narrow range, this method of task scheduling could be appropriate. After RCM application the team involved in the design process will be aware that any maintenance action that does not improve the component's safety or reliability should be eliminated.

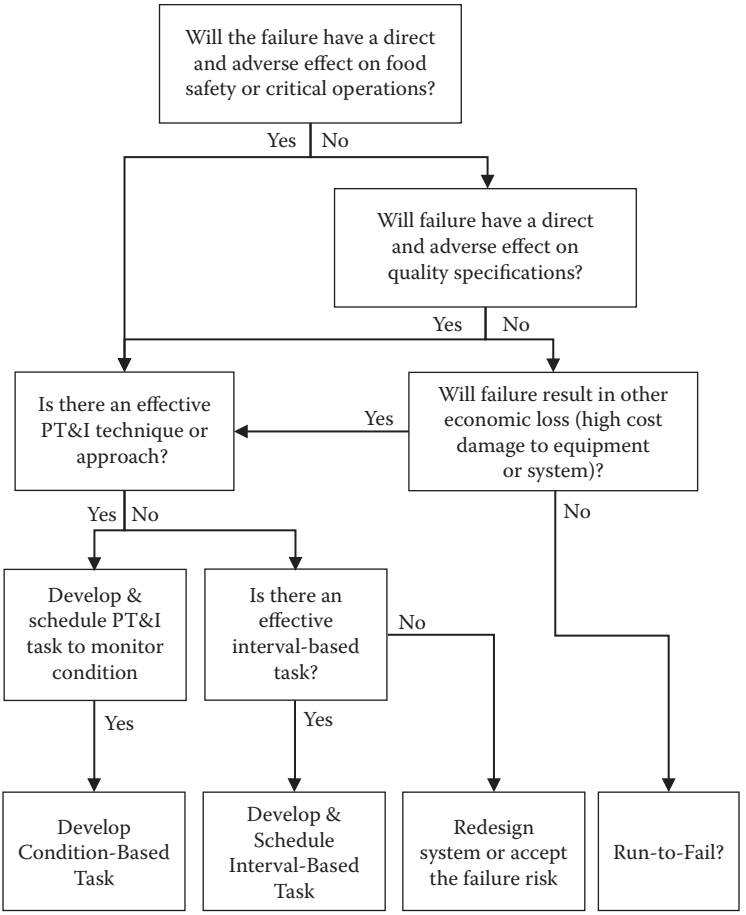


FIGURE 4.14
Types of maintenance tasks.

Some of the benefits coming from RCM implementation are

- Higher equipment reliability
- Maintenance cost reduction
- Net increase in uptime, utilization, or yield rates

The main goals of RCM are higher equipment reliability, cost reduction, and other production efficiency benefits. These benefits for the automotive or aircraft industry are absolutely of primary importance, but in the food industry, the quality and safety of food packed are the most important parameters to preserve. Equipment reliability and cost reduction

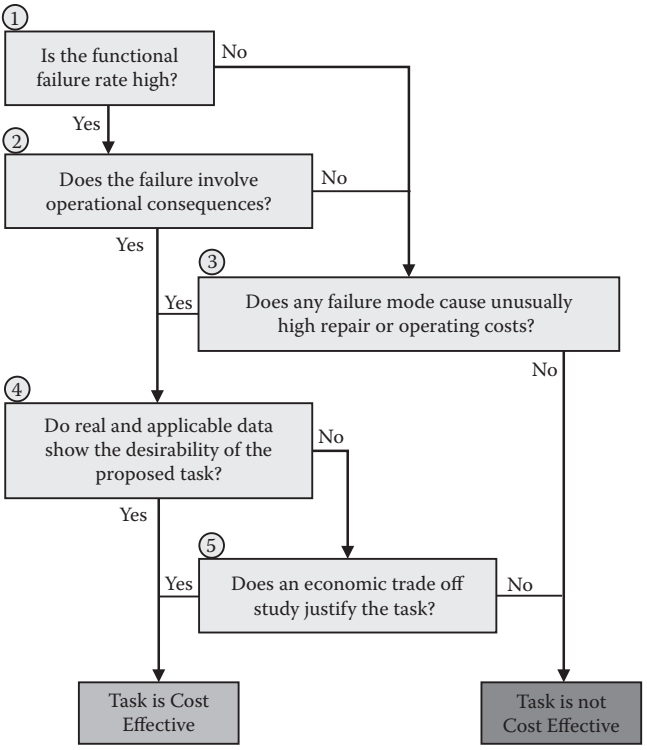


FIGURE 4.15
Cost-effective task logic tree.

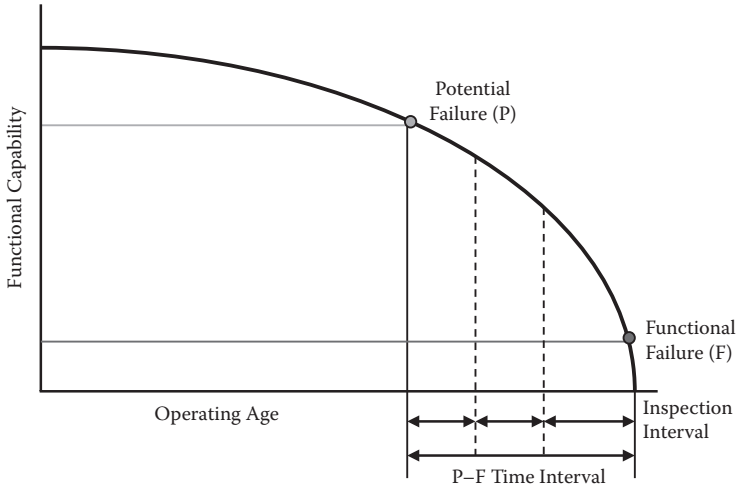


FIGURE 4.16
On-condition task based on P–F interval.

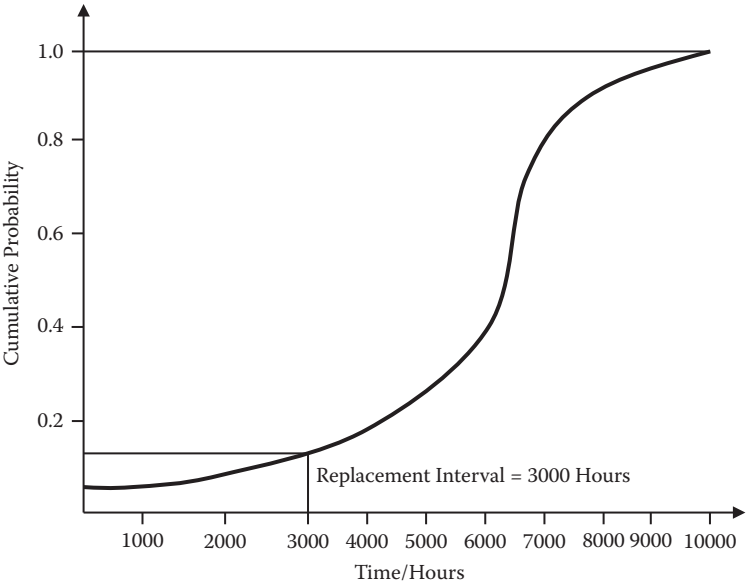


FIGURE 4.17
Inspection time interval.

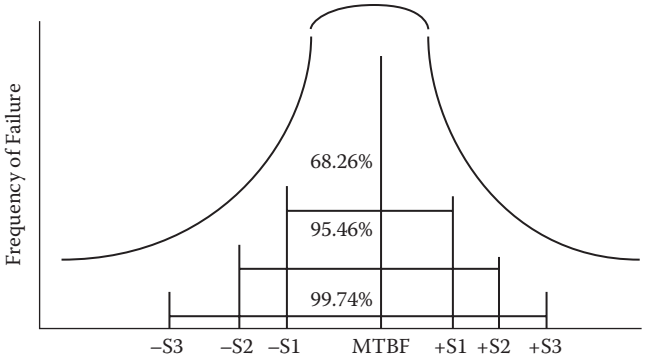
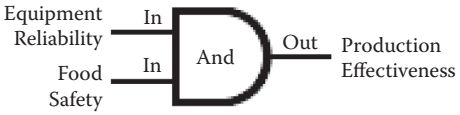


FIGURE 4.18
Normal failure distribution. (From NASA, *Reliability Centered Maintenance: Guide for Facilities and Collateral Equipment*, 2000.)

are not enough; they provide a fundamental contribution to production effectiveness, but not to the quality or safety of food product packed.

Production effectiveness in the food industry depends not only on the reliability of the systems, but also on all those critical factors that may result in a food safety hazard. The simple sketch represents an AND logic

gate where a positive output depends on two positive inputs; this summarizes the condition to be satisfied to achieve a true food production effectiveness.



While RCM allows us to achieve higher equipment reliability, other quality techniques need to be searched to define a maintenance design process able to produce both equipment reliability and food product safety.

4.4.2 Failure Reporting, Analysis, and Corrective Action System (FRACAS)

FRACAS is a continuous improvement system utilizing a closed-loop feedback path in which the maintenance technician and equipment operator work together to collect and record data relating to failures of assets/equipment. These data are then reviewed and analyzed 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 analyze historical data regarding equipment failures to identify potential and functional failures together with their impact on product safety and a 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 that can collect, quantify, and control a wide range of incoming incident or failure 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 software, that provides a process for reporting, classifying, and analyzing failures, and planning corrective actions in response to those failures.[30]

It is typically used in an industrial environment to collect data and record and analyze system failures. A FRACAS may attempt to manage

multiple failure reports that are recorded by numerous individuals in different ways. FRACAS produces a history of failure and corrective actions. The FRACAS method was first introduced in the United States in the 1970s. The method calls for a systematic failure data collection, management, analysis, and corrective action implementation. The 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. A failure reporting, analysis, and corrective action system is used to record all failures and problems related to a product or process and their associated root causes and failure analyses in order to assist in identifying and implementing corrective actions. 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 4.19 occur.

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. Some of the benefits include the following:

- Access to historical performance data
- Trending asset types and failure types
- Identifying patterns of deficiencies
- Ease of statistical analysis

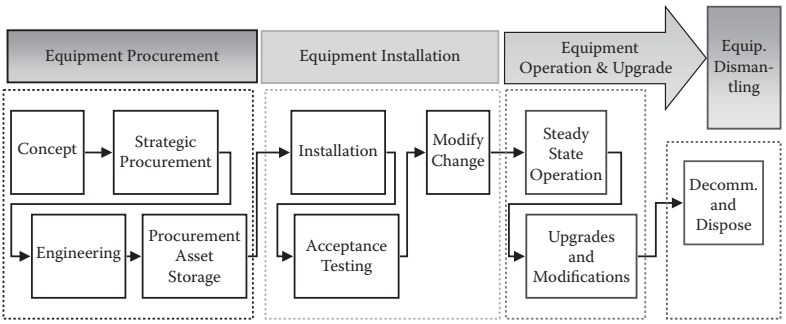


FIGURE 4.19
FRACAS phases.

In many industrial realities it is not so easy to gather and have access to reliable and consistent information, so the critical factors to successfully use the system are

- Have a formalized and documented FRACAS procedure
- Ensure that value and ease of reporting are emphasized to ensure active involvement of all stakeholders
- Create business process linkages to RCM, predictive maintenance databases, etc., to ensure consistent data
- Provide training on the FRACAS process and procedures
- Generate an audit and surveillance program to ensure compliance and proper use
- Design a tie to your management of change or configuration control process to ensure accuracy of asset data

Figure 4.20 highlights the use of FRACAS from failure reporting to improvement corrective actions. The FRACAS database is directly linked to

- Failure reporting. Through an established procedure that includes collecting and recording corrective maintenance information and times, data should be submitted in a simple, easy-to-use format.

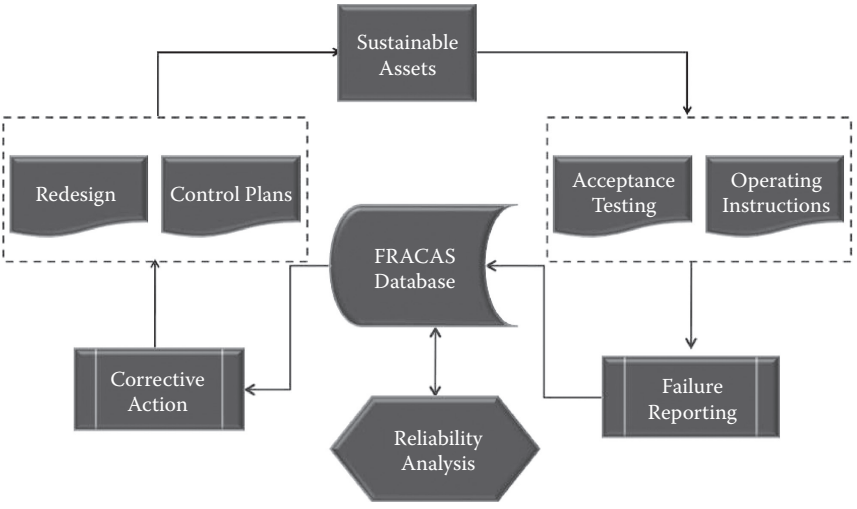


FIGURE 4.20
FRACAS from failure reporting to improvement actions. (From Life Cycle Institute, Failure Report Analysis and Corrective Action System (FRACAS), Life Cycle Engineering, 2009, available at http://www.LCE.com.)

Data are then consolidated into a central data logging system, and failures should also be ranked in terms of the criticality or severity of the error.

- Failure analysis. A detailed review of failure reports will be done in order to capture historical data from the database of any related or similar failures. At this point root cause analysis (RCA) enables us to obtain the failed items for analysis required beyond our resources for external support (as needed).
- Corrective actions. After identification of root causes for each failure, the development of corrective actions will enable us to address the equipment improvement. Assign owners for action items and track actions to completion. An effective follow-up will be based on regular measuring to monitor the results.

In conclusion, the basic benefit of FRACAS is the contribution provided by the information that it contains for the identification and correction of design errors, spare part problems, workmanship defects, and other process errors. An effective implementation of FRACAS results in savings in direct costs such as production rework and parts/materials scrap, and even greater indirect costs associated with dissatisfied customers. FRACAS contributes to reliability growth, higher maintenance effectiveness, and continuous process improvement. Continuous monitoring and tracking of data via FRACAS provides the assessment as to whether previous failure trends or reliability problems have been solved through the corrective actions implemented. Moreover, FRACAS represents a useful tool to establish a management culture based on root cause analysis, on investigation of historical facts and figures as a way to solve engineering and reliability problems.

4.4.3 Quantitative Failure Measures through Statistical Analysis

Quantitative analysis is to be used to "weight" a failure in order to gain knowledge about its importance and how it is distributed over time. Potential and functional failures must be measured through statistical tools to assess their impact on production activity. The development and use of statistical theories about distributions and how they vary have become the cornerstone of process improvement.[37] 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 ($X1, 2, n$), then it can be represented in this way: $Y = F(X)$. If we know the variations caused by the Xs, then, through SPC, it is possible to monitor the Xs first. Using SPC, we are attempting to control the critical Xs in order to control the failure Y. To get an effective result, we should be able to find the "vital few" Xs, to put them under control through SPC to achieve a desired result on Y.

Y can be defined as

- Dependent
- Output
- Effect
- Symptom
- Monitor

$X1, \ldots, Xn$ 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.

In addition, there are several different types of control charts that can test for different causes, such as how quickly major vs. minor shifts in process averages are detected. Control charts are time series charts of all the

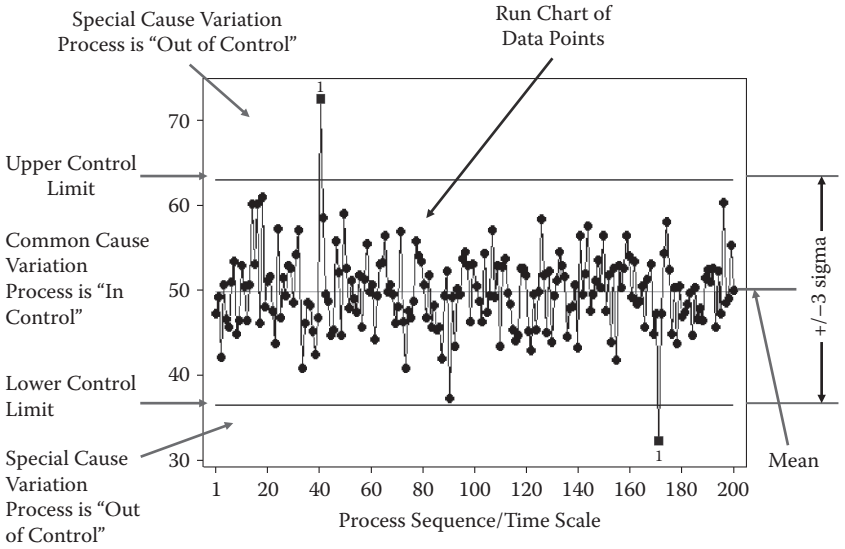


FIGURE 4.21
SPC control chart.

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 4.21, 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).

Now the chart has three zones:

1. The zone between the UCL and the LCL, which is called the zone of common variation
2. The zone above the UCL, which is called a zone of special cause variation
3. Another zone of special cause variation below the LCL

Control charts graphically highlight data points that do not fit the normal level of expected variation. This is mathematically defined as being more than ±3 standard deviations from the mean. Control charts provide two basic functions:

- First is time-based information on the performance of the process, which makes it possible to track events affecting the process
- Second is to alert when special cause variation occurs

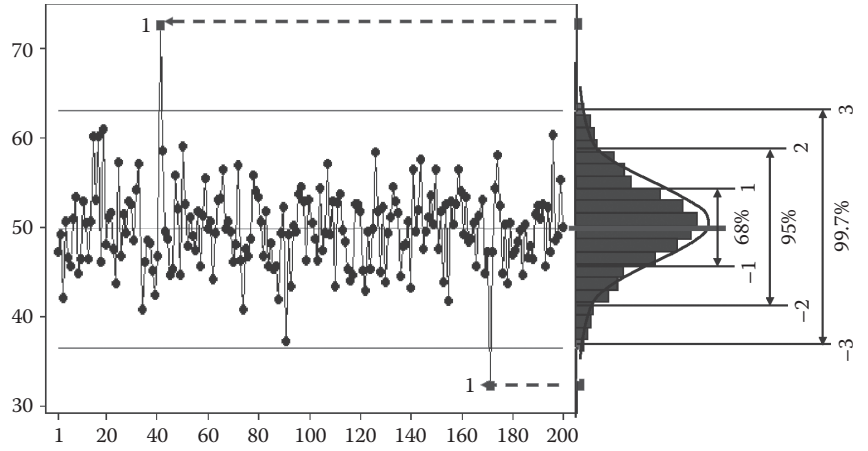


FIGURE 4.22
±3 Standard deviations on SPC control chart.

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 UCL and LCL, respectively, and it is all based on probably figures.

Looking at Figure 4.22, we have to consider that in the area under the curve, on basic statistics, ±1 standard deviation represents 68% of the distribution; ±2, 95%; and ±3, 99.7%. From a probability perspective, we know that we would expect the output of a process to have a 99.7% chance of being between ±3 standard deviations. There is only a 0.3% chance (100% – 99.7%) that a data point will be beyond ±3 standard deviations. Since we are talking about two zones, one zone above the +3 standard deviations and one below it, we have to split 0.3% in two, meaning that there is only a 0.15% chance of being in one of the zones.

There is only a 0.0015 (0.15%) probability that a data point will be either above or below the UCL or LCL. That is a very small probability compared to 0.997 (99.75%) probability the data point will be between the UCL and the LCL. What this means is there must have been something special happen to cause a data point to be that far from the mean, like a change in the preventive maintenance activities, an equipment operator mistake, etc. This is why the term *special cause* or *assignable cause variation* applies. The probability that a data point was so far from the rest of the population is so low that something special or assignable happened. Outliers are just that; they have a low probability of occurring, meaning we have lost

control of our process. This simple, quantitative approach, using probability, is the essence of all control charts. The size of subgroups aids in the detection of shifts of the mean, indicating that special cause exists. The larger the subgroup size, the greater the chance of detecting a special cause. Subgroup size for attribute data is often 50–200.

As shown in Figure 4.23, 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 that 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 our definition of subgroups. In Figure 4.24, we are tracking delivery times for spare part quotes on new equipment with an SPC chart. Since we really want to have subgroups with only common cause variation, if other sources of variation are detected, the sources will be easily found instead of buried within our definition of subgroups. The graph shows that the potential sources of variation are going to gradually increase (from left to right in the figure), and as a consequence, a wider standard deviation, due to wider dispersion of values, can be due, for instance, to

- Different equipment operators
- Different spare part supplier sources
- Different or new products

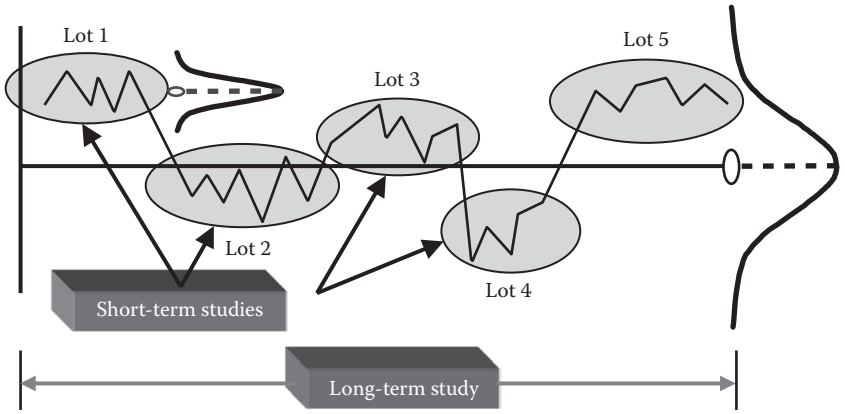


FIGURE 4.23
Short- and long-term studies of SPC subgroups. (From Predictive Maintenance and Condition Monitoring Management, April 2009, available at http://reliabilityweb.com/ee-assets/my-uploads/art09/tips_09.)

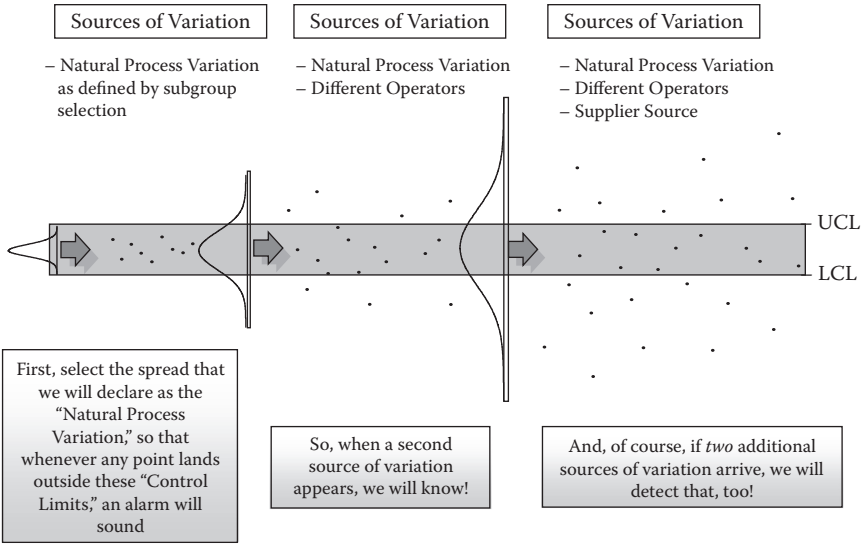


FIGURE 4.24
SPC applied to delivery times of spare parts. (From Predictive Maintenance and Condition Monitoring Management, April 2009, available at http://reliabilityweb.com/ee-assets/my-uploads/art09/tips_09.)

4.4.3.1 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 a 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 *variables* depending on condition monitoring; hence, a measurement such as a dimension or 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 nonconformity 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. Special causes of variation are problems that arise in a periodic fashion. They are somewhat unpredictable and

can be dealt with at the machine or operator level. Examples of special causes are operator error, broken tools, and machine setting drift. This type of variation is not critical and only represents a small fraction of the variation found in a process. Special causes of variation account for 5–15% of quality problems and are due to a factor that has "slipped" into the process, causing unstable or unpredictable variation.

Unpredictable variations are those that are abnormal to the process, including human error, equipment failure, defective/changed spare parts, power failures, etc. Failure to remove them can result in lower equipment efficiency, increased maintenance costs, unsafe working conditions, etc. Removal of all special causes of variation yields a process that is in statistical control.

4.4.3.2 Failure Distribution

Using reliability data to predict the equipment performance generally involves assuming that the historical performance will reflect the current performance. The latter is best measured by strategic use of machinery health 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 4.25.

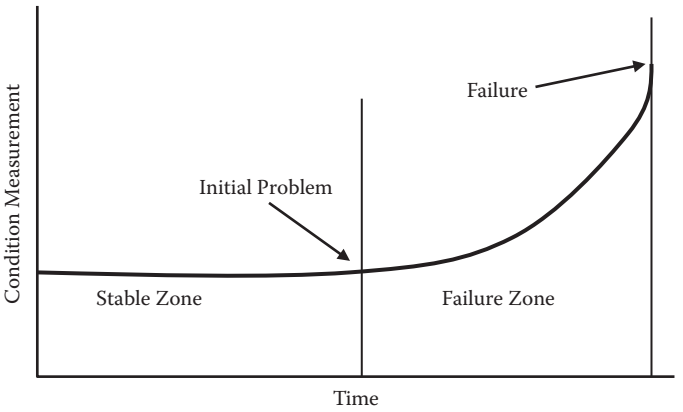


FIGURE 4.25
General mechanical failure pattern.

In the "stable zone," measurements are simply varying around an average value. The variance may be due to process changes between successive measurements or measurement error. When the measurements start to deviate from these values, it becomes apparent that a problem exists and the machine 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 act as a 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 4.26.

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 (UL) is reached 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. While this behavior 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 modeling of the stable zone. The estimate of UL

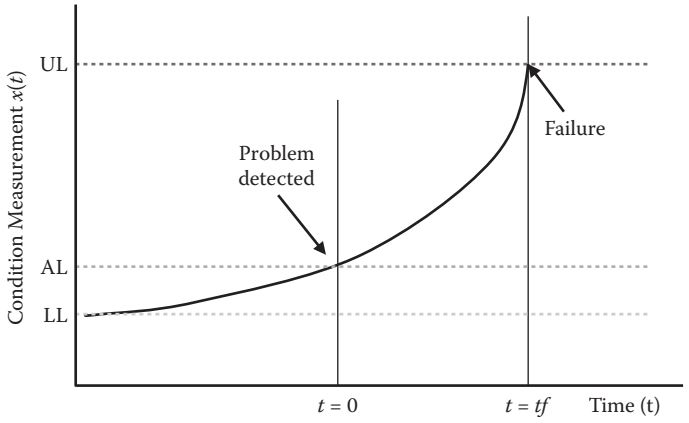


FIGURE 4.26
Failure zone model.

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 appropriate information available from either within the company or from outside sources, such as equipment suppliers, or by reference to universal standards. The time *tf* is obtained by reference to reliability analysis of previous failures.

4.4.3.3 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 that repeats itself endlessly regarding manufactured products and in nature. Measurements may be in volts, millimeters, amperes, hours, minutes, or one of many other units of measure. Normal distributions are the most common type of distribution found in nature, but they are not the only type.

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 4.27, 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 Distribution Function (CDF).

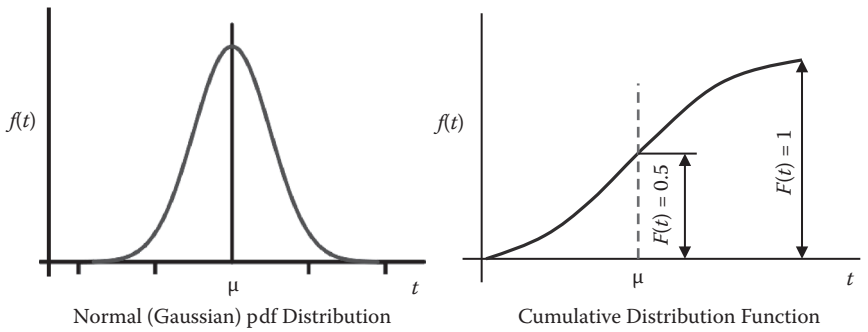


FIGURE 4.27
Normal and cumulative distributions.

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 and times to failure of electronic and mechanical components, equipment, or systems.[50] These probability distributions are related to distribution of failures, where the failure rate is proportional to a power of time. Shapes represented by different curves indicate different failure rates that, for instance, decrease, due to infant mortality following installation of new equipment or increase due to an aging process.

As shown in Figure 4.28, the Weibull distribution is related to a number of other probability distributions. It gives the distribution of failures, where the failure rate is proportional to a power of time and can be interpreted directly as follows:

- A value of k (shape parameter) < 1 indicates that the failure rate decreases over time. This happens if there is significant infant mortality, or defective items failing early and the failure rate decreasing over time as the defective items are weeded out of the population.
- A value of k = 1 indicates that the failure rate is constant over time. This might suggest random external events (human errors) are causing mortality, or failure.
- A value of k > 1 indicates that the failure rate increases with time. This happens if there is an aging process, or parts that are more likely to fail as time goes on.

Stan Nowlan and Howard Heap (1978) studied aircraft failures looking for correlations between those failures and the maintenance that was

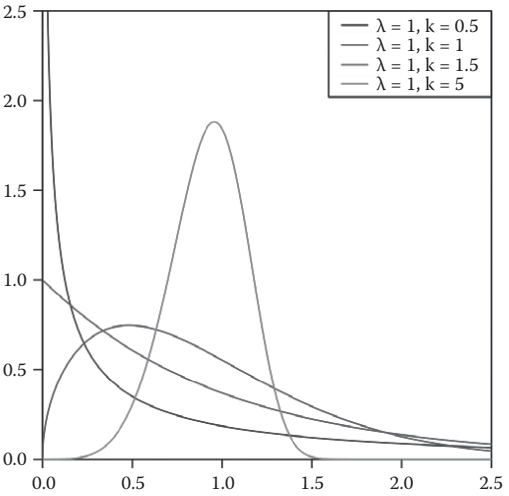


FIGURE 4.28
Weibull probability density function. (From Roymech, Failure Distributions, 2008, available at http://roymech.co.uk/Useful_Tables/ARM/Failure_Distributions.)

being performed.[41] They recognized that maintenance was a contributing factor to many of the failures, but in some other cases maintenance was able to drastically improve the situation. They looked for patterns and found them. As shown in Figure 4.29, there were actually six patterns of conditional probability of failure.

- 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. It shows constant or slowly increasing conditional probability of failure, ending in a wear-out zone. Before RCM, this was the dominant view of equipment failure. It occurs in assets that are in contact with products, process fluids, and drive 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.

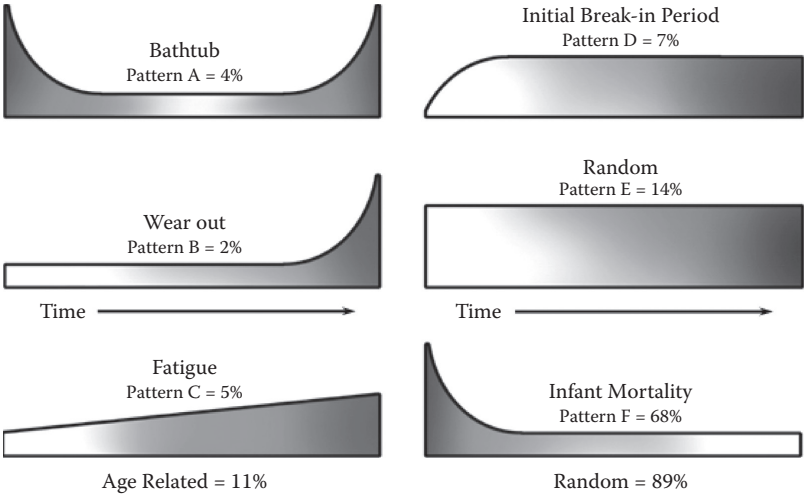


FIGURE 4.29
Failure shapes. (From Nowlan, F.S., and Heap, H.F., *Reliability Centered Maintenance*, Dolby, Access Press, San Francisco, CA, 1978.)

- Pattern D is best when new. It shows a low conditional probability of failure when the item is new or just out of the shop, and 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. It 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 lightbulbs 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 shutdown 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]

4.4.4 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 below. In the 1950s, 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.[17] As shown in Figure 4.30, it begins with a problem, and then identifies possible causes by separate categories that branch off like the bones of a fish. Its categories, typically including materials, methods, machines, measurements, environments, and people, can be modified to better match a particular issue.

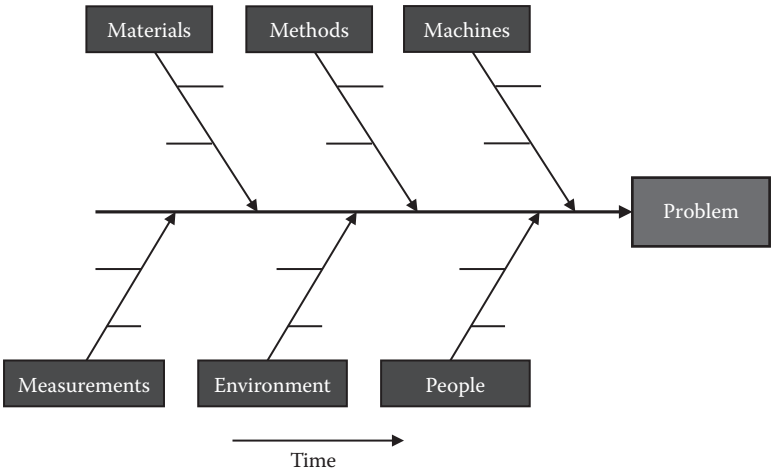


FIGURE 4.30
Ishikawa or fishbone diagram.

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 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 the fishbone and cause map, investigators ask *why* questions that move backward through time, studying effects and finding their causes.[17] 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 1, then step 2, etc.).
2. Root cause analysis and 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? What will be done to prevent it? Figure 4.31 highlights the basic principles, linking the result (symptom of the problem) to the underlying causes.

   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 4.32, 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 equipment failure.

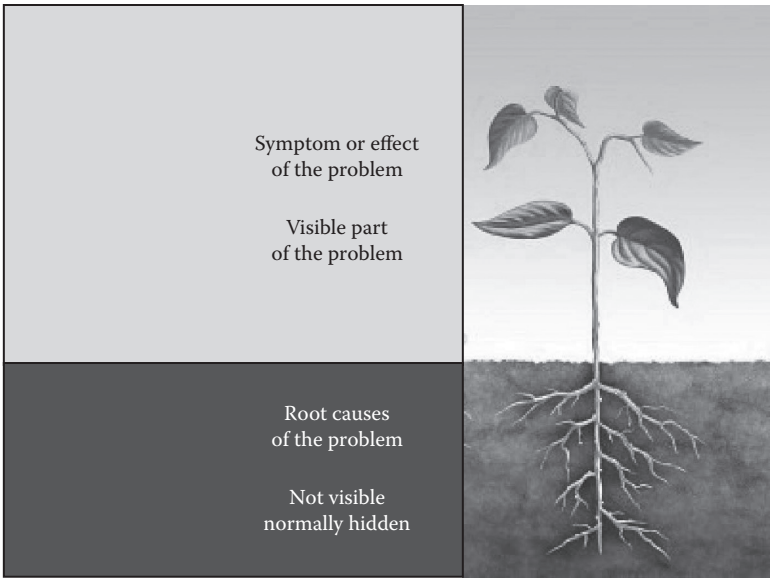


FIGURE 4.31
Basic principles of root cause analysis.

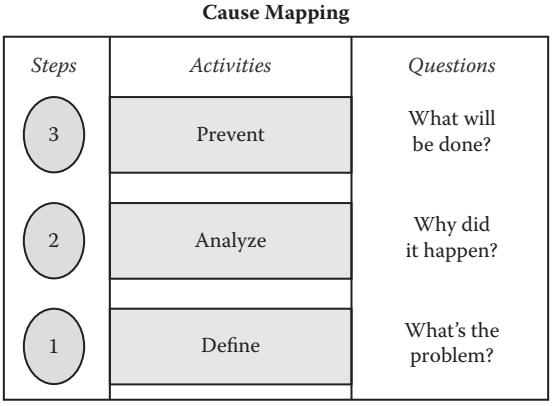


FIGURE 4.32
Cause mapping process.

3. Cause maps focus on cause and effect. As shown in Figure 4.33, an analysis breaks something down into its parts; analyzing an incident, for example, involves breaking it down into specific cause-and-effect relationships.

   Fishbone diagrams group similar causes into categories: method, machine, material, and man, and this enables us to split causes

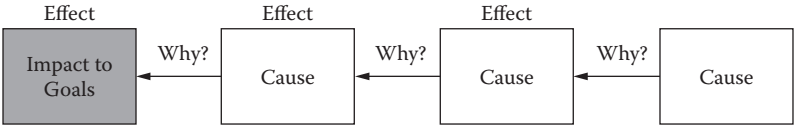


FIGURE 4.33
Cause mapping cause-and-effect boxes. (From Galley, M., Improving on the Fishbone Effective Cause-and-Effect Analysis: Cause Mapping, ThinkReliability, 2007, available at http://www.thinkreliability.com.)

per group. Categorization, however, creates generalizations and represents a small part of an 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."[17]

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.[17] 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.

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 systems of evidence-supported causes.[17]

4.4.5 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 nonconformance to system requirements. A systems failure analysis is performed to identify nonconformance 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).[43]

- 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.[43] 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.[3] As shown in Figure 4.34, there are two types of gates: AND gates and OR gates. The AND gate signifies that all events must

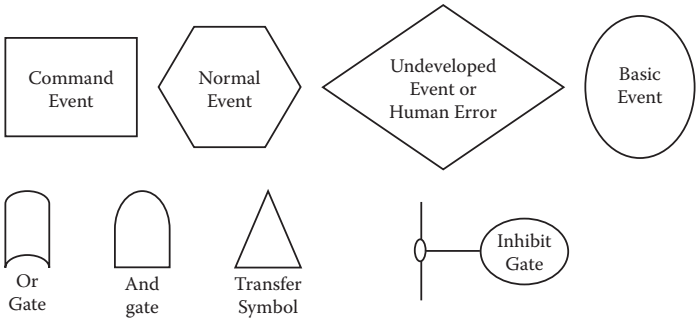


FIGURE 4.34
Fault tree symbology represented by logic gates.

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 4.35 shows the problem of a lightbulb 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.

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.[3]

- Failure mode assessment and assignment matrix. After completing the fault tree, the next step is to prepare the failure mode assessment and assignment matrix (FMA&A). As shown in Table 4.1, 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 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.

Qualitative analysis is basically dependent on the ability of a working team, normally multicultural, which has to examine problems, causes, and effects to define solutions able to solve problems or put them under control.

Qualitative analysis is the "soft" analytical component, heavily dependent on the human factor, that represents a complementary tool to quantitative analysis based instead on "hard" figures.

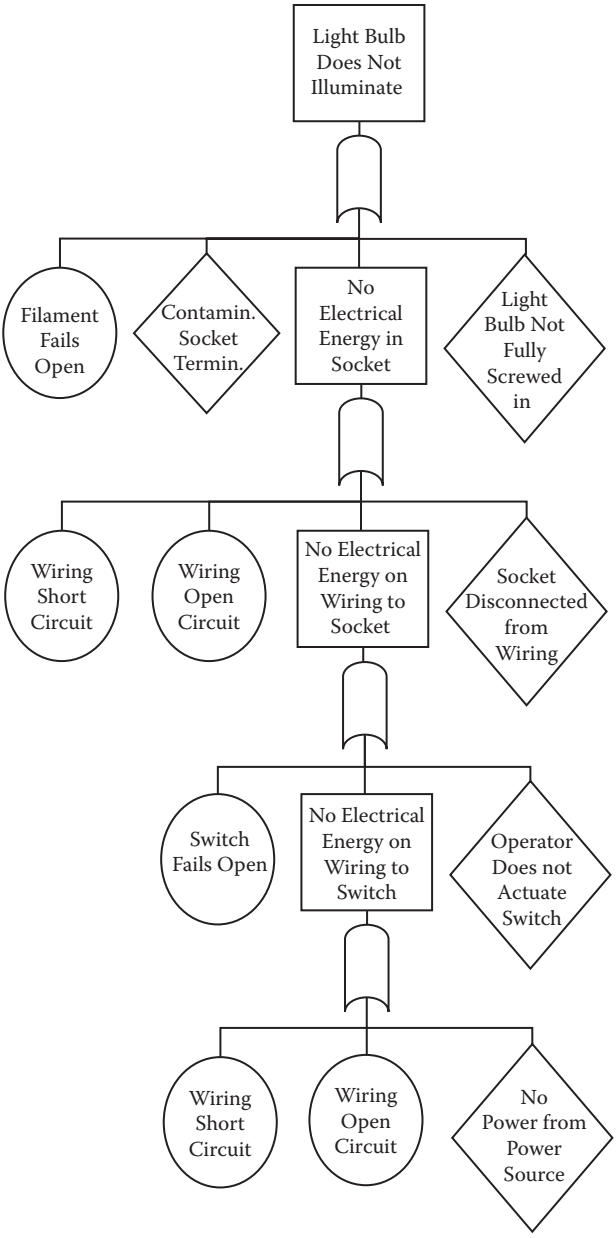


FIGURE 4.35
Fault tree applied to a light that does not illuminate. (From J. H. Berk and Associates, Systems Failure Analysis, available at http://www.jhberkandassociates.com/systems_failure_analysis.htm.)

TABLE 4.1

Failure Mode Assessment and Assignment Matrix

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	Lightbulb 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

Source: J. H. Berk and Associates, Systems Failure Analysis, available at http://www.jhberkandassociates.com/systems_failure_analysis.htm.

4.5 CRITICAL INVESTIGATION OF MAINTENANCE ENGINEERING TECHNIQUES TO DEFINE AN IMPLEMENTATION PROCESS FOR THE FOOD INDUSTRY

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

4.5.1 Total Productive Maintenance (TPM) Technique

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

- Loss of time:
  1. Equipment failure due to faults
  2. Setup 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 involves waste of product or repair activities to restore the product quality
  6. Reduced yield in the equipment start-up phase[25]

Table 4.2 lists the 12 steps, suggested by Nakajima, needed to develop and implement a TPM program. The 12 steps are combined into four main stages:

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

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).

TABLE 4.2

Twelve Steps of TPM Development

Stage		Step	Details
Preparation	1	Announce top management decision to introduce TPM	Statement from TPM lecture in an article in company newspaper
	2	Launch education and campaign to introduce TPM	Managers: seminars, retreats according to level. General: slide presentations
	3	Create organizations to promote TPM	Form special committees at every level 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-off	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 program	Promote seven steps: build diagnosis skills, establish worker certification procedure
	9	Develop a scheduled maintenance program for the maintenance department	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 program	Maintenance prevention (MP) design commissioning control
Stabilization	12	Perfect TPM implementation and raise TPM levels	Evaluate for PM prize: set higher goals

Source: Nakajima, S., *TPM: Total Productive Maintenance*, Productivity Press, Cambridge, MA, 1992.

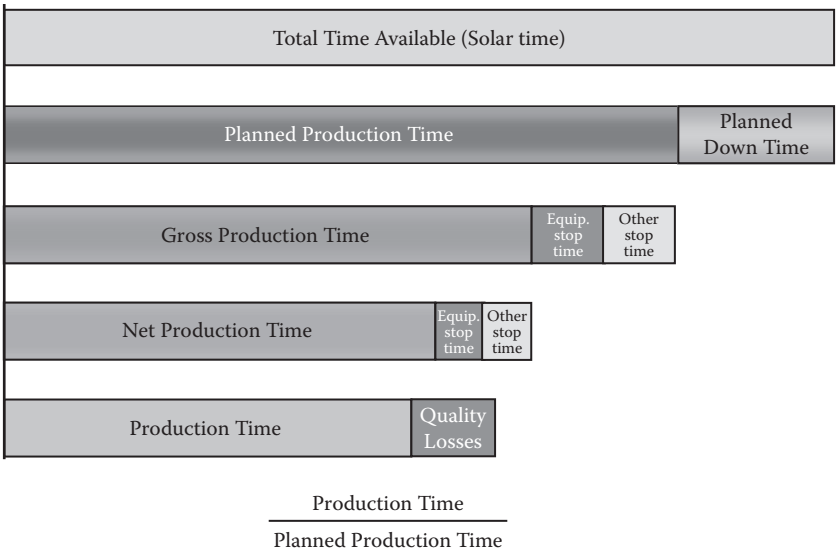


FIGURE 4.36
Production time domain with OEE formula.

Then the formula used reflects not only the equipment faults, but also all the losses regarding breakdowns, setup and registrations, short stops, speed reductions, and time spent for quality defects and rework. The OEE is the index measuring the line/machine productive effectiveness in the scheduled time. Figure 4.36 shows the time domain taken into consideration and the formula used to measure OEE.

4.5.1.1 Total Productive Maintenance (TPM) Implementation Principles

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

- Define equipment operator role in operating and maintaining the equipment. One of the most important characteristics of the 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 cleanup: This is a useful activity for discovering faults.
2. Elimination of causes of contamination and making cleaning easier.
3. Cleaning and lubrication rules.
4. Improvement of inspection and technical skills (training).
5. Development of autonomous inspection activities.
6. Standardization of procedures and workplace rules.
7. Completion of autonomous maintenance (AM).

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

1. Ability to discover anomalies
2. Ability to fix the anomalies and set the normal operating conditions
3. Ability to define the normal operating conditions and the standard valuation
4. Ability to manage and maintain the equipment

- Integration between machine operator and maintenance specialist. Figure 4.37 shows a picture that helps maintenance and equipment operator personnel to understand and learn that, based on the partnership between operations and maintenance, TPM enables operators and maintenance specialists to become multiskilled.
- Maintenance specialists and operators are trained to safely perform tasks listed in the shared task zone. In the example shown in Figure 4.37, since a replacement of a knife is in the task zone, the operator who observes the need for replacing this component can simply do it, without losing time to communicate with maintenance and operation supervisors, and then waiting for a maintenance specialist.

  Condition-based maintenance and specialist PM activities that require good electrical and mechanical skills are performed by maintenance specialists.

4.5.1.2 Operator Empowerment through Cooperation with Maintenance Specialists

TPM is, by definition, an *effective maintenance management system* supported by *autonomous maintenance,* where each production equipment

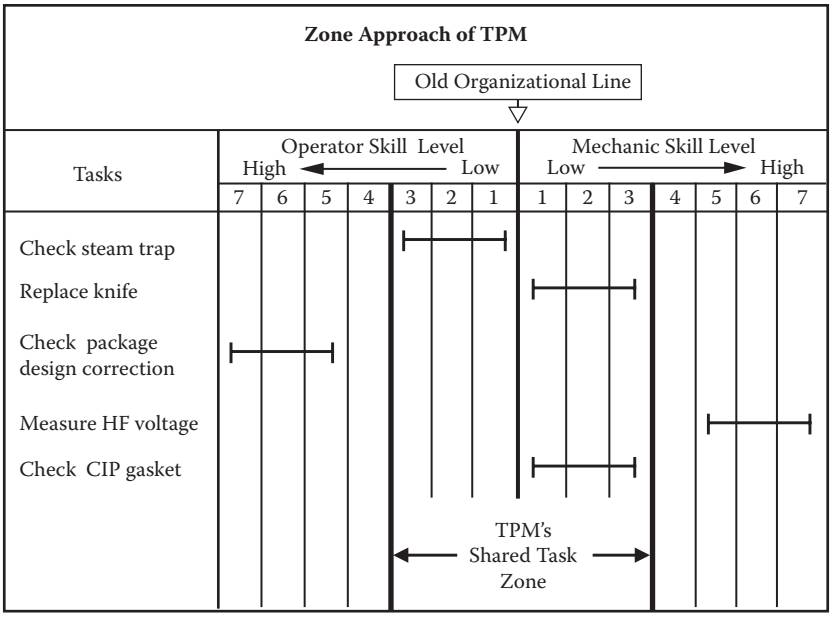


FIGURE 4.37
TPM's shared task zone.

operator becomes "proprietor" of his 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 shutdowns 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. Multiskilling of craft-workers[34]

1. Empower 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 need for a maintenance department is minimized. The equipment operator cleans and

lubricates the equipment with the recommended regularity and has access to the manufacturer specifications and the training support of the maintenance technicians. The operators also will be in charge of small adjustments, checking for screws or parts that become loose and fixing them, as well as reporting small details like noises, vibrations, or temperature rises in the operation of the equipment. Gradually, the operator becomes qualified to determine the status of different components and groups and can make small adjustments and repairs. The operator is trained on hydraulic systems, and then is qualified to find the causes of leaks and their location. The operators develop a high level of competence and make some adjustments and can correct the smaller leaks and defects. 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.

An important factor in the success of the TPM program is the pride that operators experience from the optimal shape in which their equipment is preserved. 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.[34]

2. Empower operators to assist and support maintenance specialists in the repair of equipment when it is down. As the operators become more expert on their equipment, the TPM coordinator, supported by the maintenance technicians, will give them more instruction and direction on pertinent safety measures so that they improve their capacity to intervene on the equipment. After implementation, the coordinator must maintain a continued flow of communication. At least once a week, the coordinator listens to new ideas for improvements and simplification, as well as repeating the new disciplines, such as orderliness and cleaning, autonomous inspection, and preventing the new status from going back to the previous standards. When a complex equipment failure is experienced, the operator is committed to understand the reason for failure and to assist the maintenance specialist while he is carrying out the troubleshooting activity. Under this concept, operators are trained to assist maintenance personnel in the repair

of equipment. In this case, the maintenance force is enlarged; the operators do not lose their central role due to lack of work, and ultimately the failed equipment is returned to service more quickly.

3. Empower 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 finishes the repairs, he or she assists the operators in returning the equipment to service by correcting leaks and other mechanical or electrical problems as they occur.

   By assisting the operator, until the equipment is running, the maintenance specialist eliminates many repeat calls, and overall downtime is reduced. Maintenance specialists can also be trained to perform some of the operation tasks without the assistance of the operators.
4. Empower 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 the TPM program, instrument calibration test units can be used to ensure the proper function of the instrumentation normally used to carry out preventive maintenance. These units enable more effective SPC by allowing people to periodically check and monitor the calibration of critical instruments.
6. Transfer tasks between operating groups. Through natural evolution, operating job structures frequently develop some problems that make them not as practical as desired. In many cases, unnecessary waiting time and equipment downtime are the attendant results. Identifying these nonproductive interfaces and restructuring job responsibilities can remove such inefficiencies.

7. Multiskilling 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. Multiskilling reduces the number of times an operator hears: "It is not a mechanical problem, but an electrical problem, so you need to get an electrician" or "It is not an electrical problem, so you need to get a mechanic." Multiskilled craft-workers become stewards of the problem and lose the "that's not my job" attitude.

The new TPM management concept consists of a more effective and realistic delegation of responsibilities (empowerment), and the different activities shown in Figure 4.38 enable the operators to know their equipment better than anyone else. That empowerment or responsibility delegation will be effective and realistic only after good education and training. The collective participation gives the operators greater satisfaction. That is why they will easily and happily keep doing the new assignments. According to the most recent studies of human behavior experts, our maximum potential is shown when we feel that our contribution is important.

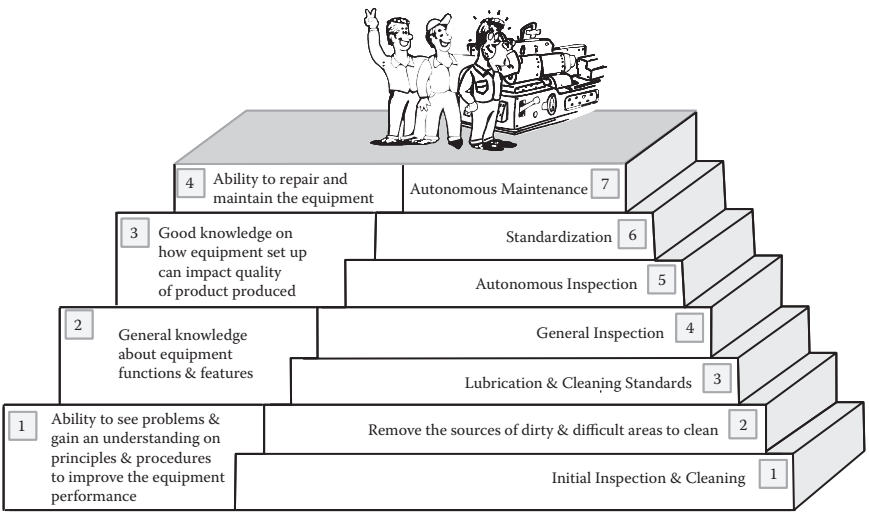


FIGURE 4.38
The different steps to become an operator able to carry out AM. (From Tetra Pak Training Department, Training material on WCM, 2002.)

Kaizen is a Japanese term that means continuous improvement.[35] When carrying out this process, constant success is obtained and the participants look for new opportunities. They put them into practice, and as they repeat it, the degree of satisfaction grows until it becomes a habit. The habit is to constantly look for more opportunities to improve the process, the workplace, the good manufacturing practices (GMPs), the quality of the product, etc. We can say then that each person has acquired the kaizen mentality. 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.

4.5.1.3 TPM Organization

The organizational structure for TPM implementation is mainly based on the TPM pillars shown in Figure 4.39.

TPM starts with the 5S's. Problems cannot be clearly seen when the workplace is unorganized. Cleaning and organizing the workplace helps the team to discover problems. Making problems visible is the first step for improvement. The following table lists the 5S's to be implemented to achieve the effective TPM organization.

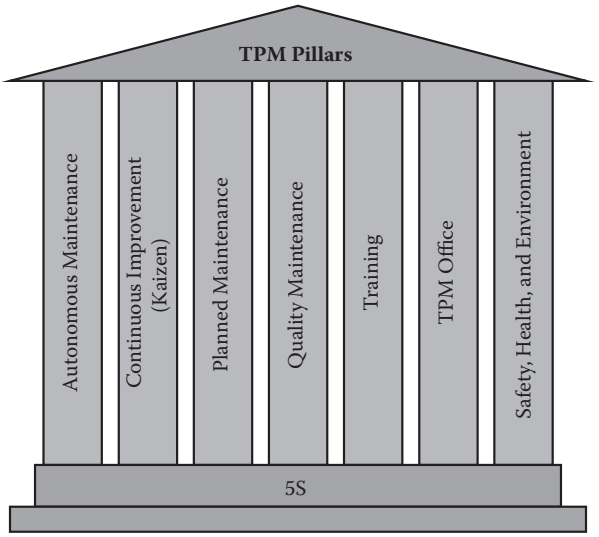


FIGURE 4.39
TPM pillars.

Japanese Term	English Translation
Seiri	Organization
Seiton	Tidiness
Seiso	Cleaning
Seiketsu	Standardization
Shitsuke	Discipline

Seiri (organization). This means sorting and organizing the items as critical, important, frequently used items. Critical items should be kept for use nearby, and items that are not be used in the near future should be stored in some place. For this step, the worth of the item should be decided based on utility and not cost. As a result of this step, the search time is reduced and item availability is improved.

Seiton (tidiness). The concept here is that each item must have a place and only one place. The items should be placed back after usage at the same place. To identify items easily, nameplates and colored tags have to be used. Vertical racks can be used for this purpose, and heavy items occupy the bottom position in the racks.

Seiso (cleaning). This involves cleaning the workplace, which must be free of grease, oil, waste, scrap, etc. No loosely hanging wires or oil leakage from machines.

Seiketsu (standardization). Employees have to meet together to discuss and decide on standards for keeping the workplace, machines, and pathways neat and clean. These standards are implemented for the whole organization, tested, and inspected.

Seitsuke (discipline). Considering the 5S's as a way of life and bringing about self-discipline among the employees of the organization. This includes wearing badges, following work procedures, punctuality, dedication to the organization, etc.

From a cultural point of view TPM pursues the changement of the old and bureaucratic attitude based on the statement that "I operate, and you fix, I fix, and you design, I design, and you operate" to a state where people say: "We are all responsible for our equipment, our plant, and our future." In this regard the success of this methodology is heavily dependent on cultural change of the people involved in the project.

The TPM goals of zero accidents, minimum life cycle cost, zero unplanned downtime, zero speed losses, zero defects, and zero waste can be pursued only if the culture that supports this methodology becomes a

way of life for all the teams (working and management teams) that play a strategic role in the project. Productivity and overall plant efficiency (OPE) increase, customer complaints and manufacturing costs reduction, and improved customer satisfaction can be achieved only if, first, a real cultural and then organizational change takes place within the company.

4.5.2 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. The emphasis on continuous improvement is the ultimate test of a world-class organization. A company may achieve a temporary advantage over its competitors by adopting a particular innovative product or process design, and it may appear initially that it has achieved parity with those other companies that truly compete through their manufacturing capability. But if this new design or facility comes to be regarded as a goal in itself, if the organization does not immediately begin experimenting and trying new things, the advantage is soon lost. Different world-class manufacturing experts suggest continual and rapid improvement as an overriding goal for world-class manufacturing. The word *kaizen* means gradual and never-ending improvement, doing "little things" better, setting and achieving ever-higher standards; this is the key for a continuous competitive success. Companies that are pursuing world-class status may take different paths that in turn require different precepts. There are four dominant principles, of which these companies may choose one or more.

1. Just in time (JIT). The JIT principle focuses on the elimination of waste, with *waste* defined as anything other than the minimum amount of equipment, materials, parts, space, and workers' time that is absolutely essential to add value to the product.

2. Total quality control (TQC). Under the TQC principle, everyone in the organization must be involved in improving the product's quality to meet customer needs. The emphasis is placed on defect prevention rather than defect detection and development of an attitude of "do it right the first time."
3. Total productive maintenance (TPM). With the TPM principle, machines and equipment are maintained so often and so thoroughly that they rarely break down or badly perform during a production run.
4. Computer-integrated manufacturing (CIM). CIM involves the integration of the company's operations from design, production, and distribution to after-sales service and support in the field through the use of computer and information technologies.

Figure 4.40 identifies the main steps to be implemented in a manufacturing company, starting from the first WCM step, which can assess the actual status of the equipment and production practices, up to the final step, which pursues a consolidation of the zero defects philosophy.

4.5.3 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.[1] 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 a 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, etc.

Modern machines are normally equipped with online measuring devices that are used where critical component breakdown can produce serious effects on process reliability and product safety. Success in TQMain is

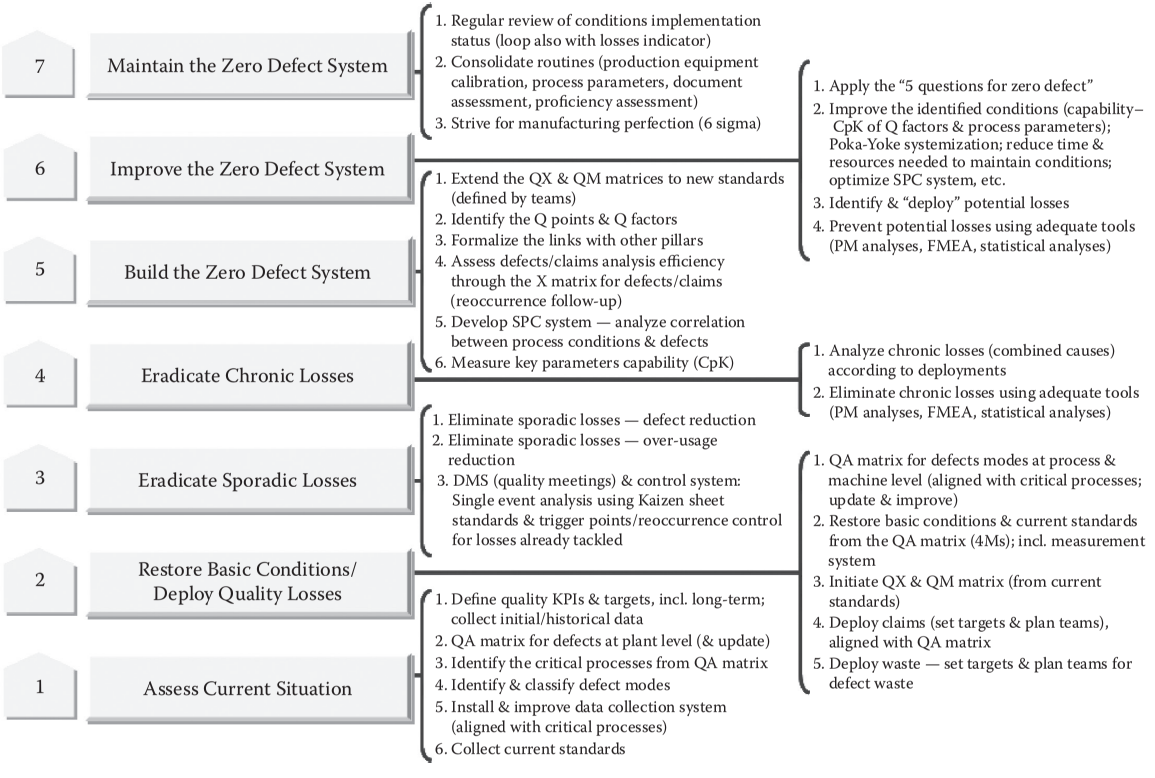


FIGURE 4.40
Main WCM steps. (From Tetra Pak Training Department, Training material on WCM, 2002.)

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 downtime), speed (actual production rate/theoretical production rate), and quality (1 – proportion defective).

$$\text{OEE} = A.\eta.(1 - p_d)$$

where A is the time loss due to equipment downtime, η is the time loss due to speed reduction, and 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 OPEs for different processes. The formula used is

$$\text{OPE} = \{1 - N_S/\mu T\} \,.\, \{1 - (n_m/\mu_m + t_r)/t_o\} \,.\, \{1 - (n_f + n_c + n_s)/n\}$$

where OPE = {1 – No stoppages/Repair rate × Loading time} × {1 – (No minor stoppages/Minor repair rate + Time lost to reduced speed operation)/Operating time} × {1 – (Defectives made just after stoppages + Defectives made when process was in control + Defectives due to assignable QC causes)/Total no. made}.

TQMain also recognizes 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.[51] To illustrate this, Al-Najjar devised the TQMain football, as shown in Figure 4.41.

4.5.4 Terotechnology Principles

The terotechnology model comes from the work done by the British government, and develops feedback criteria coming from quality gurus. Figure 4.42 shows the basic idea that expands upon the data collection, analysis, and schedule optimization that should occur during the operation phase, and emphasizes the need for failure modes effect and critical analysis (FMECA), testing new designs, and training operators and maintainers. The originators of terotechnology, led by Dennis Parker (1970), did not specifically mention optimization as such, but they did advise the revision of schedules as a result of experience. Since sensitivity of the cost

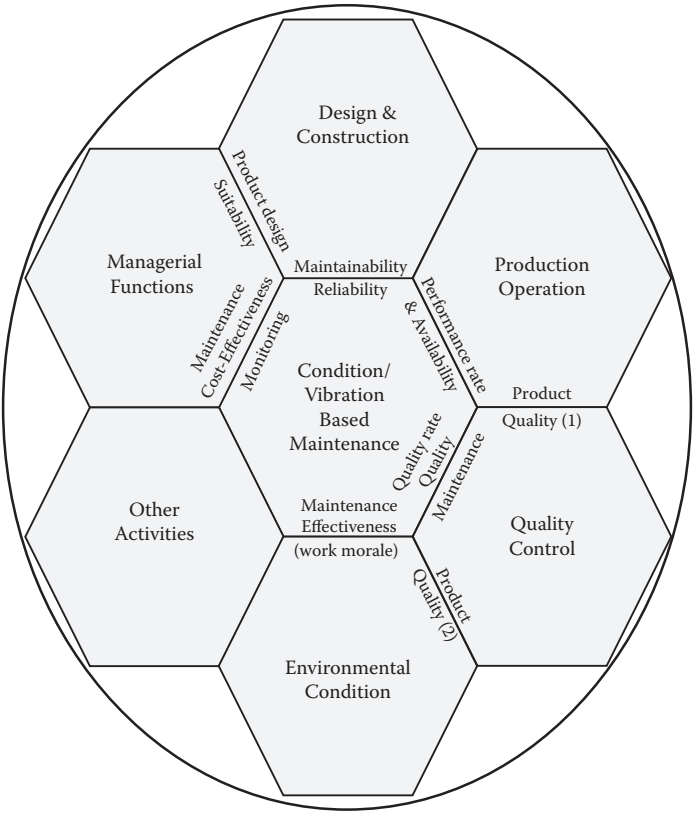


FIGURE 4.41
The TQMain football.

rate to the PM interval is very difficult to judge without data and calculation, feedback loops are very important to enable PM optimization and equipment design improvements.

Terotechnology, moving from life cycle cost (LCC) to life cycle profit (LCP), allows the maintenance function to be seen as contributing to profits rather than just spending money. To welcome 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 instance, to supply detailed and unambiguous information to feed the mathematical models and other decision-guiding calculations.

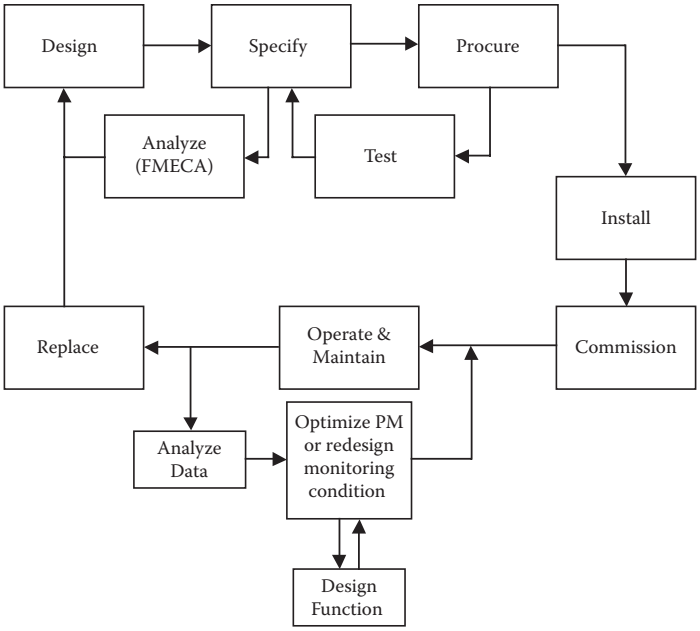


FIGURE 4.42
Terotechnology maintenance model. (From Al-Najjar, B., Presentation—Terotechnology [Systemekonomi], available at http://solescandinavia.org/pdfdokument/18-1%20Basim1.pdf.)

Figure 4.43 shows the different economical indicators, such as loss of revenues, due to equipment 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.
- Indirect maintenance costs. Indirect maintenance costs are all the costs generated by insufficient or lack of maintenance (losses, wastes, etc.). Lack of maintenance affects 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 4.44 identifies the area where an optimum cost balance can be found (between direct and indirect maintenance costs).

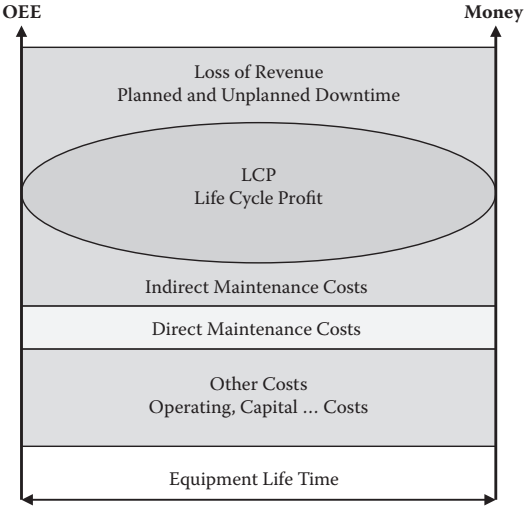


FIGURE 4.43
Life cycle profit (LCP).

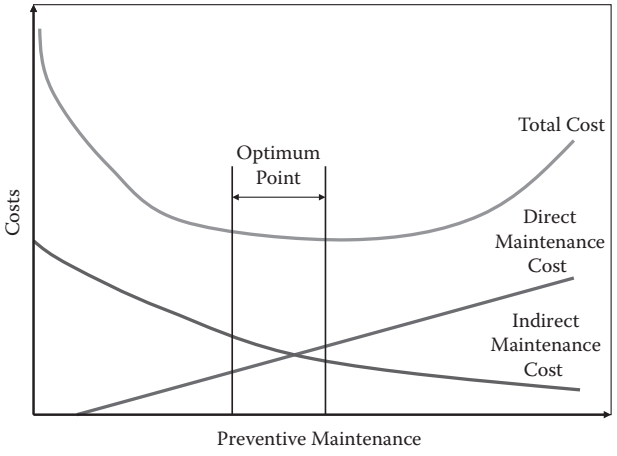


FIGURE 4.44
Maintenance costs.

Figure 4.45 shows the total costs described in Figure 4.44 and loss of revenue. The inflection point of the total cost curve represents the optimum balance between maintenance costs and unavailability losses. As availability approaches 100%, total costs increase exponentially, possibly beyond market value. That point shows that the incremental cost to run the packaging line at higher availabilities is greater than the associated increase in incremental revenue.

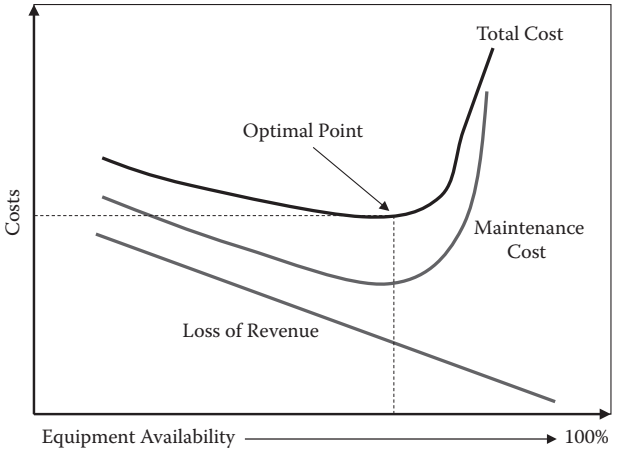


FIGURE 4.45
Total cost vs. availability.

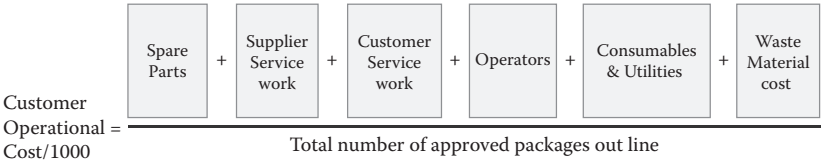


FIGURE 4.46
Producer operational cost per thousand packages produced. (From Tetra Pak Training Department, Training material on TPMS, 1999.)

The operational cost for a thousand packages produced can be calculated as shown in Figure 4.46.

The scope of this indicator is to gather all the operational costs (spare parts, service work carried out by external suppliers and internal staff, salary for operators, consumables, utilities and services, waste of material) to identify the cost to produce every single filled container.

4.6 CONCLUSION

In this chapter, a critical study of some reliability principles, product safety, and maintenance engineering techniques has been carried out to underline their value and contribution in defining the maintenance design and implementation 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 food industry equipment. 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 food 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 the food industry. Some of the factors that could partially or totally prevent the effective implementation of maintenance procedures have been examined to guide us toward the model that enables implementation effectiveness for the food industry 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. The critical study of these techniques emphasizes weaknesses and strength points together with opportunities and threats. Two critical areas need to be carefully managed to build up the maintenance design and implementation process:

- The selection of the team used to carry out the activities involved in the design and implementation phases
- The selection of principles and techniques, and their integration and implementation in the food industry environment

5

Critical Review of Condition Monitoring (CM) Techniques

5.1 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 types 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 of as a cost-effective insurance policy for critical food packaging line parameters or components.[10] Although very few machine builders incorporate condition monitoring as a standard, the equipment used for the food industry in general should incorporate monitoring systems of critical parameters, such as those linked with machine sterilization or package integrity. The different types of sensors available make a vital contribution to the reliability improvement of products and processes. The automated production lines, in the food and beverage industries, normally benefit from the use of different kinds of sensors to monitor critical parameters both online or on request.

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

- Benefits of online monitoring systems
- Condition monitoring systems available in the market
- Added value provided by different applications
- How each application can contribute to improve safety and reliability of food production lines

This chapter highlights benefits and limits derived from the use of modern monitoring systems and their contributions to increase maintenance effectiveness.

5.2 ONLINE MONITORING SYSTEMS

An online monitoring system makes use of a device that constantly monitors a specific magnitude or movement to convert one type of energy or physical parameter 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 is needed for a monitoring system, compared to what can be accomplished with a portable or protection monitoring system. Figure 5.1 provides a good representation of where surveillance monitoring traditionally lies in a vibration measurement condition monitoring program.

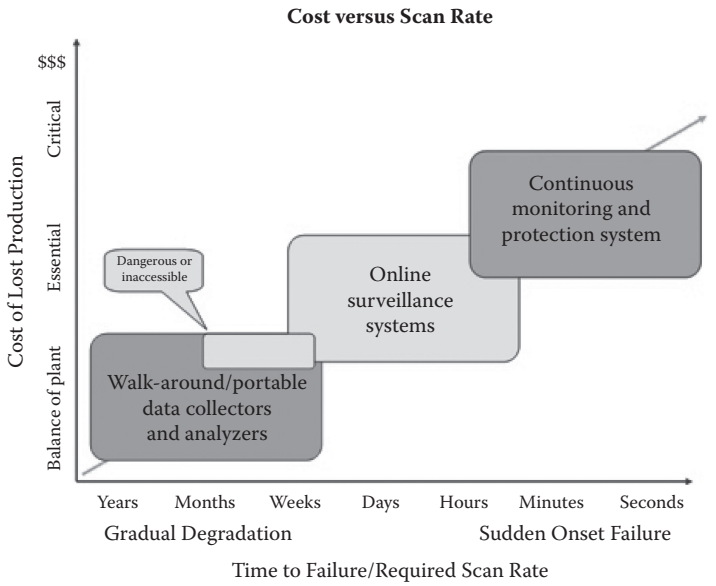


FIGURE 5.1
Cost vs. scan rate in the surveillance monitoring. (From Predictive Maintenance and Condition Monitoring Management, April 2009, available at http://reliabilityweb.com/ee-assets/my-uploads/art09/tips_09.)

As the graph in Figure 5.1 indicates, online surveillance systems are most commonly employed on equipment that is costly to maintain and equipment that negatively influences 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 online surveillance system is the most cost-effective approach. Surveillance systems have found widespread use for dangerous and inaccessible locations or for critical equipment functions.

5.2.1 Continuous Condition Monitoring and Remote Diagnosis

A PC condition monitoring is a powerfully driven hardware interface for monitoring system status in critical environments. The system directly accesses the condition of the electronic boards and systems, and delivers those data to equipment operators or service technicians as user-defined text messages (GSM SMS), e-mails, or on-site visual signals. This system can directly access sensors and hardware data via its own automation. The potentiality of the continuous remote monitoring is such that it can replace 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.[11] Along with alerts via text message or e-mail, condition data can also be displayed via standard web browsers at the equipment operator's or system technician's workstation. Some examples of measurable condition parameters are time, temperature, concentration of fluids, and monitoring of processors, as well as supply voltages and other physical parameters.

This system stores condition statistics (minimum, maximum, and average values for any given data acquisition) allowing long-term diagnosis. Data can be exported in different formats for analysis in other applications or on other sites. While some plants require remote web-based monitoring, others prefer their data to be collected and analyzed by their on-site workforce. The major difference between the centralization approach and the "divide and conquer" strategy is that despite each plant deploying its own customized condition monitoring program, all of the reporting can be set up to be delivered in a centralized web-based portal to share the figures with a global community.

Complex projects foresee the global analysis of critical factors leading to the program's overall success, including work culture changes and training issues. While training staff on new predictive maintenance (PdM) technologies and data collection techniques for the vibration, infrared, thermography, tribology, and motor testing programs requires dedication, knowledge, and experience, to achieve a change in a company's culture can prove to be more challenging.

5.3 ANALYSIS OF 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 a software system analyzes the data, removing the need for interpretation periodically by an expert technician. 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 in faulty condition or not. Manufacturers are increasingly facing tough competition, as well as pressure to maximize cost with minimum investment. A condition monitoring sensor is a tool to help to achieve this, as the maintenance personnel's work is started as the sensor signals highlight a problem.

- A 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. In the past, it was a manual process, involving a vibration expert examining details of the machine, including speed and bearing geometry, before using this information to determine critical frequencies that require monitoring.
- 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. The study of tribology is commonly

applied in bearing design, but extends into almost all other aspects of modern technology. 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.

Below is 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. Online motor circuit analysis

Electrical components:

1. Infrared thermography
2. Oil analysis
3. Airborne and structure-borne ultrasonic
4. Vibration analysis
5. Offline 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 briefly examined below to highlight the main features and benefits, and limitations from their use in predictive and preventive maintenance.

5.3.1 Infrared (IR) Thermography

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 nm, 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.[12] As a result, thermography's extensive use can historically be ascribed to the military and security services. Thermal imaging has many uses. Electrical inspections can reveal some potential problems that usually go undetected until a serious breakdown occurs. At the same time, electricity leaks or improperly balanced loads increase electricity peak loads, and thus may result in unnecessary charges. An IR inspection on electrical components can detect various problems in the electrical cabinet, like poor connections, short circuits, overloads, and load imbalances, as shown in Figure 5.2. The figure shows a high-temperature difference on two main phase fuses (about 20°C above the left fuse). This is a result of 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. Overall,

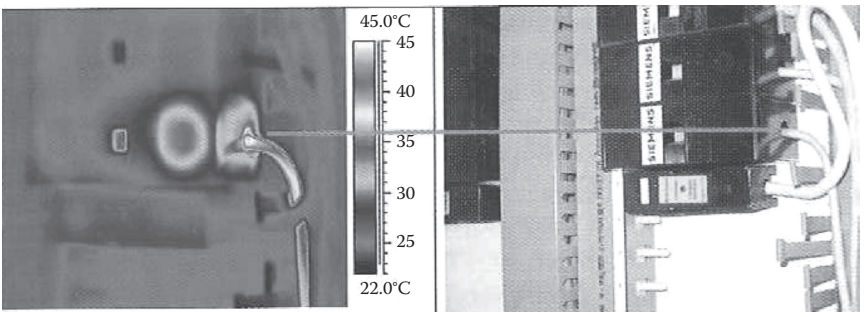


FIGURE 5.2
IR inspection showing high temperature on an electrical connection. (From *FLIR R&D Handbook*, 2009, available at http://www.flir.com.)

electrical inspections provide very useful inside information that can be of primary importance in identifying potentially hazardous problems.

Focusing on specific components will significantly cut down the time required for a short building audit. Various issues with the definition of critical equipment parts are available, but can be found through hazard analysis and critical control points (HACCP) and failure modes effect and critical analysis (FMECA) application. This system can also be used to set up an effective electrical preventive maintenance (EPM) program.

5.3.1.1 Problems and Limitations of Infrared Thermography

In general, the interpretation of IR thermographs from electrical inspections needs 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 centimeters 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 previously undetected problem may have caused local damage that is not visible any more (i.e., possible melting may have caused rejoining of the contacts). This may result in a temporary temperature drop. The magnitude of the problem may be a more serious one that 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 the 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 on critical equipment and components, and on 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 the 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 the liquid food 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.

5.3.2 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. For example, the motion of a tuning fork, the reed in a woodwind instrument or harmonica, or the cone of a loudspeaker is desirable vibration, necessary for the correct functioning of different devices. 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 bearings, in operation are typically unwanted. Such vibrations can be caused by imbalances in the rotating parts, uneven friction, the meshing of gear teeth, etc. The studies of sound and vibration are closely related. Sounds, or pressure waves, are generated by vibrating structures; these pressure waves can also induce the vibration of structures. Hence, when trying to reduce noise, it is often a problem in trying to reduce vibration.

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.[27] Different types of sensors are used to measure 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 to take them
- How to take them

Sensors are placed at strategic points on the machinery to monitor the machine's condition.

5.3.2.1 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.[38] 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 toward the surface until a piece of metal breaks away to leave a small pit or spall.

5.3.2.2 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.

5.3.2.2.1 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. Some band-pass filtering techniques have also been proposed in the time domain.

5.3.2.2.2 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 a resonant frequency of 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.

5.3.2.2.3 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 narrow-band 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.[38]

5.3.2.2.4 Use of Noncontact Transducers

The literature discussed so far has mostly considered casing-mounted transducers. Some researchers have also used noncontact 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 involves not only 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.

5.3.3 Oil Analysis (Tribology)

Tribology plays an important role in manufacturing. In metal-forming operations, friction increases tool wear and the power required to work a piece. This results in increased costs due to more frequent tool replacement, loss of tolerance as tool dimensions shift, and greater forces being required to shape a piece. 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 centers for tribology were created in the UK.[57] 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 the following:

- Abrasion
- Adhesion (friction)
- Erosion
- Corrosion

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

5.3.3.1 Application of Dempster–Shafer (D–S) Theory to Oil Monitoring

In order to solve the problem of diagnosing wear in a tribosystem, the evidence theory of Dempster–Shafer is applied to realize the information fusion of multiparameters in oil monitoring. Two diesel engine models 8NVD-48A were monitored under running conditions by the oil monitoring methods, such as:

- Spectrometric oil analysis
- Ferrographic monitoring
- Infrared spectrum analysis
- Oil quality testing

According to the results from the monitoring experiment, the types of worn parts and the relevant monitoring characteristic are summarized.[59] The worn parts mainly pointed to scoring, seizure, and corrosion between the piston (or piston ring) and cylinder liner; scratching, seizure, spalling, and corrosion in the gear; and pitting, seizure, and fatigue in the gear. Tribological failures result from tribological behavior of rubbing pairs in a machine, and the failure is different with different machines because the applied load, operation environment, working temperature, lubricating condition, and operation period are changeable. Oil monitoring can be used to diagnose the tribological failures. Generally, through a sample from a lubricating system in a monitored machine, the tribological failures are identified due to quality changes of the lubricants and wear particle analysis. For the tribological failure, we often refer to two types of

faults: wear of parts and lubricant deterioration. We should establish some mathematics model that can be used to classify these two aspects of the tribological failures.

5.3.3.2 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 of engine, the wear types of parts and their features from oil monitoring are summarized and listed in Table 5.1.

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

5.4 SENSORS FOR CONTINUOUS MONITORING OF CRITICAL PARAMETERS

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

5.4.1 Conductivity Sensor for Cleaning in Place (CIP) Applications

In the aseptic liquid food industry, equipment cleaning represents a mandatory prerequisite before equipment sterilization. The concentration of fluids used to clean the product pipes needs to be monitored, and the conductivity sensor is the component for CIP 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 (0.1 μS/cm to

TABLE 5.1

Wear Types on Parts and Information Characteristics in Oil Monitoring

Number	Part Name	Failure Type	Information Characteristics from Different Oil Monitors			
			SOA	Ferrographic Monitoring	Infrared	Quality
1	Piston and 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 elements	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 increases	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 particles		
		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

Source: Yan, X.P. et al., *Tribology International*, 38(10), 879–886, 2005.

500 mS/cm), and this technology is particularly reliable since it eliminates the polarization phenomenon normally observed with two-electrode sensors.

5.4.2 Continuous Monitoring of Liquids

In the liquid food industry different liquids are used for different proposals:

- Hydrogen peroxide as a sterilization medium to sterilize packaging material, container, and piping surfaces in contact with food product
- Cooling water to cool down the sterile air through the 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 the human factor, to increase equipment reliability and product safety through automatic control of critical parameters.

5.4.2.1 Continuous Monitoring of Liquid Concentration

A new spectrophotometric technique allows the continuous monitoring of liquid concentration, enabling us to put under control hydrogen peroxide, which is one of the most important process sterilization variables, largely used to sterilize the packaging material and containers in the aseptic liquid food industry. Inline spectroscopy also offers continuous monitoring of the concentration of liquids that consist 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 determine concentrations quickly and precisely and can even be used in hazardous area applications.

5.4.2.2 Water pH Control

The pH of water, used in food industry equipment, represents an important parameter to monitor to avoid problems with filters or mechanical

parts. Corrosion of parts or cooling inefficiency, due to water residue, 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 result in equipment downtime. To overcome problems of pH control contamination, in conventional pH monitoring systems, a solution using proportional hydroxide dosing and the implementation of an auto-clean pH controller has recently been introduced. Sensor electrodes can be user specified to ensure measurement reliability and maximum sensor lifetime.

5.4.2.3 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 equipment used in the 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 United States, 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 alert the equipment operator through a suitable alarm signal.

5.4.3 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 some food production rooms can 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 setup of an electronic nose consists of an array of chemical sensors; an airflow system, which switches the reference air and the tested air; a signal analysis technique; and a presentation unit. The main sensor principles are also the most frequently used techniques

for gas sensors. To increase the complexity of the odor system, an array of mixed sensing principles is often designed, consisting of different types of sensors, in order to create differences in operating temperatures, flow conditions, and sensor response times.[21] The next decade should see the development of electronic nose systems in a variety of applications to increase the quality of life as well as for monitoring environmental information. This means that artificial human-related sensor systems could become everyday tools for estimation of our own personal condition as well as that of the environment.

5.5 CONCLUSION

This chapter dealt with condition monitoring of critical equipment variables to avoid component degradation and then equipment failure. Equipment critical functions can be monitored using different types of sensors to detect deterioration and avoid unplanned stoppages and further damage. Some of the equipment used in the food industry, through specific sensors, automatically monitors critical parameters such as those linked with equipment sterilization or container 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 deliver data to equipment operators and service technicians. Condition monitoring represents a reliable tool to monitor equipment conditions, usually carried out on a regular basis by expert technicians. The sensors used monitor machine condition and analyze data, 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 in 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 sensors represent 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 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.

6

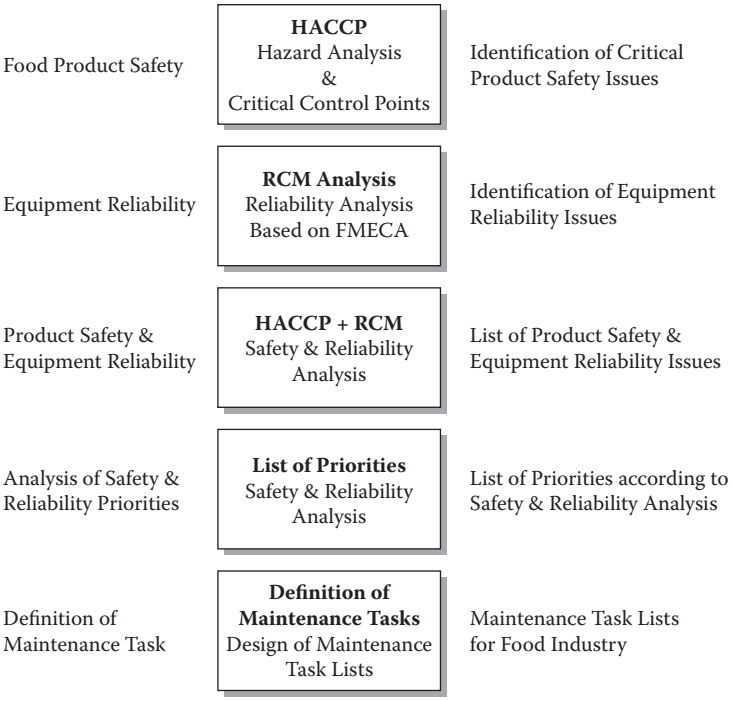
Process to Design Maintenance Procedures for the Food Industry

6.1 INTRODUCTION

Following the analysis of the engineering techniques and quality methodologies examined, this chapter describes the different phases of the process identified to design maintenance procedures (task lists) for the food industry. The reliability concepts and safety and maintenance engineering techniques presented in Chapter 4 have been compared and contrasted to identify the principles to be used in building up the maintenance design process. To reach food product safety and equipment reliability, the maintenance process designed integrates quality and engineering techniques. Hereafter, the process blocks, highlighting the main maintenance design phases, are listed in sequential order.

Since this chapter examines the content of the maintenance process to design maintenance task lists for food packaging lines, the contribution of each phase is briefly described below:

1. The first phase has been thought to identify and address all conceivable critical control points (CCPs) that could influence food product safety and quality. The application of safety methodologies such as hazard analysis and critical control points (HACCP) and hazard operability (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. This activity is considered of primary importance to avoid heavy consequences on food product safety and then on consumers' health.



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 different equipment functions, and relative solutions. The maintenance engineering techniques that can give a better contribution to the design phase have been selected and integrated to put equipment reliability criticalities under control.
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 food product safety through the identification of global risk priority numbers, which result from the analysis of food safety and equipment reliability risks.
4. In the fourth phase, a list of maintenance priorities has been developed according to the scoring resulting from previous analysis. This activity, recorded in a specific form, represents a summary of the work done in the previous phases and produces a document that list the items according to their criticality.

FIGURE 6.1
The maintenance design process goals.

5. The fifth phase enables the design team to develop maintenance task lists able to control food packaging line criticalities dependent on product safety and equipment reliability.

As shown in Figure 6.1, 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 and safety together with equipment reliability issues to produce an outcome able to address every criticality existing in the food packaging line.

The scope of this process is to give a strong contribution to identifying all critical process variables that have a negative impact on product safety and equipment reliability, and the maintenance solutions to put these criticalities under control.

6.2 STEP 1: APPLICATION OF HACCP METHODOLOGY

As a first step, through HACCP methodology, all critical machine parts and components (CCPs) that have negative effects on food product safety will be identified, together with the risks associated with different failure modes. HACCP identifies and assesses 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 hazards, are examined to devise critical control limits and preventive maintenance countermeasures. As shown in Figure 6.2, at this design stage,

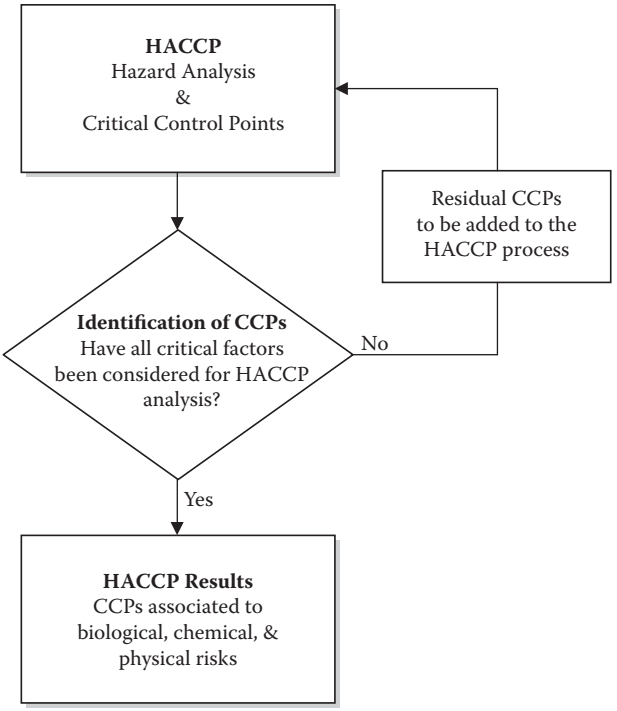


FIGURE 6.2
HACCP process blocks.

all conceivable product safety hazards coming from equipment operation and human behavior must be identified to ensure that equipment, human (operational), and external (service and utilities) criticalities that have a direct impact on biological, chemical, and physical modifications of food products packed are listed and examined.

To achieve this result, HACCP, HAZOP methodologies, and good manufacturing practices (GMPs), 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 normally being used to ensure that catastrophic incidents (like the ones that happened in the 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).

Application of HACCP and HAZOP techniques will enable identification of the following critical issues:

- Food safety hazards, directly connected to the equipment/system/component functions
- CCPs in the equipment operation (pre- and post-production, production, and cleaning)
- 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

Before starting with the main HACCP activities, the flow diagram of the process or equipment, on which the HACCP plan is to be based, must be prepared. As an example, Figure 6.3 shows the aseptic processing of milk in an ultra-high-temperature (UHT) sterilization process (continuous).

In this process, milk is preheated, sterilized, and cooled in the aseptic processing equipment, then is aseptically packed, through filling equipment,

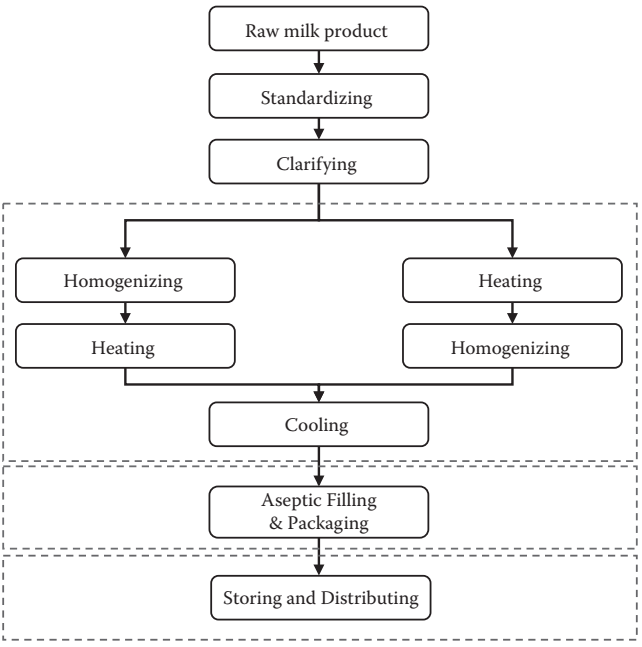


FIGURE 6.3
Flow diagram for production of UHT milk.

to be at the end stored and distributed. The first two square dotted lines identify the equipment where the main CCPs are concentrated, while the bottom square dotted line identifies the less meaningful critical area. Sterilization takes place either by indirect heating or by direct heating (through steam injection) in the aseptic processing equipment, and product packaging in the aseptic filling equipment. Since the equipment owing to the area covered by the two boxes, representing processing and packaging, is the most critical of this process, to avoid underestimating the existing CCP, it is suggested to draw other flow diagrams representing the main equipment subgroups.

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 as follows:

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) for each hazard.
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.

Below the HACCP activities are described, as an example, with regard to the aseptic liquid food environment.

6.2.1 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 to be considered during this activity are the following:

- Biological hazards. These types of food hazard represent the greatest risk for illness or injury. The categories taken into consideration by biological hazards include bacteria, fungi, viruses, and parasites, and these should be used and considered when performing

a HACCP hazard analysis. Foodborne pathogens fall into two general categories:

- Food intoxications
- Foodborne infections

In food intoxications, the levels of a biological contaminant in a food are high enough to produce a toxin that, upon ingestion, causes illness. Cases of food intoxication usually involve wrong pasteurization temperature of the product, causing bacterial growth that leads to harmful levels of toxins. Foodborne illness, caused by toxins, may produce dangerous consequences for human health. In foodborne infections, a person ingests a sufficient quantity of a living biological agent to become sick. The two basic types of foodborne infection are

1. Invasive infections. The biological agent penetrates cells and tissues in the host to cause illness.
2. Toxic infections. The biological agent takes up residence in the intestinal walls, producing a toxin that causes illness.

Bacteria represent the largest category of potential food hazards. Bacterial hazards are further categorized according to their growth and survival characteristics. With regard to growth temperature, bacteria are generally categorized as follows:

- Thermophiles: Optimum growth at relatively high temperatures (45°C or above).
- Mesophiles: Optimum growth range of 20–45°C.
- Psychrotrophs: Mesophiles that will grow under refrigeration conditions.

The majority of foodborne pathogens are mesophiles. Some foodborne pathogens are psychrotrophs and capable of growing slowly under refrigeration.

Spore-forming bacteria are highly resistant to heat treatment and other food processes. If subjected to insufficient heat treatment, spore-forming bacteria may germinate (as vegetative cells) and grow, depending upon conditions.

Biological hazards include all potential sources of food product contamination (direct and indirect) dependent on equipment functions and operational tasks. These can include

1. Cleaning errors, depending on equipment or human factors
2. Lack of package integrity
3. Lack of equipment sterilization
4. Wrong equipment settings

5. Lack of or wrong preventive maintenance procedures
6. Equipment operator mistakes

These are some of the critical areas normally taken under consideration as potential sources for biological hazard.

- Chemical hazards. Chemicals to be taken under consideration include, among the others, cleaning compounds, sterilization agents, and mineral oil used in hydraulic and lubrication circuits. Hydrogen peroxide, normally used to sterilize the packaging material or containers, could come in contact with the food product if critical conditions of some equipment components are not monitored and inspected through maintenance activities. Alkaline and acid solutions, used to clean equipment and piping, could come in contact with food product pumped to the filling machines if the seals of product valves are not working correctly. Mineral oil could accidentally come in contact with packaging materials or containers if all conceivable sources of potential contamination are not properly discovered and examined.
- Physical hazards. These include objects or parts, such as metal fragments and 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 equipment normally uses a variable amount of moving parts, the analysis must consider and examine all critical components and operations to avoid solid fragments (metals, plastics, glass and other materials) from coming into contact with the food product packed.

The team involved in this activity must consider all conceivable sources of equipment and operational hazards, and list them under the three (biological, chemical, and physical) main areas of risk. Figure 6.4 shows the main equipment functions to pack aseptic liquid food through aseptic filling equipment. The main criticalities are associated with the following equipment functions:

1. The packaging material (PM) sterilization
2. The aseptic transfer of the sterile liquid food
3. The creation of a sterile surrounding to form, fill, seal, and cut the filled packages/containers

Figure 6.5 shows how to gain a global view of the aseptic filler hazards linking the different circuits to the program phases of the equipment. To be able to identify the aseptic filler HACCP hazards, the block diagram of the main circuits has been deployed, showing

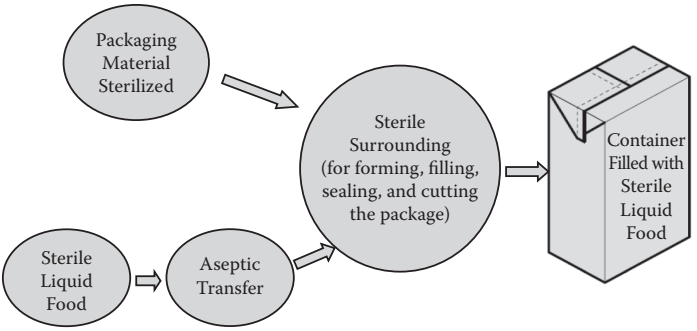


FIGURE 6.4
Critical operations of an aseptic filler.

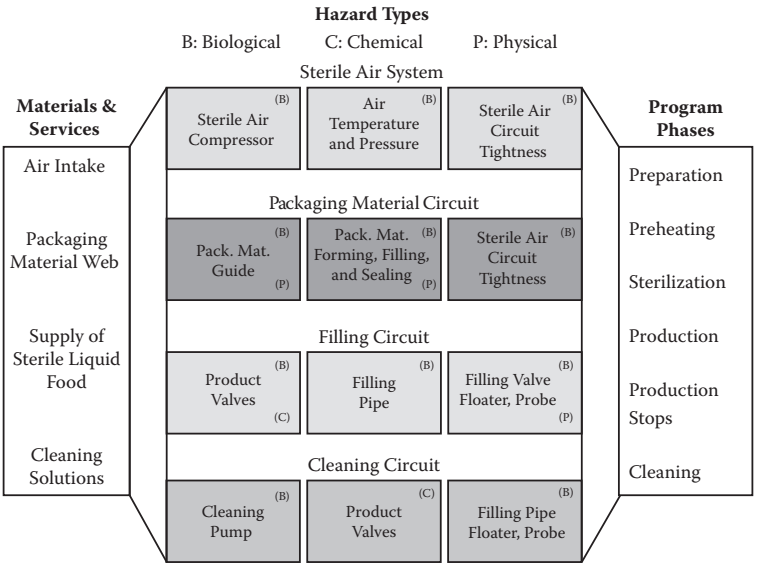


FIGURE 6.5
List of the aseptic filler hazard components, functions, and parameters.

some of the critical phases. The letter B (biological), C (chemical), and P (physical) indicate the hazard types we have on each block.

Block diagrams or more complex algorithm states of machine (ASMs) and other visual techniques should be used to identify the following:

- Equipment circuits
- Equipment parts or components
- Critical parameters that may determine food safety hazards

- Program and equipment conditions that may produce food safety hazards
- The type of hazard that may result from wrong operating conditions

This exercise must be developed by a multidisciplinary team composed of quality experts, maintenance specialists, equipment suppliers, and operational representatives.

The activities to be carried out at this step should enable us to display the equipment circuits and the program phases in a way that helps the team to identify all potential food safety hazards. The question to answer at this stage is: "What type of hazards might we have in the equipment or in the unit under consideration in this phase of the program?"

The hazards to be considered must also regard those related to the production of packaging material or container used to pack liquid or solid food. If during the process to produce packaging material or container we discover criticalities that can produce a food safety hazard, we need to identify, define, and put these under control. Typical biological hazards may depend on the following:

- Material thickness
- Container sealing
- Material stiffness
- Material permeability to oxygen, light, and gases
- Material cleanliness
- Hermetic characteristics of materials and sealing

All hazards that may be produced by the equipment, operational activities, or materials used must be identified to be examined in the HACCP process.

6.2.2 Activity 2: Establishment of Critical Control Points (CCPs)

After all hazards have been identified, a CCP decision tree module, shown in Figure 4.6, is used to determine whether a CCP can be identified for each 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 an acceptable or minimal levels. CCPs are mainly concentrated on equipment groups and parts used to:

- Pasteurize or sterilize food products
- Sterilize filling equipment, containers, and packaging materials

- Form, fill, seal, and cut packaging materials or containers
- Clean product circuits (piping and valves) in contact with food products

The module shown in Figure 4.6 is a typical HACCP decision tree normally used for establishing CCPs. If a CCP refers to an operational activity carried out by the equipment operator, this has to be clearly described and specific critical practices identified. Critical operational procedures need to be described without gray areas: adjustment, registrations, and mechanical settings must be verified and possibly monitored through automatic monitoring devices.

A modified, and complementary, decision tree has been produced in Figure 6.6 to help maintenance designers go through the different steps of the HACCP plan.

Following the flow diagram of Figure 6.3, showing a production process for UHT milk, some of the critical parameters to control in the aseptic processing are as follows:

- Product flow rate
- Product pressure
- Correct functioning of flow diversion valve
- Cleanliness of the equipment before starting the sterilization treatment
- Heat exchangers used to cool the sterilized milk to room temperature

These devices should be free from pinholes and with sufficient overpressure on the sterile side to prevent any milk contamination.

To be able to identify the existing CCPs with the relative hazards, the aseptic process of a dairy can be represented through drawings, process flows, and block diagrams.

These tools should enable us to display the critical groups, parts, and components and potential interaction among them. Figure 6.7 shows an example regarding a production process for fresh and UHT milk. The picture shows the different blocks of the process and the drawings of main circuits/equipment, to help the team identify the critical control points and parts that need to be examined together with the components considered critical.

To pursue the identification of critical parameters, processes, equipment, components, and parts of the food packaging line under examination, it is strongly suggested to deploy as many as possible of the processes, circuits, and components to identify parameters, processes, and parts linked to food safety hazards. Figure 6.8 shows a direct sterilization system and

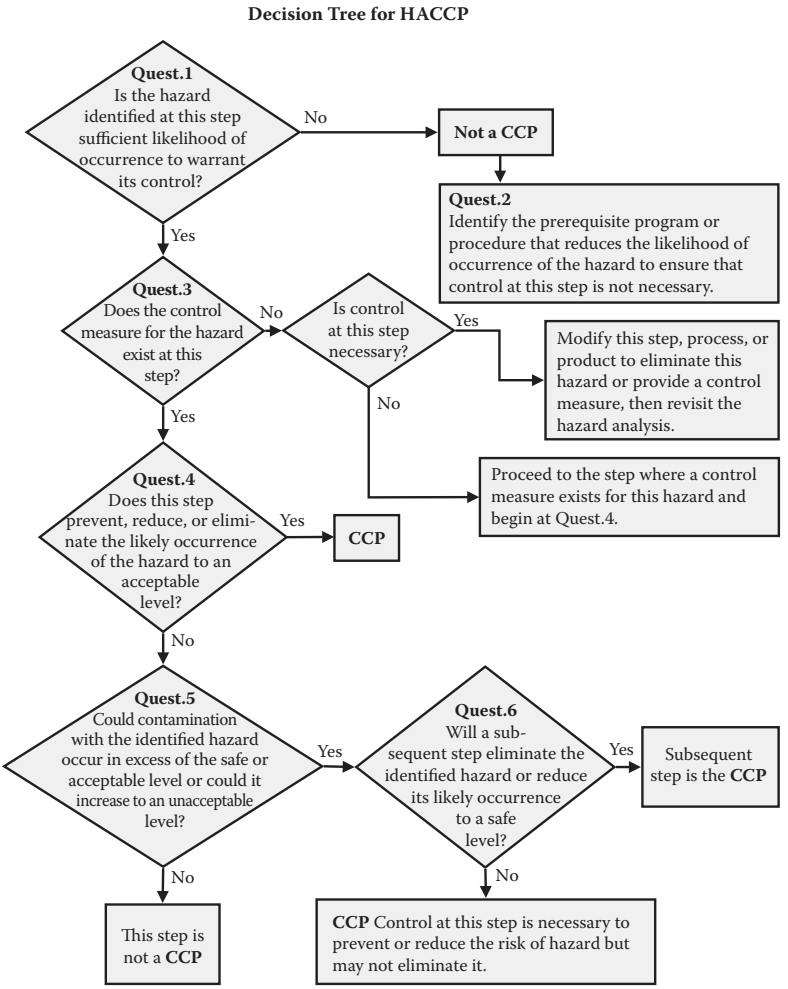


FIGURE 6.6
Decision tree to identify CCPs.

circuit containing a steam injector that need to be examined to identify the link existing between critical parts and food safety hazards.

Sterilized milk is introduced, under aseptic conditions, into sterilized containers (flexible or rigid). Containers could be partially or totally formed in the filling equipment, sterilized by hydrogen peroxide (H_2O_2), UV light, or other means, before or after forming the pack, filled, and sealed by heat (induction heating or ultrasonic systems). The environment within the filling section of the aseptic filler must be sterile, with sterile air with a slight overpressure.

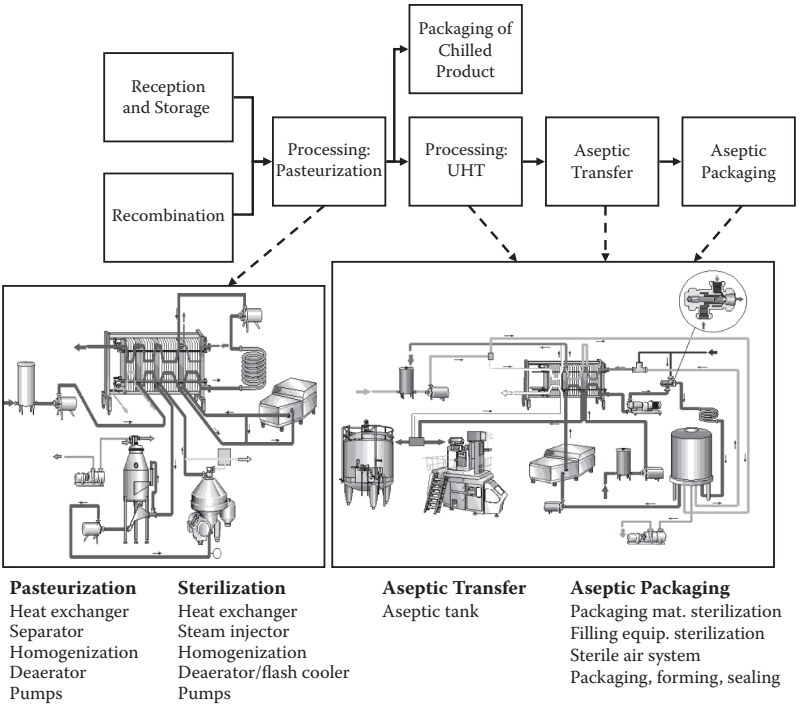


FIGURE 6.7
Flow diagram of fresh and UHT milk process with critical components.

Some of the critical parts and parameters worthy of special attention in the aseptic filler are as follows:

- Aseptic filling valves and pipes
- Forming section
- Sealing system (induction heating elements or ultrasonic horns)
- Cutting unit
- Sterile air overpressure in the aseptic chamber
- Sterilization system of packaging material or container

Figure 6.9 shows one important critical control point to be taken into consideration in an aseptic filler, that is, packaging material sterilization. As we see in the figure, to carry out this activity effectively, it is important to identify:

1. The critical parameters to put under control. These normally are the physical magnitudes, such as concentration, temperature, pressure, and so on, that need to be to put under control.

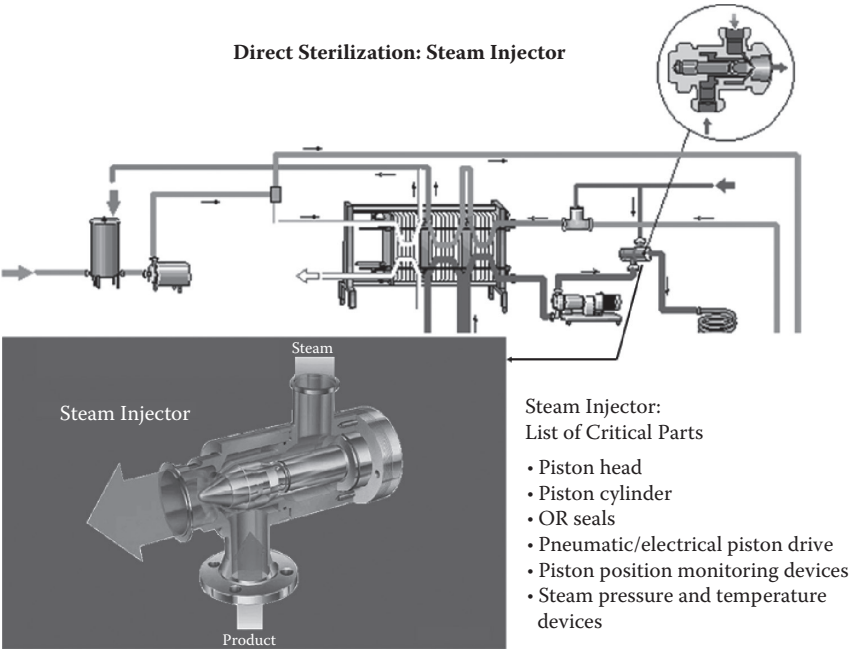


FIGURE 6.8
Direct sterilization circuit with steam injector.

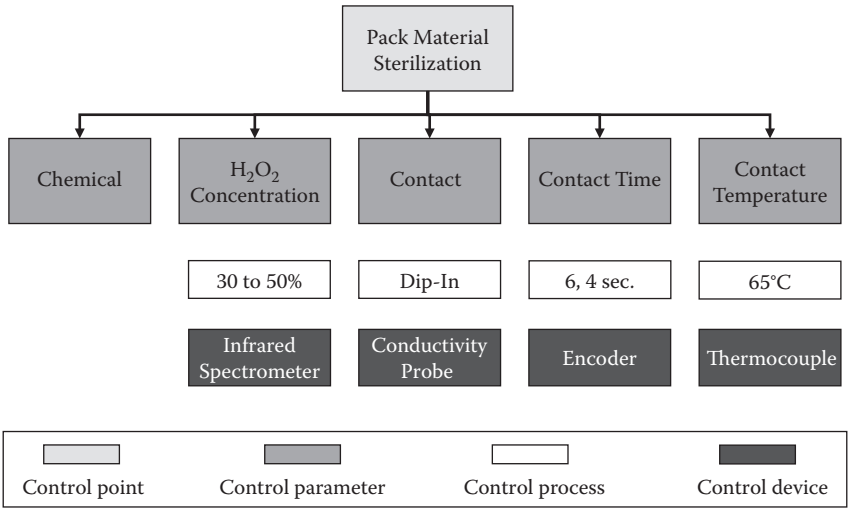


FIGURE 6.9
Packaging material sterilization with control point and parameters.

2. The critical control processes. These refer to the processes used to control critical parameters.

Packaging material sterilization is a chemical process that has five control parameters regarding:

1. The chemical used
2. The concentration of chemical
3. The contact between the chemical and packaging material used
4. The contact time of the chemical with the packaging material
5. The temperature of chemical used

The quality of chemical used is normally controlled by the supplier, but periodical, parallel quality control can be carried out by the user to ensure the conformity of the product to declared standards and specifications. The concentration is measured by either the equipment operator or laboratory staff. In the latest equipment this parameter is controlled by an automatic system that provides a continuous and inline measurement of hydrogen peroxide. The hydrogen peroxide concentration can be measured over the entire pH range, over a wide concentration range of hydrogen peroxide, and with high precision and accuracy (errors less than 1%). The system consists of a bypass in which some electrodes are positioned and electronically controlled. The hydrogen peroxide consumption is measured by the equipment operators or by automatic systems. If the packaging material is dipped in the H_2O_2 bath, contact time depends on equipment design (length of bath and equipment speed). Since this process is a constant, this parameter does not need to be measured by the equipment operator. If packaging material is sterilized through a spraying system, combined with a UV light, then a sensor should ensure its contact time and radiation exposure. The systems used to control process parameters must be examined to identify criticalities for which maintenance procedures need to be designed.

Table 6.1 shows a hazard analysis of some critical components located in the aseptic filler. Sealing inductors and pressure rubbers are used in the package sealing section of the filler, and they have to be regarded as highly critical components for biological hazard. Once a CCP has been identified, the hazard analysis table allows us to define its characteristic through a proper definition of risks, control measures available, monitoring procedures, and corrective actions.

If, according to Figure 6.5, we carry out the analysis of a sterile air system, which can be considered one of the most important critical control points

TABLE 6.1

Hazard Analysis Summary

Step	Critical Control Points (CCPs)	Identify Specific Potential Hazards Biological (B) Chemical (C) Physical (P)	Control Measures	Critical Limits for Each CCP	Monitoring Procedure(s)			Corrective Action(s)	Verification	Record(s)
					What	Frequency	Who			
Production	Sealing inductors	(B) Vegetative pathogens	(a) Mechanical (b) Electrical	Mechanical (see mechanical manual, p. x) Electrical (see electrical manual, p. x)	(a) Mechanical integrity (b) Electrical parameters	(a) Daily (b) Weekly	(a) Equipment operator (b) Technical specialist	(a) Replacement (b) Replacement of worn-out parts	Electrical deviation: ±10% Mechanical deviation: +5%/−7%	Mechanical and electrical parameters Corrective actions Adjustments
Production	Pressure rubbers	(B) Vegetative pathogens	Mechanical	See operator manual, p. x	Mechanical integrity Stiffness	Daily	Equipment operator	Replacement	Thickness Stiffness	Thickness and stiffness measures Corrective actions
Production	Floater	(P) Mechanical parts in the product	Mechanical	See mechanical manual, p. x	Mechanical wear (diameter)	Weekly	Equipment operator	Replacement	Mechanical deviation	Corrective actions

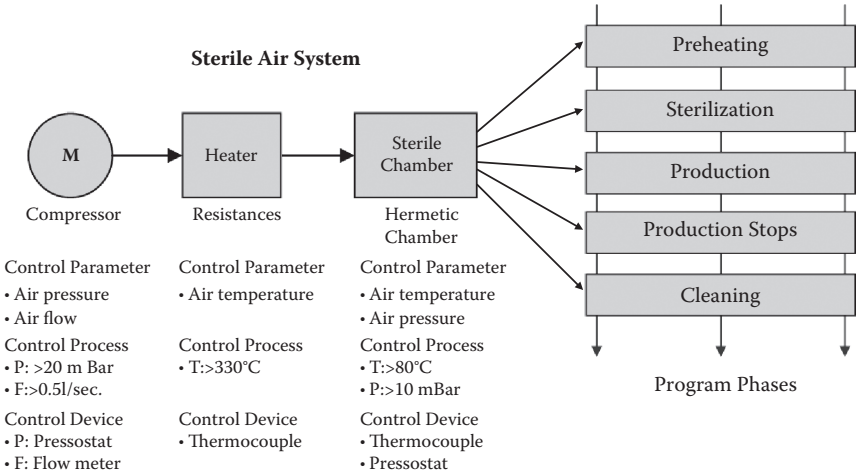


FIGURE 6.10
Critical control parameters and processes of a sterile air system.

of an aseptic filler, Figure 6.10 shows a simple way to identify control parameters and processes.

First, a block diagram, highlighting the sequence of operations or functions linked together, is to be identified and drawn. Second, describe the physical sequence of events: as we see above, a compressor produces a positive air pressure that is directly conveyed to the superheater to be sterilized at an average temperature of 360°C. The sterile air is directed into the sterile chamber where operations such as filling, forming, and sealing of the container take place. Third, the critical physical parameters involved in the sequence of functions need to be identified: they are pressure, flow, and air temperature. These parameters are controlled by the critical process tools needed to monitor their performance and any out of control. Fourth, the critical issues related to different parameters and control processes must be examined not in a static way, but relating them to the various phases of the program of the machine, thus identifying the variability of processes and values to be checked.

At this stage of the maintenance design process it is very important to identify CCPs, critical working parameters, and critical control processes to define potential hazards linked to functions and operations of components and critical parts whose failure may produce food safety hazards. Following the suggested path, the team involved in this activity should acquire a deeper understanding of the links existing between critical components and parts and food safety hazards.

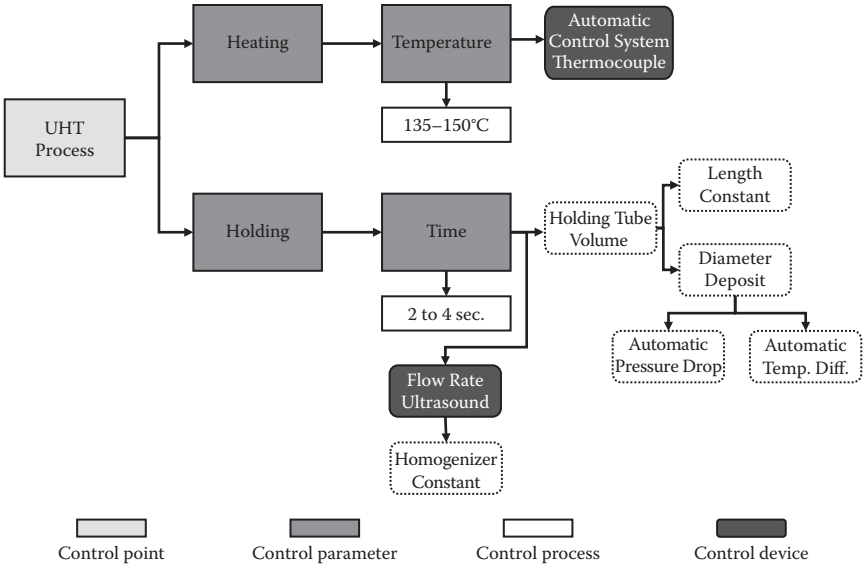


FIGURE 6.11
UHT critical control point with parameters and processes.

The critical control points and parameters of the ultra-high-temperature (UHT) process are shown in Figure 6.11. In the manufacturing of long-life liquid food products, the UHT process represents a critical control point. Sterilization temperature is normally automatically controlled through thermocouples or sensors that supply a feedback loop signal to a regulating system working on two or more limit comparators. Pressure drop and temperature differential should be registered and connected to a safe guardian system.

The sterilization process of an aseptic transfer line is normally controlled, monitored, and the temperature recorded through a sensor placed in the product return line.

In the storing and distribution area, particular attention is to be dedicated to equipment and parts that handle semirigid and flexible containers. Semirigid packs are less robust than rigid containers, such as metal cans, and therefore require extra care during storage and distribution. Equipment used to move filled containers, or to transport filled carton trays, assemble different packing patterns on the pallets, and distribute the final product, must be carefully examined to identify CCPs.

This operation of the process cannot be underestimated: equipment used to form packing pattern and pallet layers needs to be carefully examined to identify CCPs and critical parameters to put under control.

FIGURE 6.12
Pallets of product stored and transported by forklift.

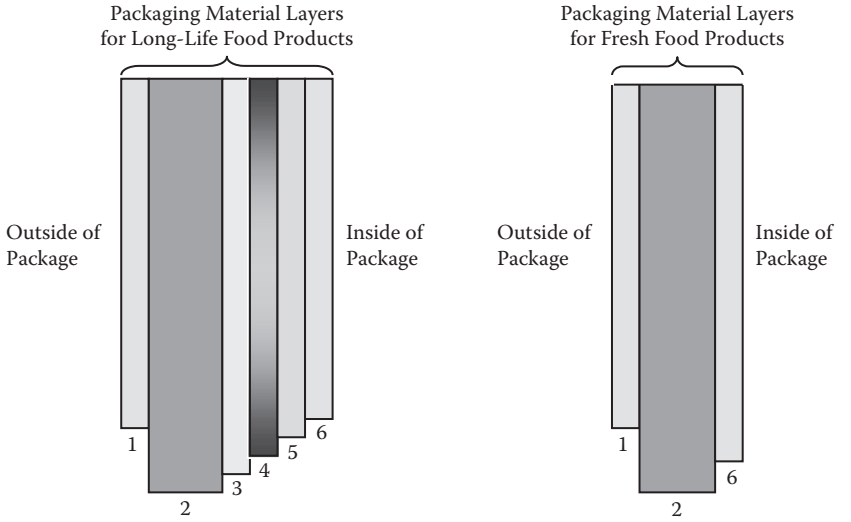
As shown in Figure 6.12, simple operations like transportation and storage can hide insidious threats that need to be known and managed. Maintenance can play a fundamental role in managing critical variables, depending on human control.

Since retailers reject the whole pallet of product if a single package is blown due to a small micro-pinhole or leakage, this activity is worthy of higher consideration.

Normally, the packaging material used to pack liquid food is multilayer, and the different combinations of layers determine the type of material to be used for one liquid food or another. In the packaging material manufacturing process, different materials (paperboard, polyethylene, and aluminum) are combined through various process phases; existing critical control points must be identified and properly defined. The raw materials, originally supplied by reels and granulates, are laminated, stretched, and pressed to form a unique sandwich to protect food goodness against external environment agents. Figure 6.13 shows the packaging material layers normally used for long-life and fresh liquid food products.

If we consider the packaging material manufacturing process shown in Figure 6.14, the typical CCPs to be taken into serious consideration are the following:

1. Creasing deepness: Avoids small cracks in packaging material.
2. Polyethylene extrusion coating temperature and pressure: Allows an even distribution of plastic.
3. Surface inspection: Avoids polyethylene lamination disconformities.



1. **Outside Plastic Layer**: Protects the package against external humidity
2. **Paperboard and Printing Layer**: Strengthens the package and offers a good printing surface
3. **Lamination Layer**: Plastic layer which allows paperboard to stick to the aluminium (Al) foil
4. **Aluminium Foil Layer**: Protects food product against oxygen and light
5. **Internal Coating Layer**: To offer adhesion between the Al foil and the inner plastic layer
6. **Inner Plastic Layer**: Prevents the liquid food contents from soaking into the material

FIGURE 6.13
Packaging material layers for long life and fresh liquid food products.

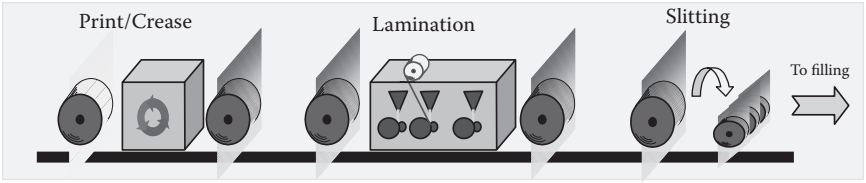


FIGURE 6.14
The packaging material manufacturing process. (From Tetra Pak Training Department, Training material on WCM, 2002.)

Figure 6.15 shows the polyethylene extrusion coating that represents a critical control point normally controlled through automatic means. The manufacturing criticalities and the control parameters and processes to be put under control in this manufacturing process can produce problems on

- Package stability
- Packaging material permeability

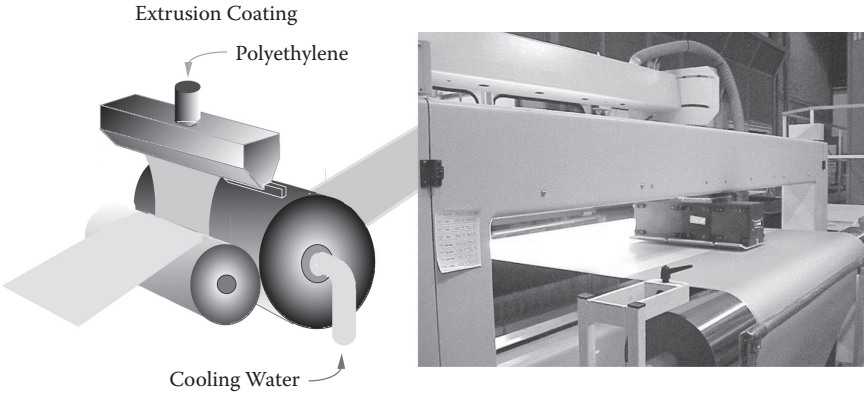


FIGURE 6.15
Polyethylene extrusion coating and control.

- Package sealing
- Microbiological stability of food products

These manufacturing critical control points all interact with package characteristics that prevent food product from light, oxygen, and external agents that produce food biological hazard.

Figure 6.16 has been realized to summarize the activities done in this phase:

1. A critical control point is normally associated with one or more hazard types.
2. For each CCP, the critical control parameters that define the dynamic functions of the point must be found (these normally are physical magnitudes for which control processes need to be established). The question to answer at this stage is: Which parameter allows us to control this CCP?
3. For each critical control parameter, different critical control processes must be found (these normally are the processes used to control the physical parameters). The question to answer at this stage is: What process allows us to control this parameter?
4. For each critical control process, different parts and components must be used to control each critical process (these normally are parts, components, groups, or instruments used to control the process). The question to answer at this stage is: How do we control this process?

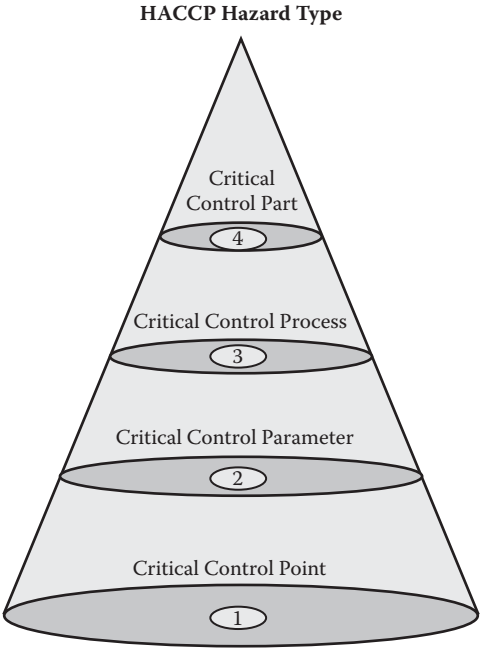


FIGURE 6.16
Process to define the content of each CCP.

At the end, as soon as we identify the critical parameters, processes, and parts, we are in a position to design the maintenance activities to control critical parts and components.

6.2.3 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- or post-production or production practices that are directly linked to biological, chemical, and physical hazards, potential deviations need to be identified together with critical limits. Just as an example, in an aseptic filling equipment we can consider the following applications:

1. Hydrogen peroxide (H_2O_2) concentration. This is normally the chemical used to sterilize packaging material, product pipes, and

the environment where package forming, filling, sealing, and cutting take place. Since H_2O_2 concentration is the most critical parameter to control, a lowest concentration measure must be carefully defined to avoid biological hazard as a consequence of low sterilization efficiency. On the other side, a highest concentration threshold must also be defined to avoid the risk of explosion due to chemical reactions following H_2O_2 contaminations due to contact with some metal fragments (impurities).

2. Sterile air pressure. Sterile air overpressure is normally used in the aseptic chamber of a filler to avoid contaminants entering in the aseptic area from an external environment. This critical parameter needs to be measured together with the airflow, generated by the sterile air compressor, to ensure that the air compressor is working properly and that no flow reductions or chamber tightness problems are causing food biological hazards. To avoid sterilization problems and biological hazards, the lowest limits for air pressure and flow must be defined for systems working with transducers located in different parts of the circuit. Sterile air temperature can be considered a complementary parameter to be measured together with airflow and pressure to monitor the effectiveness of a sterile air system. If the air temperature and airflow are going below the lower limit thresholds, this could be due to air compressor problems or to the formation of calcium residues in the heating exchanger producing airflow drop.
3. Package sealing. Package sealing represents a critical food packaging line operation that needs to be monitored to avoid package leaks or pinholes and then biological hazards.

   When the sealing element is an inductor, an ultrasonic horn, or a resistive bar, the parameters to monitor could be electrical, such as voltage, current, phase angle, frequency, and so on, but more important, mechanical, to ensure that electrical power generated is correctly applied and distributed to the packaging material. For this reason, to be sure that the electrical power applied to a sealing element has been properly transferred to the packaging material, pressure and thermal transducers can be used to measure both temperature and pressure developed by the sealing elements on the packaging material. Automatic monitoring of the lowest critical limits will prevent package integrity problems that may produce biological hazards.

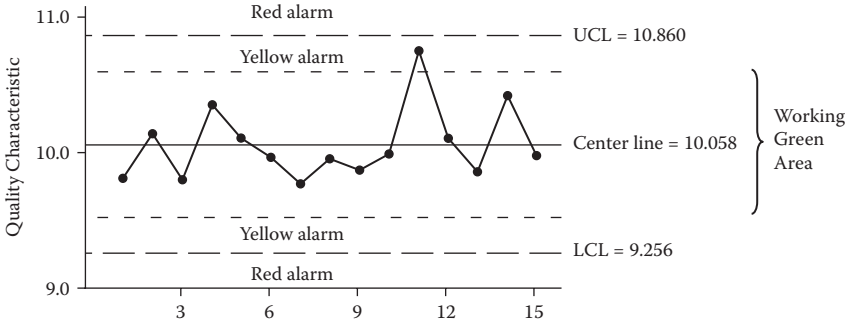


FIGURE 6.17
Critical limits for a CCP.

According to Figure 6.17, depending on criticality under examination, we can have different limit thresholds: upper control limit (UCL) and lower control limit (LCL). Beyond these limits, a red alarm identifies a critical measure that will cause a food safety hazard, while a yellow alarm identifies a value that requires a corrective action intended to reestablish the standard operating conditions within the green limits.

Since heat treatment (pasteurization and sterilization) produces changes in the food constituents (fat, protein, minerals, vitamins, etc.), equipment used to pasteurize and sterilize can use different temperature thresholds to control quality and safety deviations of food product processed.

A food container must protect its product and preserve food quality value (vitamins, proteins, and sensorial parameters) along the way to the consumer. Liquid food tends to be perishable, so a clean nontainting package is a mandatory and essential requisite. The container must also protect food from mechanical shock, light, and oxygen. Milk, for instance, is a sensitive product; exposure to daylight or artificial light destroys some of its essential vitamins and has a deleterious effect on product taste. This means that the equipment that controls the storage conditions of sensible foods must have threshold values intended to preserve food from quality deterioration. Other food products, such as flavored milk, contain flavoring substances or vitamins that are oxygen sensitive. The container must therefore exclude oxygen. Critical limits must be established in the equipment used to manufacture packaging materials or produce containers, to put under control critical variables that enable the container to protect food value. Critical limits must be established for flexible containers to control packaging material thickness and stiffness, which makes the material resistant to different forms of mechanical stress. Other critical

limits must be identified for polyethylene, aluminum, and paperboard layers to protect food product against leakages, atmospheric agents, and light. These all are critical manufacturing control points that must be identified and put under control during the manufacturing process. Laser, ultrasonic sensors and other online means must control physical manufacturing critical values to ensure that packaging material will preserve food quality along its whole shelf life. To avoid product deterioration, critical limits must be established for the application of barrier elements (aluminum, silicon oxide, and other means) to preserve sensitive food products in plastic or glass bottles, with a long nonrefrigerated shelf life.

Figure 6.18 shows a transversal profile of a polyethylene layer laminated on packaging material paperboard or on aluminum foil. Critical limits must be established to automatically control paperboard, polyethylene, and aluminum layers to avoid losing the barrier characteristics of materials against external agents such as oxygen, light, and living bacteria that could contaminate food products.

Establishment of manufacturing critical limits, regarding packaging materials and containers used to pack food products, represents a mandatory prerequisite to avoid supplying materials or containers out of specification that can cause food quality deterioration. Future food product nonconformities and troubleshooting can be avoided if critical limits of critical equipment parameters are clearly established in the manufacturing process of packaging materials and containers.

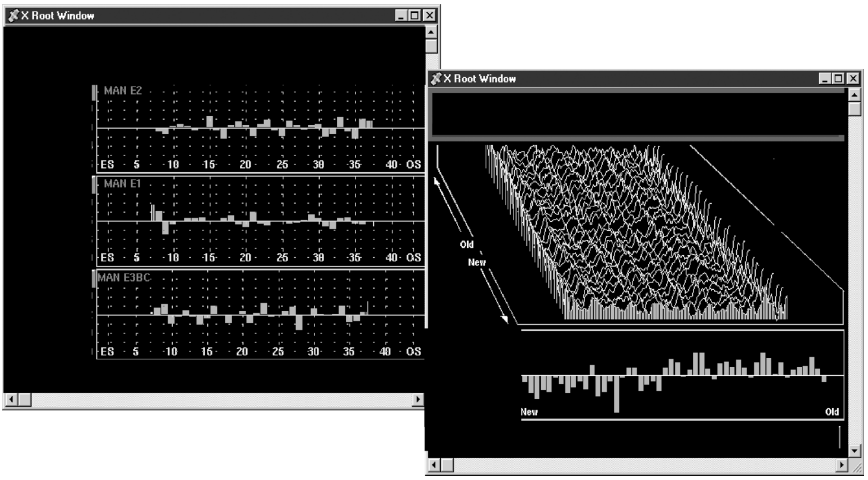


FIGURE 6.18
Transversal profile of polyethylene layer laminated on paperboard.

6.2.4 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 this hazard, optical systems can also be used to monitor critical operational practices or physical conditions of critical equipment parts.

Figure 6.19 shows some critical parameters of an aseptic filler; since the processes used to control critical parameters make use of automatic monitoring systems, we need to examine risks depending on lack of periodical calibration. Sometimes thermocouples, transducers, or systems used to transform a variation of a physical magnitude in a variation of voltage or electric current can show anomalies dependent on probes malfunctioning or on changes in the insulation between signal and ground. There are different critical conditions that need to be taken into consideration and put under maintenance control to avoid measures read by an automatic system being completely unreliable. Unsterility cases and food product safety problems are often dependent on lack of maintenance control on automatic devices used to monitor critical parameters like temperature, flow, and pressure.

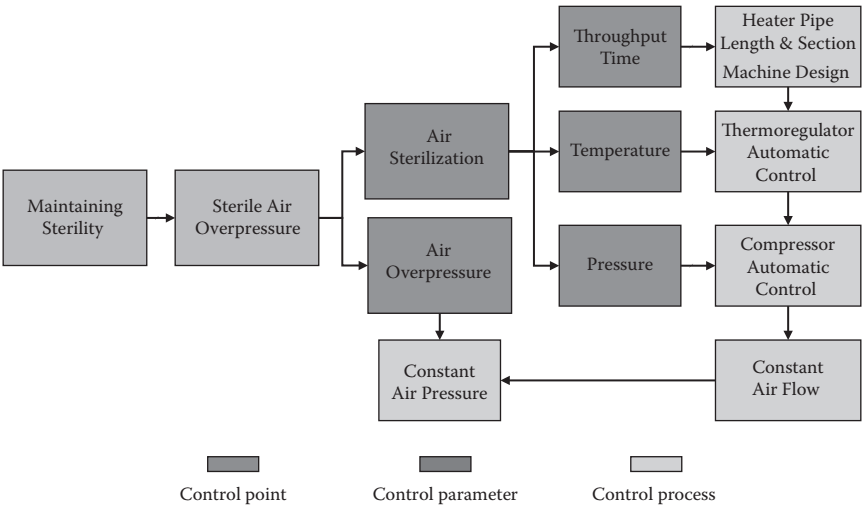


FIGURE 6.19
Control points, parameters, and processes of an aseptic filler.

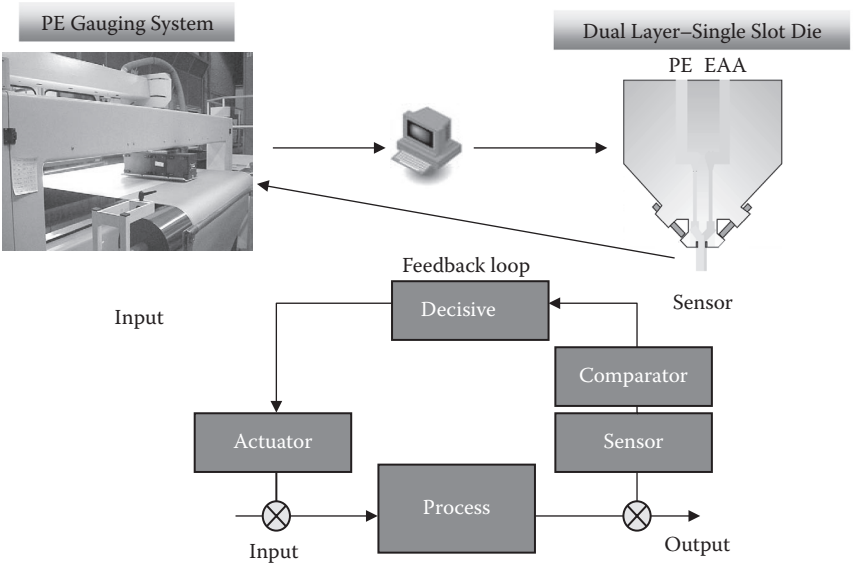


FIGURE 6.20
Automatic monitoring of polyethylene lamination process. (From Tetra Pak Training Department, Training material on WCM, 2002.)

Figure 6.20 shows an automatic monitoring system for packaging material manufacturing: it automatically controls CCP regarding the polyethylene lamination process. This system is based on a feedback loop that enables the sensor to measure the transversal profile of the polyethylene layer while packaging material is fed at the speed of 500 mt/min. If the value measured is outside of the limit comparators, then a decision to correct the extrusion coating system is carried out by the actuator. When anomalous values are recorded, a tracking system identifies the exact position for later correction.

6.2.5 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 be referred either to deviations regarding potential hazard or to loss of control at the specific CCP. Potential failure can be due to a deviation beyond the lowest upper limit, caused, for instance, by an anomalous vibration of a mechanical part used to form

the package. This phenomenon indicates that a corrective action is needed to avoid functional failure and then biological hazard. If the equipment function, automatically monitored, is particularly critical, the measure read by the transducer can be analyzed by software able to compare the incoming measure with the historical one to measure the deviation value.

6.2.6 Activity 6: Establishment of Verification Procedures

Procedures for verification must be established to ensure that the 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 analyses can be used to assess if the activities designed fulfill the safety targets identified for each CCP.

6.2.7 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 the HACCP plan, CCP monitoring records, a file with deviations, and preventive maintenance procedures, included in the checklists and checklist review. CCP monitoring records, resident on the computer, must be kept for a long time to allow the specialists, in case of unsterility, to discover the potential cause behind food contamination.

Application of the 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. Potential links between critical equipment functions and food safety hazards must be discovered at this step of the design process.

6.3 STEP 2: APPLICATION OF RELIABILITY-CENTERED MAINTENANCE (RCM)

Basically, the outcome from the first maintenance design step is the identification of criticalities associated with product safety and quality. After identification of CCPs (biological, chemical, and physical) linked

to equipment functions, parts, and operational practices, reliability-centered maintenance (RCM) can been used for the following reasons:

1. To make an analysis of the different failure modes and their effects on equipment operation: Application of the failure mode effect and critical analysis (FMECA) technique enables the identification of different priorities associated with different failure effects.
2. Furthermore, RCM supplies the right methodology to define the most effective maintenance approach to effectively manage food product safety and equipment reliability issues.

As shown in Figure 6.21, the RCM process should ensure that all types of failures and their effects are analyzed to design effective maintenance tasks for each failure type.

In implementing an RCM design program, it is strongly recommended that one system at a time is taken into consideration. It is also important to choose a single system and take it all the way through each step of

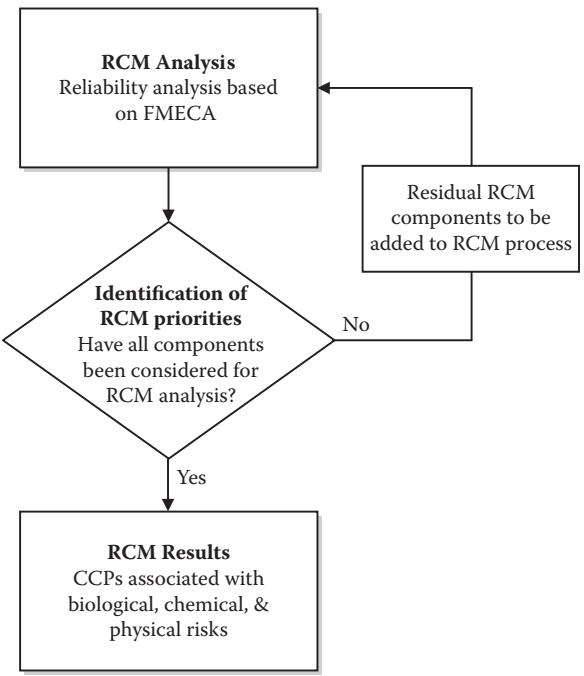


FIGURE 6.21
RCM process.

the RCM process before moving on to the next. The customized approach chosen includes the following activities:

1. System selection
2. Boundary definition and operational mode summary
3. Failure analysis (quantitative and 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

6.3.1 System Selection

According to the results of HACCP analysis, safety and health issues should determine the priorities in the selection of equipment systems and subsystems. The use of the failure reporting, analysis, and corrective action system (FRACAS) technique can provide a framework for controlling corrective action processes and then identifying the priorities in choosing equipment systems and subsystems. The FRACAS process, known also as DRACAS (data reporting, analysis, and corrective action system) or PRACA (problem reporting, analysis, and corrective action system), as well as a CA (corrective action) system, is a comprehensive closed-loop corrective action system that can collect, quantify, and control a wide range of incoming failure reports. These reports refer to information coming from activities such as test data, breakdown and unsterility data, or repair data. Data coming from field experience should also support HACCP analysis.

6.3.2 Boundary Definition and Operational Mode Summary

After identification of a machine system, as shown in Figure 6.22, groups and parts, directly linked to each subsystem, should be listed to define both component functions 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.

Figure 6.23 shows a few examples referred to as aseptic liquid food (ALF) fillers. Packaging and auxiliary materials, together with the liquid food product, previously sterilized by the processing equipment, represent two aseptic filler inputs that will be transformed in an output made by a tight container filled with sterile liquid food.

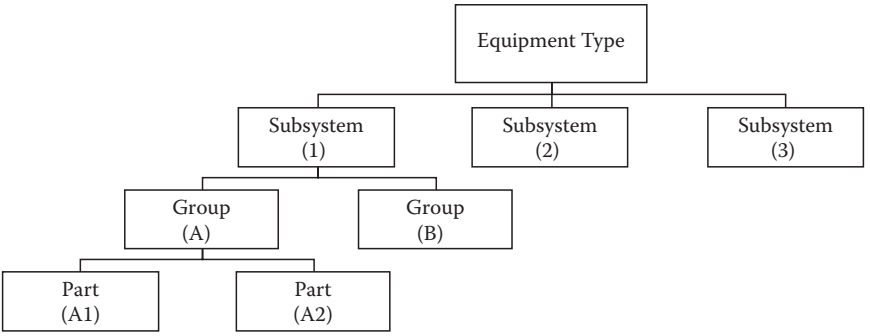


FIGURE 6.22
List of equipment subsystems, groups, and parts.

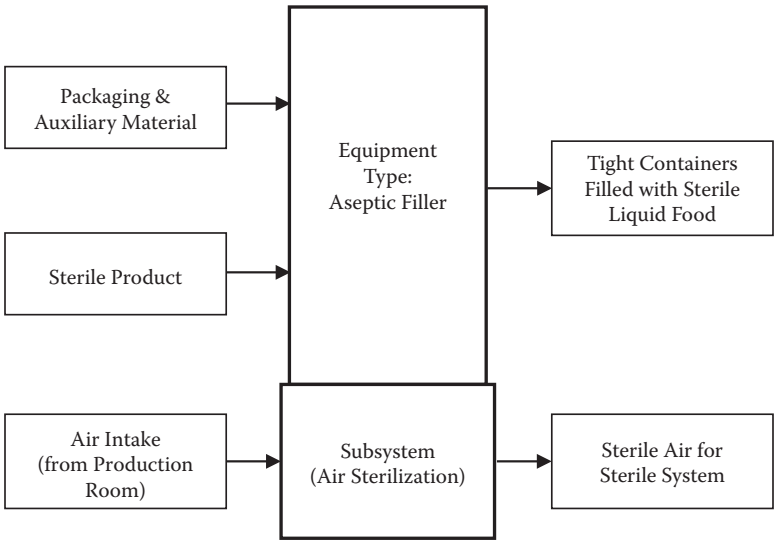


FIGURE 6.23
Transformation of inputs in outputs in an ALF filler.

A subsystem is, for instance, the sterile air system that sucks air from the external environment (input) and transforms it into sterile air (output). The sterile air is used inside the sterile system where operations such as package forming, filling, and sealing take place.

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 our maintenance program must support.

6.3.3 Failure Analysis

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

- Quantitative analysis of failures. First, as we saw in Section 4.4.3, 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 6.24, the different control limit thresholds used by SPC can weight each failure type (potential and functional) and 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 probability figures.

  The use of SPC will provide two basic pieces of information:

  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 *variables* monitored through condition monitoring,

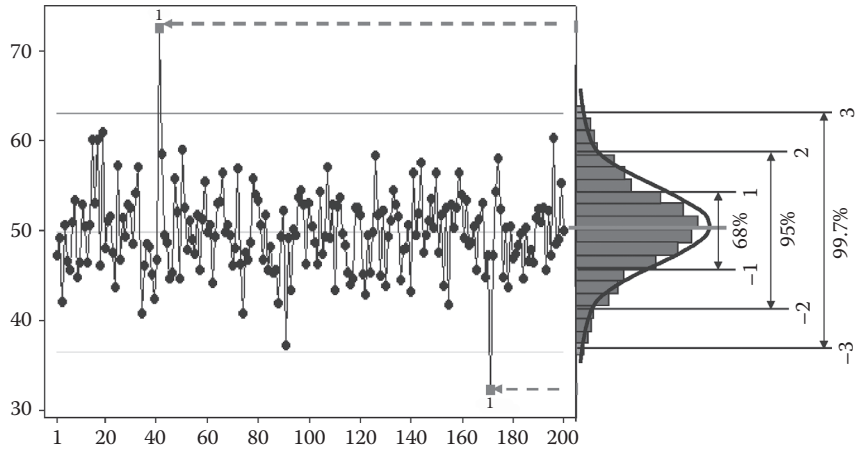


FIGURE 6.24
±3 Standard deviation warning lines on SPC chart.

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 that detect the special cause variation will be affected.

Control limits enable us to monitor the average time that elapses from installation of a new part to its potential failure. The components subject to wear that guide, form, and seal the packaging material should be manually or automatically checked to verify if their critical measures are operating within the control limits.

The air pressure and flow, to be monitored against different control limit thresholds, allows us to measure the working efficiency of components, such as the heat exchanger, the air compressor, and the whole system tightness. Different control limits are useful for measuring hydrogen peroxide concentration, cleaning solutions (alkaline, acid, and water for rinsing), speed temperature, and so on. HACCP analysis of identified parts or components, with specific food safety criticalities, is mandatory for defining critical limits and avoiding subjective evaluations. The identification of standard deviations for potential failures allows us to establish the component lifetime and study how to improve the conditional variables that enable us to improve the component lifetime. Normally we really want to have subgroups and parts with only common cause variation, so if other sources of variation are detected, the sources will be easily found instead of buried within the 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 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. Quantitative analysis is a mandatory step that provides objective information about the component lifetime for functional failures, and information on component degradation that leads to potential failure. Potential and functional failures can be reliably defined through monitoring devices associated with an SPC system.

- 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 have 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 following:
  - Links existing between causes and effects
  - Reasons behind each cause
  - Link existing between each cause and the global equipment and manufacturing context
  - Logical order of the events that produce a failure

6.3.3.1 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 nonconformance to system requirements leads to the identification of nonconformance 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. Section 4.4.5 shows figures and symbols used by the fault tree technique.

In Figure 6.25 a simple example applied to a bad package transversal sealing is shown to highlight how different causes behind a specific failure (potential or functional) can be linked together. The center row shows the real cause that produces this failure (failure and effect), and the lateral rows show the hidden causes or human errors. This technique allows us to link cause and effect in a logical order showing a global view of the dynamic of the events that produce critical failures. More complex trees can be developed with the logic gates OR and AND, other operators, and tools to combine the potential failure causes and the existing relationship among them.

After production of the tree that links 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,

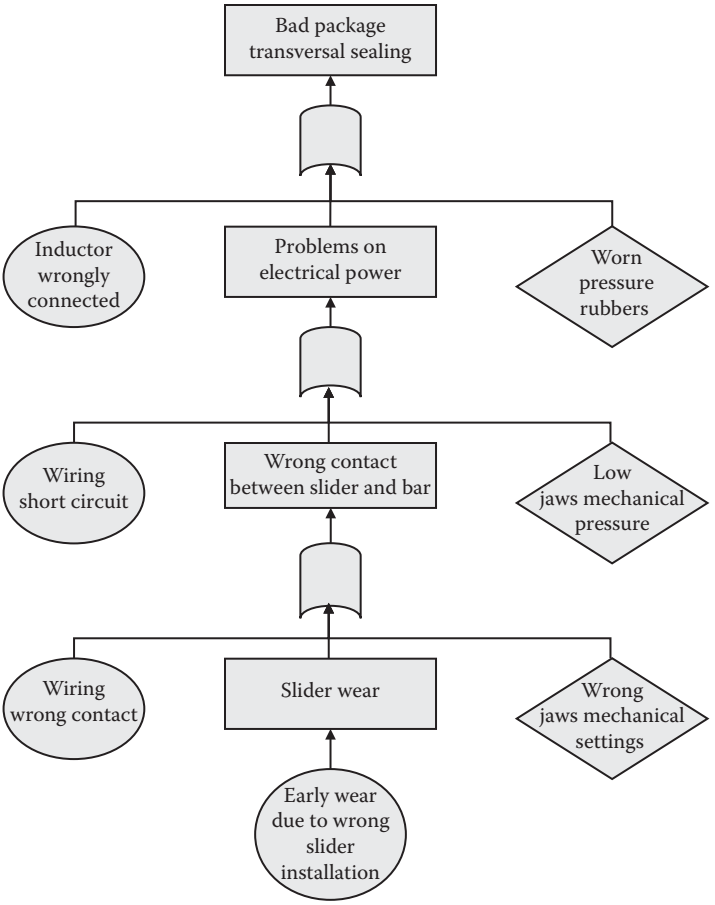


FIGURE 6.25
Fault tree analysis for bad package transversal sealing.

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
- Some other factors

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

6.3.3.2 Second: Root Cause Analysis and 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 necessarily reflect the global nature of a failure, cause mapping defines problems within the context of a manufacturing's overall goals. Looking at Figure 6.26, we see that the analysis breaks the problem down into its parts, analyzing a failure and breaking it down into a specific cause-and-effect relationship.

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. The circuit shown in

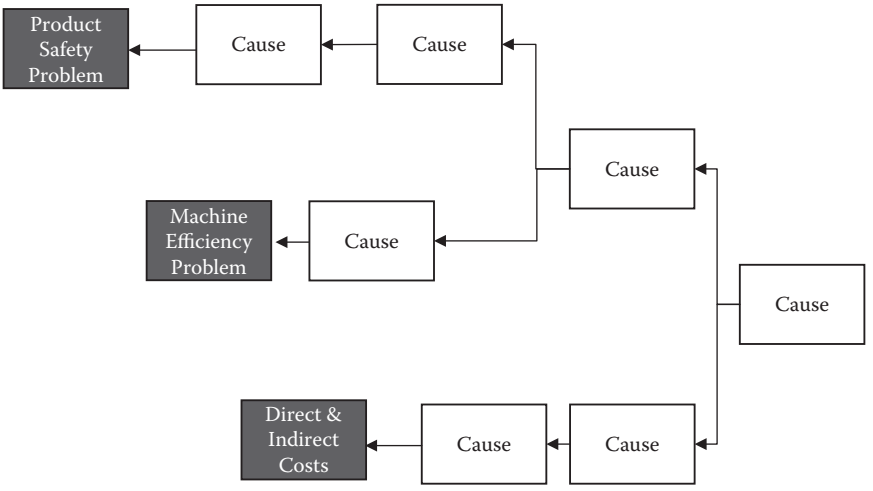


FIGURE 6.26
Cause mapping applied to overall organization's goals.

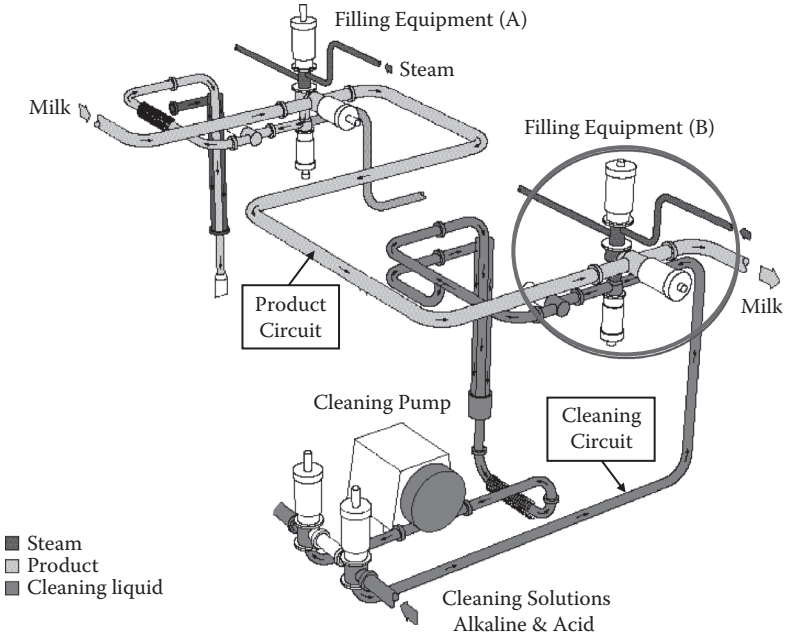


FIGURE 6.27
Cleaning of equipment (B) while equipment (A) is in production. (From Tetra Pak Training Department, Training material on equipment, 1996.)

Figure 6.27 represents a cleaning circuit, and the circle shows the valve that enables liquid food product to flow away while the filling equipment (A) is in production and the equipment (B) in the cleaning position.

Because of a lack of a reliable maintenance program, it has been found that cleaning solutions enter in the product pipes since product and cleaning valves of filling equipment (B) are not closing correctly. Small leakages of alkali and acid solutions come into contact with liquid food product if worn-out valve heads are not replaced in due time. The RCA diagram shown in Figure 6.28 identifies different causes that produce, as an effect, problems on

- Product safety
- Equipment efficiency
- Production costs

The connections existing among different causes and effects allow us to deploy a clear picture that shows the sequence of events and results split for different subjects.

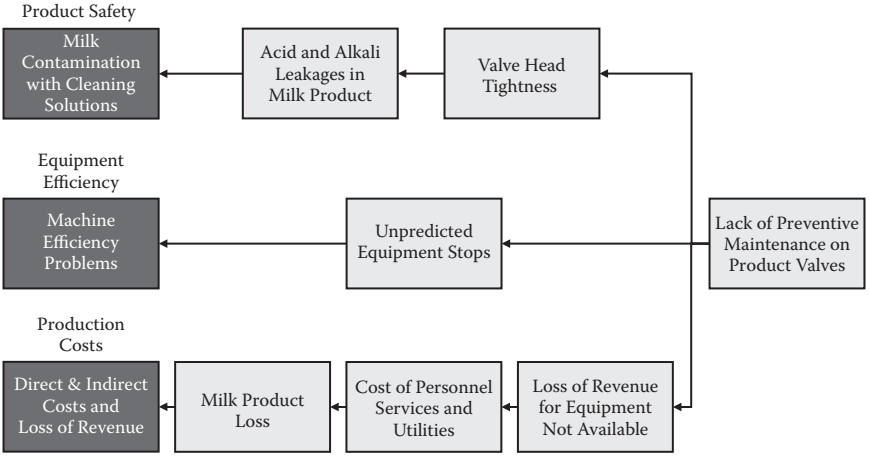


FIGURE 6.28
Effects of lack of maintenance on safety, efficiency, and costs.

These diagrams, beyond their use for troubleshooting purposes, can be particularly effective when used as training material.

6.3.3.3 Third: Ishikawa with His Fishbone Diagram

This technique helped visually to capture a problem and all possible causes. As we saw in Figure 4.30, 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, etc. 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 finds causes, enabling us 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. Figure 6.29 shows an Ishikawa diagram applied to an outfeed overload mechanism. The different causes that produce an overload are listed under the main "four M" branches.

On each branch, we list the causes that contribute to produce the problem, that is, a single effect, and these causes are grouped under the main arms. This technique draws attention to a single effect and all the potential

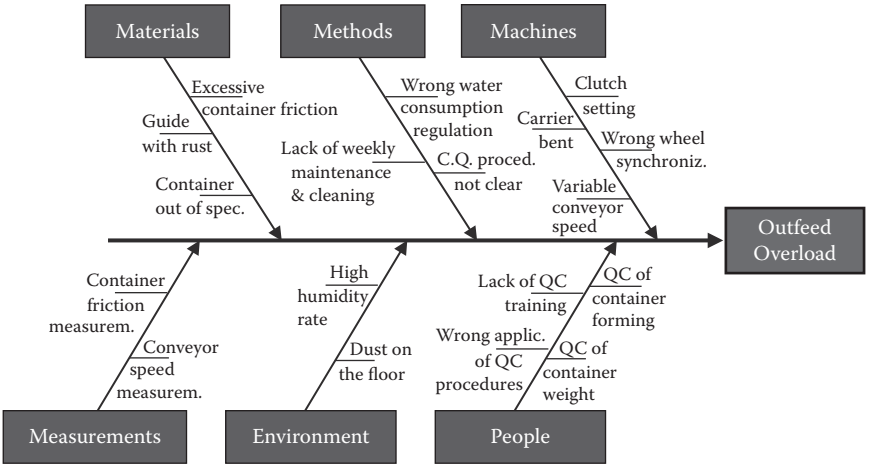


FIGURE 6.29
Ishikawa applied to an outfeed overload mechanism.

causes behind this effect. Despite its not being a dynamic representation of the evolution of causes and effects, it has to be used as a complementary tool to depict all causes that produce a single effect.

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.

6.3.3.4 Fourth: Five Whys Technique

Five whys is a complementary tool to Ishikawa. It helps to begin with the end result, reflect on what caused that, and question the answer five times. This elementary but often effective approach to problem solving promotes deep thinking through questioning, and can be adapted quickly and applied to most problems. Figure 6.30 simply shows each why as a door to be opened to enter in a specific context to discover its content.

There are three key elements for an effective use of the five whys technique:

1. Accurate and complete statements of problems
2. Complete honesty in answering the questions
3. Determination to get to the bottom of problems and resolve them

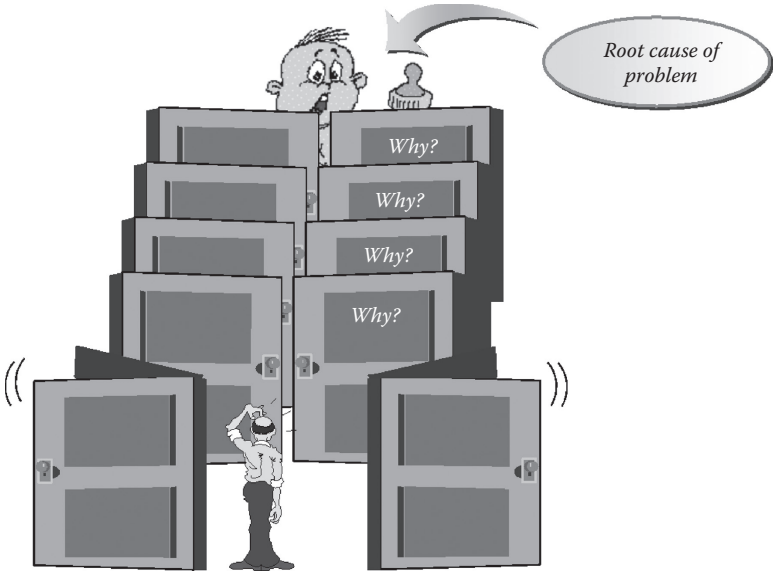


FIGURE 6.30
Five whys. (From Tetra Pak Training Department, Training material on WCM, 2002.)

The five whys exercise is improved when applied by a team. There are five basic steps to conducting it:

1. Gather a team and develop the problem statement in agreement, and decide whether or not additional individuals are needed to resolve the problem.
2. Ask the first *why* of the team: Why is this or that problem taking place? There will probably be three or four sensible answers: record them all on a flip chart or whiteboard.
3. Ask four more successive *why*s, repeating the process for every statement on the flip chart or whiteboard. Post each answer near its "parent." Follow up on all plausible answers. You will have identified the root cause when asking *why* yields no further useful information.
4. Among the dozen answers to the last asked *why* look for systemic causes of the problem. Discuss these and settle on the most likely systemic cause. Follow the team session with a debriefing, and show the product to others to confirm that they see logic in the analysis.
5. After settling on the most probable root cause of the problem and obtaining confirmation of the logic behind the analysis, develop appropriate corrective actions to remove the root cause from the system.

To make an effective use of this tool, it must be avoided to stop at symptoms, and not proceed to lower-level root causes.

Figure 6.31 shows the application of this technique to a conveyor jam problem. Each single cause found becomes itself an effect of many other causes, and this process ends with the definition of countermeasures to avoid or correct the problem.

The failure funnel shown in Figure 6.32 represents the result produced by the key methods and techniques (quantitative and qualitative) used. Through quantitative analysis we are able to identify and consolidate the different types of failures in a system.

Through qualitative analysis we define the relationship existing between causes and effects, in the specific context, and then, as a result, we are able to prioritize and classify the failures. Table 6.2 summarizes the repetitive and chronic failures, showing their frequency, complexity, and the potential causes, with the main findings coming from quantitative and qualitative analysis.

6.3.4 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 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 that 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.

Problem	#	1 why	No	2 why	No	3 why	No	4 why	No	5 why	No	Countermeasures
Conveyor Jam	1	Outfeed FF	1.1	Wrong speed of the conveyor chain								Check and compare the speed of the outfeeder and the speed of the conveyor
			1.2	Missing lubrication	1.2.1	There's no lubricant	1.2.1.1	Nobody has filled the lubrication tank	1.2.1.1.1	The operators don't care about the low level alarm		Highlight the importance of the lubrication to the operators
					1.2.2	The lubrication sprinklers are clogged	1.2.2.1	The sprinkler got clogged due to calcium residue	1.2.2.1.1	Clean the sprinkler		Put in place a cleaning routine
									1.2.2.1.2	The hole of the sprinkler is too small		Replace the sprinkler with a bigger type
			1.3	The shape of the rails is not suitable								New rails to be installed
	2	Packages fall in correspondence to chain joints	2.1	Lack of guides in the conveyor								New side rails to be installed

FIGURE 6.31
Five whys matrix.

Problem	#	1 why	No	2 why	No	3 why	No	4 why	No	5 why	No	Countermeasures
			2.2	Missing lubrication	2.2.1	There's no lubricant	2.2.1.1	Nobody has filled the lubrication tank	2.2.1.1.1	The operators don't care about the low level alarm		Highlight the importance of the lubrication to the operators
			2.3	Too big of a speed difference between the two parts of conveyor								In case different speed setting can be tested
	3	Packages fall in the middle parts of the conveyor	3.1	Missing lubrication	3.1.1	There's no lubricant	3.1.1.1	Nobody has filled the lubrication tank	3.1.1.1.1	The operators don't care about the low level alarm		Highlight the importance of the lubrication to the operators
			3.2	Vibration on the chain								Different chain (flat) to be tested
			3.3	Installation not correct	3.3.1	Loosen parts						Check and restore basic conditions
					3.3.2	Parts not in level						Check and restore basic conditions
	4	Wrong signal, the queue is created by DE stops										Install "catch DE" on PLMS
	5	Packages fall in the trap	5.1	The trap is not suitable for this package	5.1.1	The rails of the trap are weak						Reinforce the rails
			5.2	The trap is not placed in the proper position								Verify the position and eventually move it

FIGURE 6.31 (*Continued*)

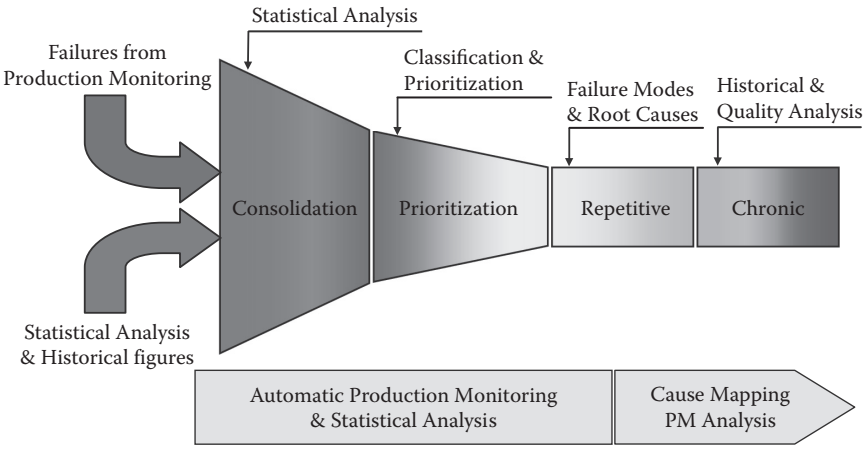


FIGURE 6.32
Failure funnel.

TABLE 6.2

Repetitive and Chronic Failures

	Repetitive		Chronic
Frequency	High	Low	Low
Complexity		Low	High
Cause	• Mainly one cause • Known	• Easy to identify • Sometimes unknown	• More than one cause • Difficult to identify
Tools	Restore basic conditions and standards	SPC, Ishikawa, FTA, cause mapping	SPC, historical analysis, and PM analysis

In these circumstances items are removed or repaired/adjusted to prevent functional failures.

As an example, Figure 6.33 shows how the operational condition of a common ball bearing changes, from potential to functional failure, after potential failure is detected. From vibration deviation detection (potential failure threshold), to steel particles found in mineral oil, to an increase of noise and temperature level, 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.

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

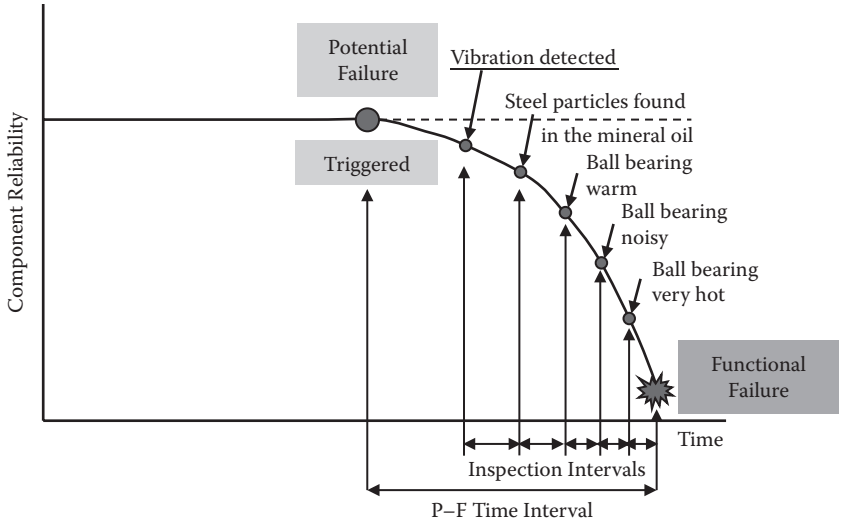


FIGURE 6.33
From potential to functional failure in a ball bearing.

into manageable segments (components) in order to identify all possible failures. This process is known as a work breakdown structure (WBS).

6.3.5 Failure Modes and Effects Analysis (FMEA)

FMEA or failure mode effects and criticality analysis (FMECA) represents 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 they are 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 the 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, like 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 the following:

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 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 × Occurrence × 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 multicriterion 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 *Failure Modes and Effects Analysis: Predicting and Preventing Problems before They Occur* by Paul Palady (1995).[44] 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 6.34 shows a potential failure modes and effects analysis form used for this purpose.

   The FMEA form identifies potential failures modes and assesses the potential customer effects of failures. As shown in Figure 6.35, 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.

Part or Process name				*Design/Manufacturing Resp.*			
Product Regulating Valve				Production Dep.			
Series No./Dev.Step				*Engineering Release Date*			
Aseptic Filler AF201				15.09.02			
Part/Process Description	*Process Purpose*	*Potential Failure Mode*	*Potential Effects of Failure(s)*	*Severity*	*Potential Causes of Failure*	*Occurrence*	*Current Controls*
Product regulating valve: it is regulating the product flow to the forming section	Product flow control according to the product level in the forming section	Valve movement sticking	(a) Overfilling (b) Paper tube opening and machine stop due to product level out of range	6	Shutter blocked	5	(a) Check the valve movement every 250 hours (b) Change the shutter bushings every 1000 work hours

Other Areas Involved			*Suppliers & Plants Affected*				
Production & Maintenance			Engineering Dep.				
Prepared By			*FMEA Date*				
Mario Bianchi			15:09:02				
Detection	*RPN*	*Recommended Action(s)*	*Area Individual Responsibility & Completion Date*	*Actions Taken*	*Severity*	*Occurrence*	*Detection*	*RPN*
2	60	(a) Introduce a cooling system on the valve body frame (b) Change the shutter bushings with the larger one as the movement force increases (c) Check the valve movement to measure the movement force	(a) ST 15.09.02 (b) ST15.09.02 (c) Production dep. (machine operator) 15.09.02	(a) Cooling sy. modific. on valve frame (higher comp. life time) (b) Shutter bushing modification (c) Weekly checks modif.	6	4	2	48

FIGURE 6.34
Process FMEA form.

RISK EVALUATION

Product: _____

Compiled from: _____ Date: _____

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

FIGURE 6.35
Example of a risk evaluation form.

Potential failure modes and effects analysis is a combination of different steps:

1. 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.
2. Failure effect and severity (the consequences). This is the effect that a failure mode has on the operation, and on the 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 that may cause unsterility or equipment system loss.

   Critical: A failure that may cause severe injury, major property damage, or major system damage that will result in operation loss.

   Marginal: A failure that may cause minor injury, minor property damage, or minor system damage that will result in delay or loss of availability.

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

3. Probability of failure occurrence. Failure modes identified in the failure modes and effects analyses are assessed in terms of probability of occurrence when specific part configurations 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 that 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 that 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 that 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 that will indicate a priority of failure modes. During research and development, those failure modes possessing the highest priority should be redesigned if possible.

4. Failure detection. To assign detection rankings, the process or product-related controls for each failure mode need to be identified and then assigned a detection ranking. 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. Mean time between failures (MTBF) was a basic data element needed for RCM analysis. This number is derived by the following formula:

(Production Time/Number of Equipment Stops)

6.3.6 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 are necessary to define the criticality, to mathematically describe the failure process, and to optimize the time between Preventive Maintenance tasks. Reliability data include an 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, etc.) are rather flexible, and may be used for detailed modeling 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 effects 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
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. In a similar problem, a phenomenon or physical mechanism pursues the elimination of chronic failures through the following activities:

- Problem definition
- Physical analysis of the problem
- Identifying the likely causes of the problem
- Equipment, materials, and methods assessment
- Developing techniques for analysis and inspection
- Eliminating disturbing factors
- Devising proposals and improvements

6.3.7 Determine Maintenance Approach for Each Failure Effect

There are four major maintenance components of the reliability-centered maintenance program:

- Reactive maintenance (corrective maintenance)
- Preventive maintenance
- Predictive maintenance (condition monitoring)
- 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 the 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

remachining, cleaning, flushing, sharpening, repositioning, tightening, and adjusting. Sometimes preventive maintenance tasks can include calibration where this is done on a hard time basis.

- Condition-directed maintenance (preventive and CBM). This task is 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 is 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 for 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 lightbulb 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, standby pumps, switches on conveyor systems, and 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 standby pumps. Although often associated with safety-related failures, this is not always the case. Within RCM it provides the last line of defense for routine maintenance when a failure mode cannot be predicted or prevented.

Figure 6.36 provides a quick summary of the four main maintenance programs to be selected when RCM is applied.

6.3.7.1 RCM Logic Tree for Task Selection

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 that provide the pathway to identify the right

Reactive Maintenance	**Preventive Maintenance**	**Predictive Maintenance**	**Proactive Maintenance**
Can be applied on			
▪ Small items ▪ Non-critical ▪ Unlikely to fail ▪ Inconsequential ▪ Redundant	▪ Items subject to wear-out ▪ Consumable replacement ▪ Known failure pattern	▪ Items not subject to wear-out ▪ PM induced failures ▪ Random failure patterns	▪ Root cause failure analysis ▪ Age exploration (PM optimiz.) ▪ Failure modes & effects analysis

FIGURE 6.36
RCM maintenance programs.

maintenance approach for each failure pattern.[39] A simple decision logic tree for task selection, shown in Figure 6.37, can be used to identify the criteria needed to apply condition monitoring and time-directed tasks. This tool takes into consideration evident or hidden failures and consequences (effects) on product safety and on direct and indirect costs. As a result, it suggests different maintenance tasks according to potential failure effects.

To better define the maintenance task, Figure 6.38 shows a diagram that contains the technical and economical criteria that can help the design team identify the most convenient maintenance task.

- Quadrant A. This identifies assets characterized by low maintainability and low cost. For them it is not convenient to do maintenance.
- Quadrant B. This identifies assets characterized by high maintainability and low cost. The decision between maintenance and replacement will be made on the basis of economic convenience between service costs and replacement costs.
- Quadrant C. This identifies assets characterized by high maintainability and high cost. For them it is convenient to perform maintenance.
- Quadrant D. This identifies assets characterized by high cost and low maintainability. Their maintainability should be enhanced through improvements, modifications, or restoring them through tailor-made equipment.

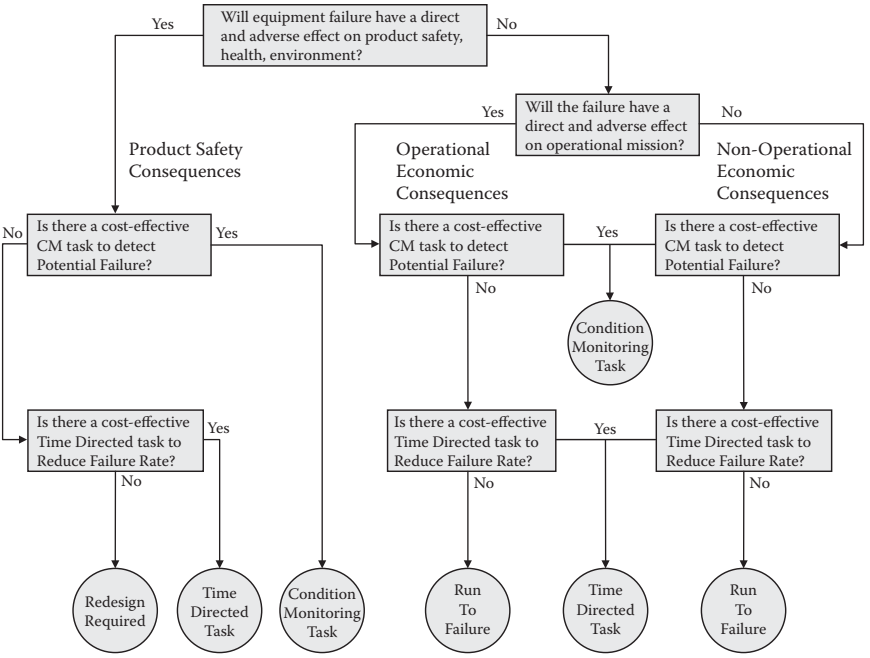


FIGURE 6.37
Decision logic tree for task selection.

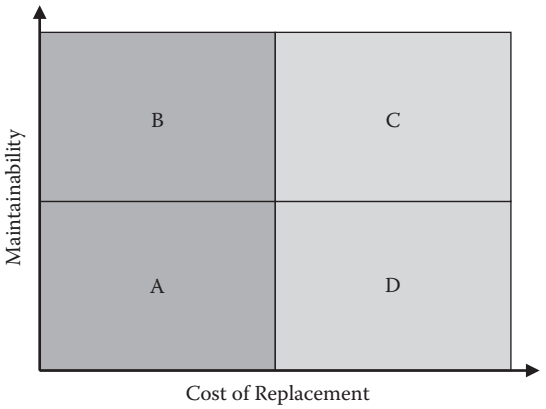


FIGURE 6.38
Summary of technical and economical criteria for maintenance tasks.

6.3.7.2 Determining the Task Interval

On-condition maintenance relies on the capability to detect failures before they happen, so that preventive maintenance can be activated. 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 than allowing the failure to occur, and possibly cause severe consequences. In this section the methodology to estimate the P (potential) and F (functional) intervals or failure detection threshold (FDT), which are two typical ways to describe the detectability of a failure, is introduced.[48] As shown in Figure 6.39, 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.

In addition to P–F intervals, the indication of when the approaching failure will become detectable during inspections can be specified using

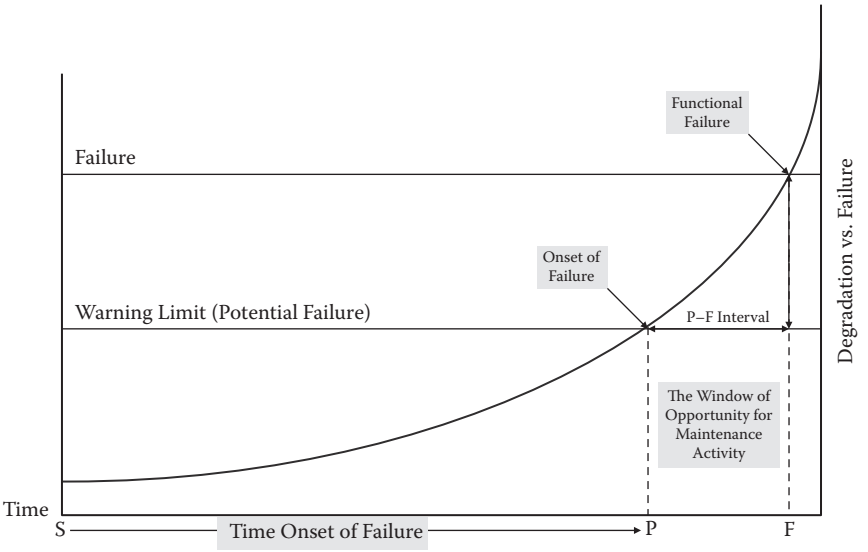


FIGURE 6.39
Degradation vs. failure (P–F curve).

a factor called the failure detection threshold (FDT). FDT is a number between 0 and 1 that indicates the percentage of an item's 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 ($0.9 \times 1000 = 900$). 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 statistical analysis of historical figures. Note that estimation of the 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.

A plot of different degradations vs. time, shown in Figure 6.40, enables us to gain better knowledge of component or system degradation with relative P–F intervals. In other words, if an inspection interval is based

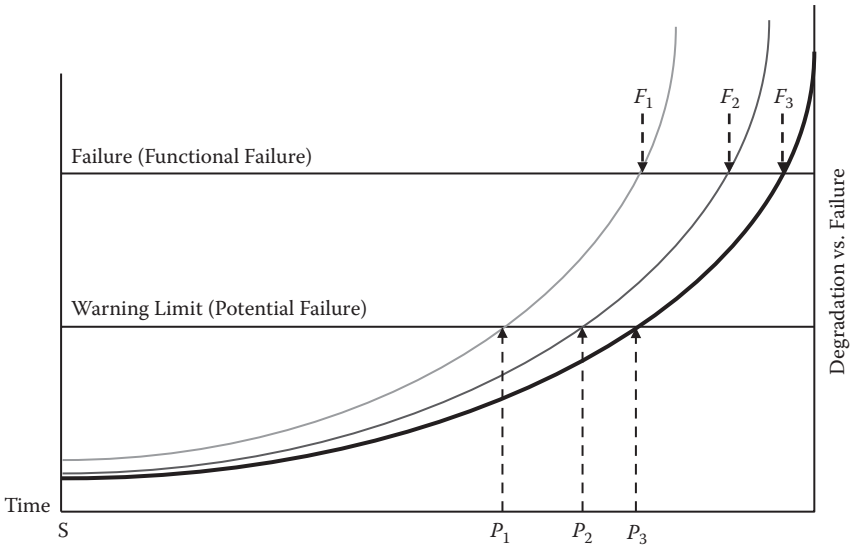


FIGURE 6.40
A plot of different degradations vs. time.

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), which 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 ensure that an inspection to detect impending failure will occur between the appearance of potential and functional failure, inspection intervals must be shorter than Tos.

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 and 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 6.41, 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 6000 operating hours, where the probability of failure exceeds 0.15 (15%). This decision is mainly dependent on the HACCP evaluations of the effects produced by these critical components on product safety. When historical data available show that failures are evenly distributed around the mean, the MTBF can be used to schedule maintenance intervals.

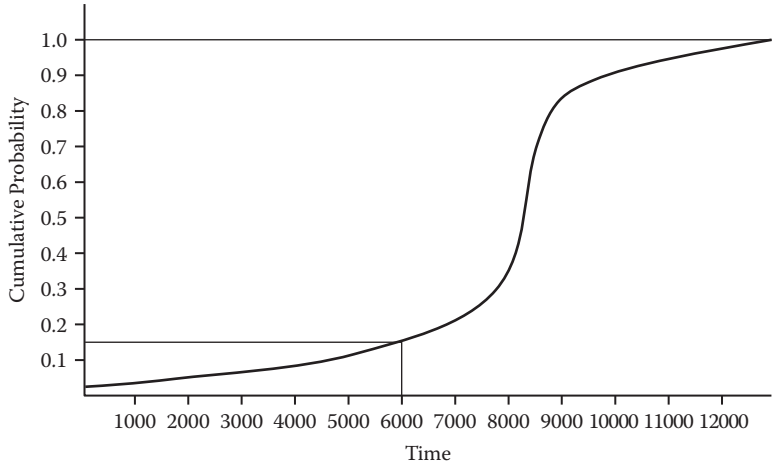


FIGURE 6.41
Inspection time interval.

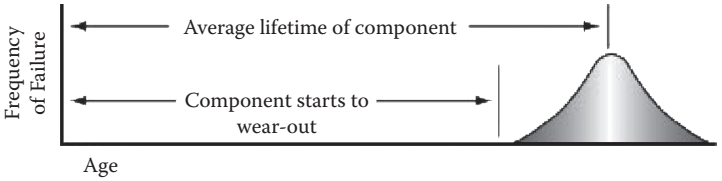


FIGURE 6.42
Average and starting times to failure.

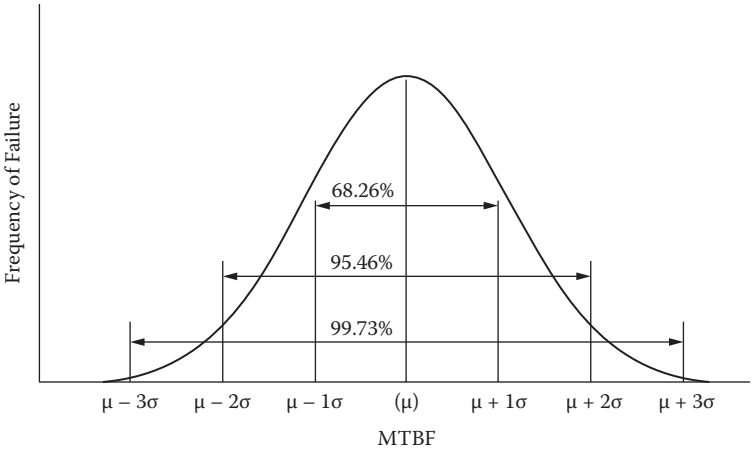


FIGURE 6.43
Normal failure distribution.

Figure 6.42 shows the normal distribution indicating the average time and the time at which the component starts to wear out. The effort of the team is to identify the critical factors that allow the component to improve its lifetime.

When failures occur in a narrow range, a normal failure distribution curve can be used for task scheduling. Scheduling a replacement or overhaul task is an exercise based upon the curve shown in Figure 6.43 representing a normal failure distribution.

When the failures occurred in a narrow range, this method of task scheduling could be appropriate. There have been many models, or combinations of models, 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 that does not improve the component's safety or reliability should be eliminated.

6.4 STEP 3: SAFETY AND RELIABILITY ANALYSIS THROUGH HACCP AND RCM

The design process started with the application of HACCP to identify the food safety critical issues; as a second step, the application of RCM (quantitative and qualitative analysis) highlighted equipment reliability criticalities. Now, at this point of the design process, HACCP and RCM techniques are combined to carry out food safety and equipment reliability analysis. The purpose of this analysis is to identify the whole risk produced by the failure effects on food product safety, 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 the following:

- Final product (food quality and safety)
- Equipment functions
- Production activity (interaction between equipment and packages)

This step has been designed for equipment or production lines operating in the 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 with food product safety. Figure 6.44 shows a form that combines failure modes effect and critical analysis (FMECA) with some of the meaningful HACCP and HAZOP criteria and parameters. This form has been called failure mode effect and hazard analysis (FMEHA) to display the integrated assessment (measure) of food 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.

The purpose of this form is to record both equipment reliability and product safety issues to highlight all the criticalities, to gain, as a result, a global view and a total risk priority number (RPN) based on CCP and critical reliability issues identified in the design process. Below are short

Part or Process name							Design/Manufacturing Resp.			
Series No./Dev. Step							Engineering Release 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

		Other Areas Involved			Suppliers & Plants Affected					
		Prepared By			FMEA Date					
Existing monitoring procedures	Frequency	Detection	RPN	Recommended Action(s)	Area Individual Responsibility & Completion Date	Actions Taken	Severity	Occurrence	Detection	RPN

FIGURE 6.44
FMEHA form designed for the food industry.

descriptions 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, and (3) operational practice. This is the description of the equipment part, or the critical control point or operational practice that should be provided with reference to a specific critical reliability or safety issue.
- Process purpose. This 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 has to be classified in one of the three HAACP categories: (B) biological, (C) chemical, or (P) physical. The type of hazard, depending on the specific failure, should be identified, and this has to be classified in the three HACCP categories:
- 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 with that failure mode.
- Severity. According to Table 6.3, 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. 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 6.4, the scores introduced in these fields identify the failure probabilities of occurrence. Also in this

TABLE 6.3

Failure Severity Classification

Score No.	Severity Classification	Failure Severity Assessment Criteria	Potential HACCP Effects
1	I	No damages on product packed or 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, etc.).	Small package shape/ appearance problems
4–6	III	Failure effects are serious enough. There could be safety problems with the product, and the event will be noticed by the customer.	There could be random problems of 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 on national laws on product safety.	Package integrity and product safety problems (defect rate > 1/100)

TABLE 6.4

Failure Occurrence Classification

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 occur
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 events happen very frequently

Source: NASA, *Reliability Centered Maintenance: Guide for Facilities and Collateral Equipment,* 2000.

TABLE 6.5

Failure Detection Classification

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 probably not be detected
9–10	Failure will rarely be detected

Source: NASA, *Reliability Centered Maintenance: Guide for Facilities and Collateral Equipment,* 2000.

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

- 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 6.5 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.
- Risk priority number (RPN). This number is the result of the product of three scoring numbers:
  1. Severity
  2. Occurrence
  3. Detection

  For example, severity (7), occurrence (4), detection (2): RPN (S × O × D) = 56.
- Recommended action(s). If the RPN obtained, to multiply severity, occurrence, and detection, shows a number that calls for a corrective action to improve the global equipment reliability and

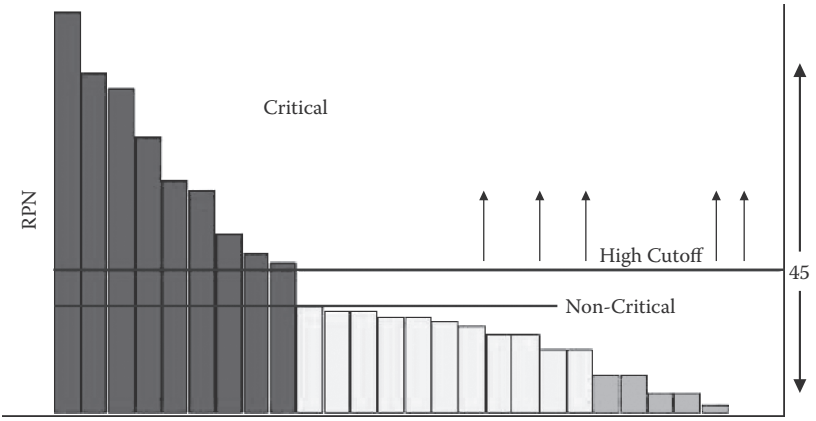


FIGURE 6.45
Example of RPN threshold.

product safety, then a recommended action is needed. As shown in Figure 6.45, for each failure mode it is advisable to identify different RPN thresholds to highlight a number above which a corrective action is needed.

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

- Area of individual responsibility and 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 reflect 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.

Figure 6.46 shows a FMEHA form applied to two critical components of a transversal sealing (TS) system of an aseptic filler:

1. Sealing inductor
2. Pressure rubber

Part or Process name							Design/Manufacturing Resp.			
CONTAINER SEALING							A. Bianchi			
Series No./Dev. Step							Engineering Release Date			
20125/050V							6425/02			
Part/Process Description CCP	Process Purpose	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
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	Voltage, Current and Phase angle Visual inspection: mechanical integrity
Pressure Rubbers	Package Sealing	B	Mechanical (see OM 7.1)	Concave shape >0,5mm	(a) Concave shape (b) Wrong installation (c) Irregular shape	(a) Bad TS sealings (b) No TS sealings (c) Blocked TS sealings	8	Human error	5	Visual inspection: mechanical integrity

FIGURE 6.46
FMEHA form applied to a TS sealing of an aseptic filler.

		Other Areas Involved			Suppliers & Plants Affected					
		Quality and Manitenance								
		Prepared By			FMEA Date					
		A. Ferrari			08-04-2010					
Existing monitoring procedures	Frequency	Detection	RPN	Recommended Action(s)	Area Individual Responsibility & Completion Date	Actions Taken	Severity	Occurrence	Detection	RPN
Electrical: continuous. Mechanical: Manual	Electrical: Automatic Mechanical: Weekly	2	**64**	Daily checks, included in the AM check list	Production: Equipment Operator	Definition of: - AM check content - Op. training - Tools necessary	8	4	1	**32**
Manual through a vernier	Daily Weekly	2	**80**	(a) Daily checks included in the AM check list (b) Improved daily practices & instructions	Production: Equipment Operator	Definition of: - AM check content - Op. training - Tools necessary	8	3	1	**24**

FIGURE 6.46 (*Continued*)

This form enables us to list and rate all food safety critical factors, together with equipment reliability issues, to get, as a result, an overall RPN that, in one shot, assembles food safety and equipment reliability criticalities.

6.5 STEP 4: LIST OF PRIORITIES (SAFETY AND RELIABILITY ANALYSIS)

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

The form shown in Figure 6.47 describes (from the left):

- Part or process taken under consideration
- Hazard type (B, C, and P)
- Risk priority number (RPN) found
- Potential effects produced by that failure
- Condition monitoring tools used
- Tools and templates available to carry out maintenance activities (objective tools for measurements)
- Critical or warning limits to be monitored or checked
- Competence level required (operator or technician, electrical, mechanical, etc.)
- Time (working hours) interval or number of cycles at which maintenance needs to be planned
- Maintenance action devised in the previous section

Since through RCM analysis we already split the equipment/line or system into different subsystems, groups, component functions, and system boundaries, at this step of the design process a list of priorities is to be defined for each subsystem. According to RPN scoring results, for each subsystem, 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.

Equipment Name (System)						Design/Manufacturing Resp.	
Series No./Dev. Step						Engineering Release 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

Sub-System		Areas Involved		
Prepared By		Date		
Tools & Templates	Critical Limits or Warning Limits	Competence Level Required	Time/Cycle Interval	Maintenance Actions (Chk, Adj, Rep)

FIGURE 6.47
List of safety and reliability priorities.

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 display the criticalities in place within the different subsystems defined in the equipment.

6.6 STEP 5: DESIGN OF MAINTENANCE TASKS

As a 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 6.48, from the

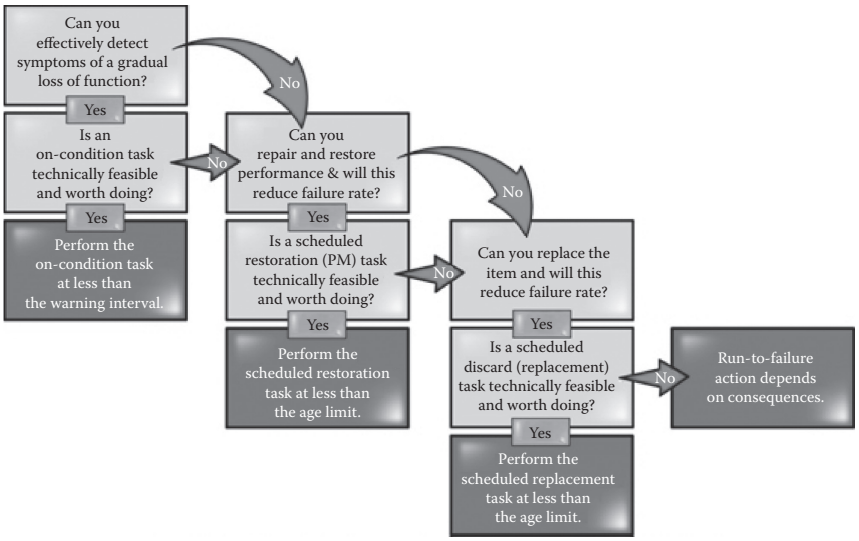


FIGURE 6.48
Decision logic tree. (From Keeter, B., and Plucknette, D.J., The Seven Questions of Reliability Centered Maintenance, Allied Reliability, June 2009, available at http://www.alliedreliability.com/2009.)

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
    - Predictive maintenance. This task aimed to detect 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 is predicted so that they can be mitigated through planned activities. Where applicable, the use of online and condition monitoring systems can detect the deviation of physical parameters (temperature, vibration, oil residues, etc.) 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 liters 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 remachining, cleaning, flushing, sharpening, repositioning, tightening, and adjusting. Often preventive restoration tasks 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 lightbulb 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, standby 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 standby pumps. Although often associated with safety-related failures, this is not always the case. Within RCM it provides the last line of defense 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 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.[45] 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 multiple failures to a tolerable level. The detective task is then performed on a routine basis to detect whether an asset has failed or is still working. Regardless of whether the part under consideration is a switch, a circuit breaker, a sensor, or a standby 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 and three are corrective tasks, but all are proactive. 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 cycle model. Below is a summary of the tasks described above:

- 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, and then calculating this by the frequency of the task until the end of a life event or threshold time 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 the case of the corrective tasks these are often estimates based on manufacturer's data, our own maintenance history records, or 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.

6.7 CONCLUSION

In this chapter, the process used to design maintenance procedures for the food industry has been examined. This chapter presents an original design process, conceived to combine reliability concepts, safety, and maintenance engineering techniques to effectively manage food product safety and equipment reliability issues. The reliability concepts, safety, and maintenance engineering techniques found in the literature, and analyzed in Chapter 4, have been compared and contrasted and selected to identify:

1. The process to design maintenance procedures
2. The techniques to be used in the design process

Below the contents of the maintenance design process and the benefits coming from each design step are briefly summarized.

6.7.1 Step 1: 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 GMPs, suggested by ISO 22000, can highlight both critical areas, depending on human errors and 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 points of view. This step represents an original contribution to the maintenance design process since it addresses the critical practices and equipment parts that can produce food product safety hazards.

6.7.2 Step 2: 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 subsystems and definition of boundaries and the operational modes, equipment failures have been analyzed under quantitative and qualitative points of view. The use of statistical tools can identify and quantify the various types of failures, their distribution, and component/part lifetimes.

Qualitative tools like fault tree analysis, root cause analysis, and Ishikawa tied problems to the global context to identify the categories of causes and link 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.

6.7.3 Step 3: Safety and 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 that identifies a risk priority number that embodies both food 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 satisfies the necessities to integrate product quality and safety with equipment reliability issues to gain, as a result, a global scoring system that is appropriate to the food industry environment.

6.7.4 Step 4: List of Priorities (Safety and Reliability Analysis)

This step has been conceived to produce a list of priorities based on RPN scoring that 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 subsystem, represents a process rationalization that leads to the execution of the next design step more effectively.

6.7.5 Step 5: Design of Maintenance Tasks

As a 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 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.

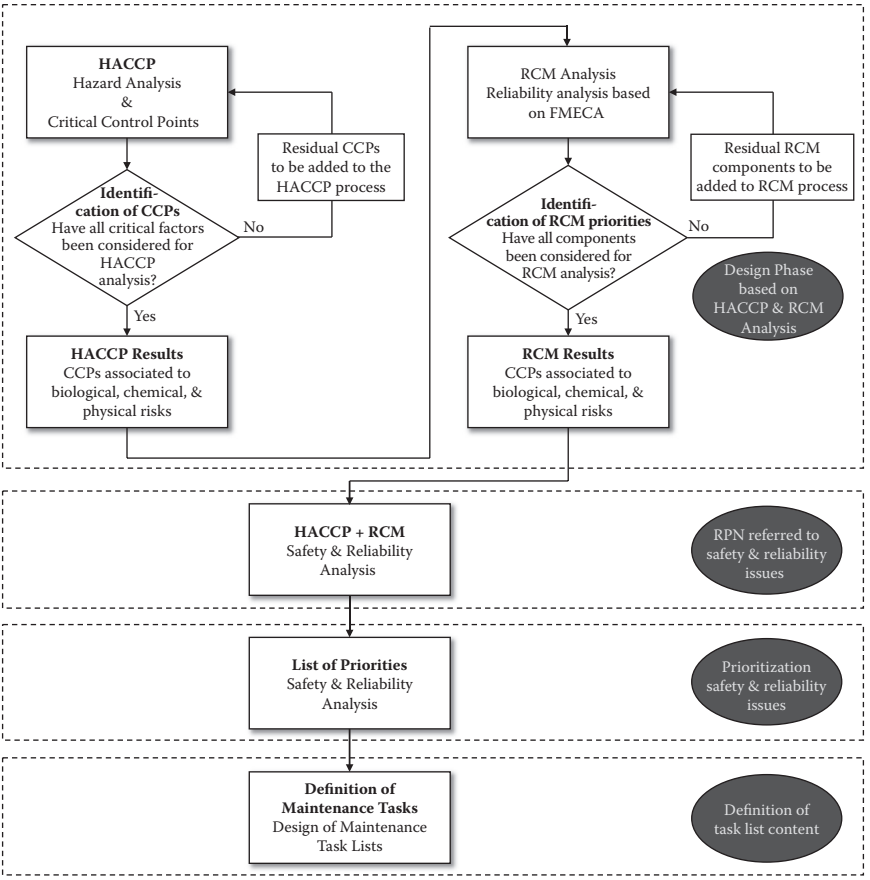


FIGURE 6.49
The process to design maintenance tasks for food packaging lines.

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 6.49 summarizes the described process steps to design maintenance procedures for the food industry.

7

Proposals for a Maintenance Implementation Model for the Food Industry

7.1 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. A reliable implementation model should address and answer important questions such as the following:

1. Who is committed to carry out a specific maintenance task?
2. When is a specific task to be implemented?
3. How should we perform the tasks and overcome the complexities?
4. What are the critical elements that can reduce maintenance effectiveness?
5. What are the key performance indicators (KPIs) to be used to monitor maintenance implementation effectiveness?

In this chapter these questions are properly addressed to find out, as a result, the proposal for an implementation model able to maximize the outcomes and benefits produced by the maintenance design process. This chapter identifies the problems existing in food packaging and the solutions proposed to implement maintenance tasks effectively. The effort spent to design maintenance procedures and the results obtained in the design phase, with the production of reliable task lists, need to find continuity through proposals that effectively address and solve technical and cultural problems during maintenance task implementation.

7.2 ANALYSIS OF IMPLEMENTATION PRINCIPLES CONSIDERED

In this section some of the implementation techniques described in Chapter 4 are examined to identify the implementation criteria that best address and solve problems and constrictions placed by the food packaging environment. Among the techniques and methodologies taken under consideration we find the following:

1. Total productive maintenance (TPM)
2. Reliability-centered maintenance (RCM)
3. Total quality maintenance (TQMain)
4. Terotechnology principles
5. World-class manufacturing (WCM) 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 a result, equipment reliability together with food quality and safety. The implementation process should be able to catch, address, and solve not only reliability issues, but also:

- 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 that embodies a choice of techniques able to pursue higher reliability, product safety, and quality, with the right people, and at the minimum cost.

7.2.1 Total Productive Maintenance (TPM)

TPM had its genesis in the Japanese car industry; it was originally thought to incorporate total quality control (TQC), just in time (JIT), and total employee involvement (TEI). At that time it became obvious that TPM

not only was a critical missing link in successfully achieving world-class equipment performance to support TQC (reduction of variation) and JIT (lead time reduction), but also was a powerful new means for improving overall company performance. Since the early 1990s, TPM has had a major impact on bottom-line results by revitalizing and enhancing the quality management approach to improve capacity while reducing not only maintenance costs, but also overall operational costs. Statistical process control (SPC), supported by quality at the source, was introduced to ensure right quality the first time to provide maximum customer value. The quality approach changed to prevention at the source by controlling process variables and equipment performance, discovering problems in the earlier phases, and detecting quality deviations to avoid nonconformity products. Since production and quality departments demand equipment availability, quick response time from maintenance, and right quality the first time, TPM emphasized prevention at the source through equipment operator 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 greater return on investment)
- Maintenance (by caring for the plant and equipment to maximize its performance, safety, and output)

Ultimately operators become responsible for the overall equipment effectiveness (which combines 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 and 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 and predictive maintenance services, and when they should call in maintenance specialists (experts) to repair or solve problems that they have clearly identified. Asa result, TPM recognizes 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,

quality, and safety at the source. In this regard, RCM provides the path for failure findings through techniques that enable a deeper knowledge of failure causes and effects, but TPM involves production, maintenance, and quality functions to enable the equipment operators to implement prevention, quality, and safety immediately at the source. The equipment operator empowerment, achieved through autonomous maintenance, and close collaboration with company specialists, represents one of the most important and crucial success factors of TPM.

Different from other engineering and reliability techniques, the success of TPM is heavily dependent on personnel morals and a company's culture. If personnel involved in different roles do not share the ethical values of TPM, and if these values do not become a way of life, TPM will lose its opportunity to generate the claimed benefits. On the other hand, if a company implements the methodology disregarding the cultural values that support this technique, and if managers are not available to embody and represent these values as part of their role, sooner or later the TPM implementation will show its inconsistency. In conclusion, we can say that TPM represents a powerful weapon in the company's hands, but its success is heavily dependent on the cultural values of people committed to its implementation.

7.2.2 World-Class Manufacturing

World-class manufacturing (WCM) is a philosophy that provides the path to aggregate everyone in the organization and motivate the people to constantly pursue continuous improvement. It challenges 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 keyword that makes use of different quality and engineering tools to create competitive success. The temple shown in Figure 7.1 lists the main pillars that focus on maintenance, quality, training, continuous improvement, etc., but it emphasizes the necessity to build up a problem-solving culture that stands at the base of the whole temple.

Starting from assessing the current situation, to identify improvement areas and bottlenecks, WCM guides 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

FIGURE 7.1
World-class manufacturing temple.

represents the central steps that make use of engineering techniques able to identify both causes and solutions for eradication of multiple forms of losses. The main steps of WCM methodology are briefly described below.

7.2.2.1 Step 1: Assess Current Situation

In Step 1, it is necessary to define the quality KPIs and targets, including long-term collection of initial and historical data. The quality assurance matrix for defects at the plant level identifies and scores the existing defects and the critical processes. Identification and classification of defect modes and operator training is the activity that highlights defect content and trains people on how to overcome them.

The data collection system (aligned with critical processes) and collection of current standards are the two activities that complete Step 1.

7.2.2.2 Step 2: Restore Basic Conditions/Deploy Quality Losses

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

7.2.2.3 Step 3: 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 and root cause analysis can be carried out to identify the causes of sporadic and chronic hidden problems. Eliminate sporadic losses through the use of the plan–do–check–act (PDCA) methodology. Use a daily management system (DMS) based on data collection, data analysis, loss prioritization, loss analysis, countermeasures definition, and implementation follow-up.

7.2.2.4 Step 4: Eradicate Chronic Losses

Analyze chronic losses (with combined causes) according to the deployment carried out through Preventive Maintenance (PM) analysis, fault tree analysis (FTA), root cause analysis (RCA), failure modes and effects analysis (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.

7.2.2.5 Step 5: Build the Zero Defect System

Extend the QA matrixes to new standards. The established teams identify the quality factors to be implemented in order to pursue the zero defect objectives. Quality results can be achieved through a close link with other pillars. Assessment of defects, claims analysis, and equipment efficiency allows us to gain a holistic view of the production reality.

Development of an SPC system is necessary to analyze the existing correlation between process condition and defects.

7.2.2.6 Step 6: Improve the Zero Defect System

Apply the five questions for zero defects:

1. Is the condition clear?
2. Is it easy to set conditions?
3. Is the value variable?
4. Is the variance visible?
5. Is it easy to restore?

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

7.2.2.7 Step 7: Maintain the Zero Defect System

In the last step, regular review of conditions of the implementation status, with monitoring of loss indicators, is the never-ending activity necessary to consolidate the gains obtained. Quality activities are regularly carried out in striving for higher manufacturing effectiveness that makes use of Six Sigma methodology.

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 the 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 the highest result at a reasonable cost.

7.2.3 Total Quality Maintenance

Total quality maintenance (TQMain) puts its focus on condition monitoring (CM), recognizing that where critical component breakdown can produce serious effects on process reliability and product safety, online measuring devices should be used. The use of CM devices can provide reliable facts and figures on equipment performance, and, as shown in Figure 7.2, through a holistic view of the production process, it is necessary to involve all the interested parties in pursuing continuous improvement projects.

Continuous improvement necessarily calls for wider involvement of those who play different company roles, but also those identified as key enablers to push projects forward for the achievement of the highest results. A modified version of the overall equipment effectiveness (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 also on the whole process. The Deming cycle (plan–do–check–act), used in the TQMain process, is an effective tool to pursue a continuous improvement of the task lists through online monitoring and feedback from the field. Figure 7.3 shows the simple block diagram with PDCA activities plus an improvement step.

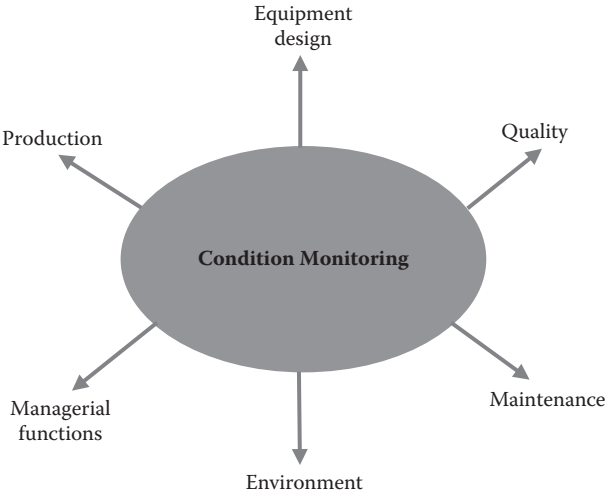


FIGURE 7.2
The TQMain interaction.

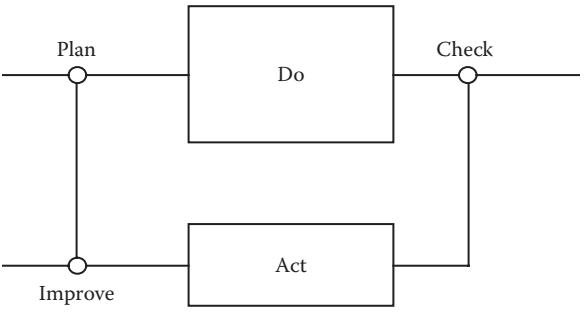


FIGURE 7.3
Plan–do–check–act improvement loop.

- Plan. The execution of maintenance task lists is regularly planned according to the task lists designed.
- Do. The task list results are introduced into a PC software program, together with the list of spare parts used and the time taken to execute each service.
- Check. Line efficiency, packaging material waste, and maintenance costs are regularly measured and checked to draw a picture of maintenance effectiveness. Task list results, following maintenance task list execution, are recorded to assess their impact on component/group lifetime and on machine efficiency/reliability.

- Act. Checklist results are analyzed to evaluate if planned tasks reached the goal or if some corrective action is required.
- Improve. Task list improvement can be sought through the team formed by the line supplier, customer operators, and maintenance specialists. Line effectiveness, instead of line efficiency, can be introduced through the overall equipment effectiveness (OEE) formula shown in Figure 7.4.

The formula used was based on the time domains listed in Figure 7.5.

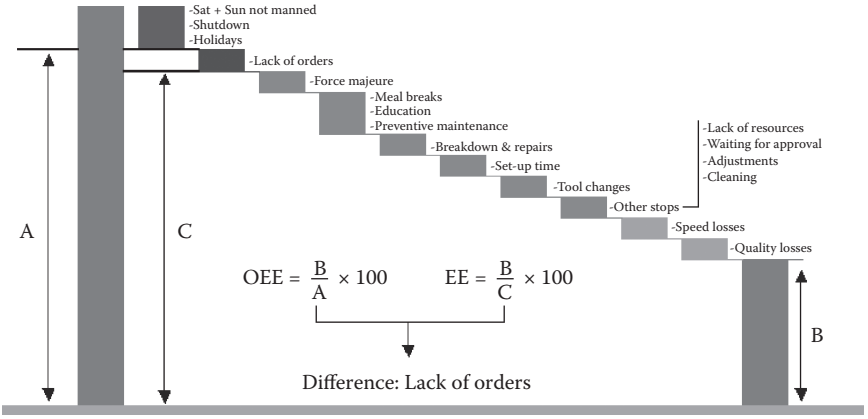


FIGURE 7.4
Overall equipment effectiveness (OEE) criteria.

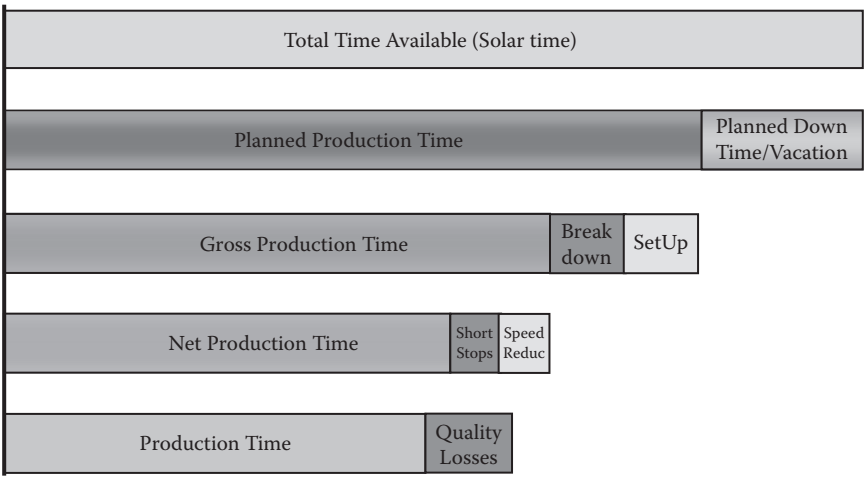


FIGURE 7.5
OEE time domains.

7.2.4 Terotechnology Principles

Terotechnology highlights the importance of revision of scheduled activities as a result of experience: it recognizes that the original task lists, designed by the equipment designers, can be improved through feedback coming from the field. Feedback loops are also the basis to constantly introduce equipment design improvements. Moreover, maintenance should not be considered 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 and indirect maintenance costs and loss of revenue parameters are monitored to identify the areas where maintenance generates its maximum profit.

Below the principles that allow us to achieve this result are fully described: the economical indicators used to measure loss of revenues due to machine stop, and the direct and indirect costs throughout the entire equipment lifetime.

- Direct maintenance costs. Direct maintenance costs take into consideration cost issues like manpower (salaries), spare parts used in the equipment, templates, diagnostic instrumentations, and technical documentation.
- Indirect maintenance costs. Indirect maintenance costs are all the costs produced by lack of a reliable maintenance design and implementation process. Packaging material, food product, and energy waste, together with waste of time and resources, can be considered costs depending on low equipment and maintenance effectiveness.
- Loss of revenue. Loss of revenue depends on the inability of the producer to make use of the equipment and generate added value, because of lack of equipment availability dependent on its low efficiency. The graph in Figure 7.6 identifies direct and indirect maintenance costs and the area where an optimum cost balance can be found.

7.3 PROPOSAL OF A MAINTENANCE IMPLEMENTATION MODEL FOR THE FOOD 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 food

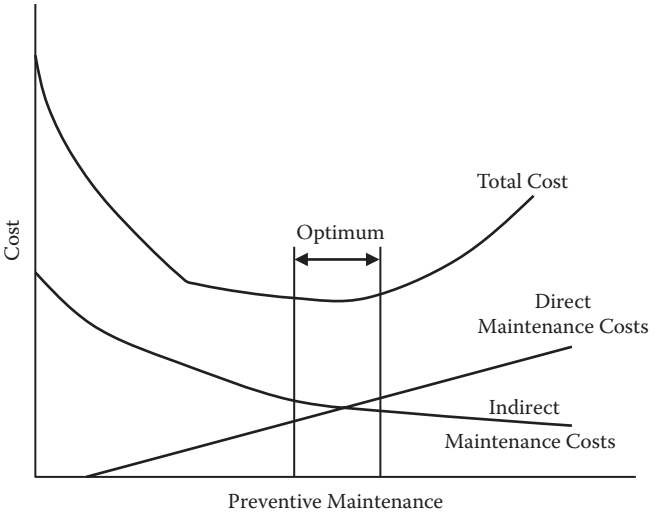


FIGURE 7.6
Maintenance costs.

packaging line constrictions and opportunities are well defined regarding the three main company dimensions:

1. Technical
2. Organizational
3. Cultural

Threats, opportunities, limits, and constrictions need to be described to identify the problems and how the implementation model can provide positive answers and solutions for an effective implementation of the task lists designed. The scope of this chapter is not a production of an academic treaty on implementation, but the production of a tool able to provide positive answers to different food industry problems and complexities.

7.3.1 Step 1: Situation Analysis

Situation analysis should be the first phase able to identify the following:

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

Problems identification is the first activity: the scope is to shoot a photograph of the whole production environment in order to capture problems and their nature, making use of automatic data collection (to highlight problems coming from the technical environment) and production audit with interviews (to highlight problems coming from the 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, etc.) and the relative time associated, to calculate efficiency through different formulas. Data can be collected over a period of 2–4 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 analyze production practices, procedures, training programs, etc., to compare and contrast technical figures with organizational and cultural facts.

Figure 7.7 represents just an example of how to display restraining and driving forces that work against and in favor of the new maintenance implementation philosophy. In order to analyze the elements that form

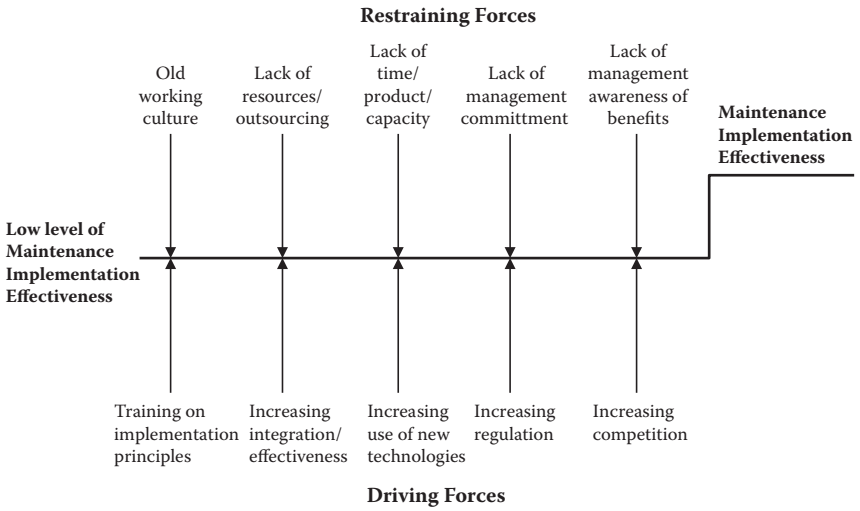


FIGURE 7.7
Restraining and driving forces.

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 organization 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 exercise the present situation is the low level of maintenance implementation effectiveness within the food industry. A more desirable situation would be an increased maintenance implementation effectiveness. These two situations, existing and desirable, are illustrated in Figure 7.7.

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 labor force and a well-organized maintenance approach)
- Increasing integration and effectiveness
- Structured training on implementation principles

The forces that oppose or restrain 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 7.8 shows a practical example of how to display some of the restraining and driving forces that work against the achievement of maintenance implementation effectiveness on a specific food packaging line.

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

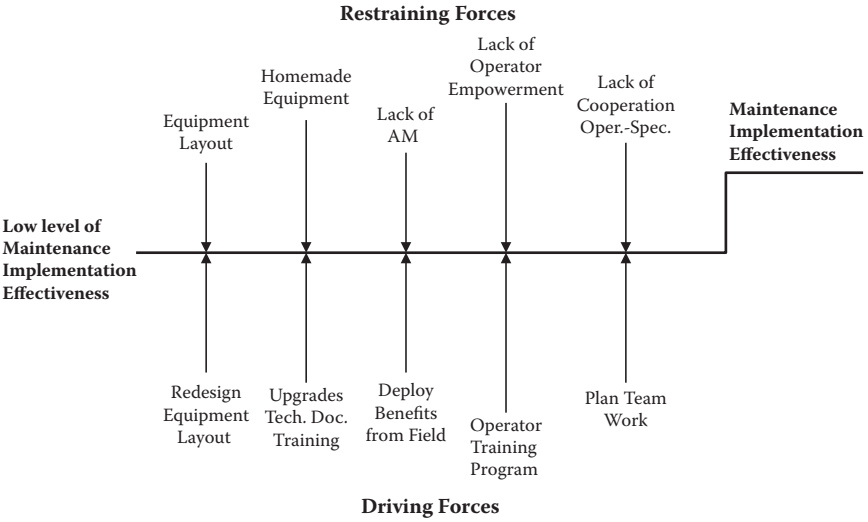


FIGURE 7.8
FFA applied to a food packaging line.

7.3.2 Step 2: Define the Food Packaging Line Mandatory Requirements

The food packaging lines tend 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 requires that appropriate measures for the prevention of failures 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 the hazard analysis and critical control points (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 good manufacturing practices (GMPs) have 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 these 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 program 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 also as an opportunity to develop a real manufacturing competitive advantage.

7.3.3 Step 3: Top Management Involvement and Commitment

Implementation of new maintenance procedures has to be sold to the whole workforce. In the third phase, after top management commitment, the different management categories, following the top-down communication process, have to inform all the company's employees and share their enthusiasm for the project. Experience showed a contradiction existing between theory and practice; therefore, from 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 the full support of top management in order to overcome resistances and conflicts coming from middle management, and promote the involvement of all company employees. Because of mandatory requirements and results found in the situation analysis, implementation of new maintenance procedures must be initiated as a top-down process to enable bottom-up implementation.

7.3.4 Step 4: Training and Education Campaign for Implementation of New Maintenance Procedures

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

- Train the different categories of people on new maintenance procedure philosophies (from design to implementation)
- Train the people involved on new implementation models
- Provide the necessary motivation to overcome early resistance

Training should be used to present new maintenance procedures, features, and advantages, to gain the involvement of the workforce that consider this a costly process, and to show the advantages for all company roles.

Training represents a powerful tool to promote a personal and collective proactive participation; its extension should not be limited to the beginning of a project, but cover the whole company's life. At this stage, training should primarily create a positive attitude toward new maintenance procedures and their implementation.

7.3.5 Step 5: Design the Organization to Implement New Maintenance Procedures

The organizational structure to implement the new maintenance procedures is based on committees and project teams formed at every level of the organization. To enable good communication, every organizational 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 proactive participation of the food industry managers who consider this implementation as threatening to their position. Regular communications, results, and decisions have to be officially shared with the workforce involved in the implementation to promote better involvement and ownership. Accurate planning and design of the activities listed above will enable the organization to overcome the difficulties that will arise at different levels of the company's organization. If the organization 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 that is likely to be very unsettling to the workforce. A complete redesign would be a revolution, probably imposed by senior management. In contrast, this must be an evolutionary process.

7.3.6 Step 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:

1. Technical deviations:
   - Chronic and sporadic losses

- Availability and efficiency problems
- Quality and safety problems

2. Organizational deviations:
   - Operator and maintenance specialist roles
   - Claims management
   - KPIs and measurement system
   - Support and improvement teams

In the sixth phase, correlation between technical and organizational deviations enables us to gain a deeper understanding of the causes and effects produced by the deviations from the standards, on both technical and organizational environments. Restoring the basic and standard conditions, under technical and organizational points 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.

7.3.7 Step 7: Develop a Scheduled Maintenance Checklist

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 the manufacturing environment are not globally taken into consideration.

Following the analysis of the implementation principles carried out in Section 7.2, Table 7.1 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 the roles and responsibilities produces uncertainty on the following:

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

Operators and maintenance specialists have to be trained to safely perform tasks and share the execution of maintenance activities that can be performed by either operators or maintenance specialists. Maintenance performance optimization, necessary to reduce maintenance cost and

TABLE 7.1

Guidelines Proposed for Implementation of Cleaning and Maintenance Activities

Activity	Content	Competence	Role
Routine cleaning and maintenance	a. Daily (pre- and postproduction) b. Weekly cleaning and inspection	Daily cleaning procedures Weekly cleaning and inspection	Equipment Operator
Basic maintenance	a. Time based (daily and weekly) b. Based on number of cycles, packages c. Based on condition monitoring deviations	Mechanical preventive and predictive maintenance based on low-complexity systems and deviations	Equipment Operator
Advanced maintenance	a. Time based (250/500 running hours) b. Based on number of cycles, packages c. Based on condition monitoring deviations	Mechanical–electromechanical preventive and predictive maintenance based on medium-complexity systems and deviations	Equipment Operator
Specialistic maintenance	a. Time based (1000/2000 running hours) b. Based on number of cycles, packages c. Based on condition monitoring deviations	Mechanical–electromechanical preventive and predictive maintenance based on high-complexity systems and deviations	Maintenance Technical Specialist

improve its effectiveness, can be achieved sharing maintenance task lists responsibility in this way:

- Daily cleaning practices 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 h checklists, based on equipment running hours: preventive and predictive maintenance (carried out by equipment operators and shared by maintenance specialists)
- 1000 h checklists, based on equipment running hours: preventive and predictive maintenance (carried out by maintenance specialists and shared by equipment operators)

The checklist content comes directly from the activities carried out in the design phase, and each list is strictly linked to the others, to build up a unique task list structure. The definition of task list responsibility is to be done identifying the right role for the right maintenance task, and then improving personnel commitment and maintenance effectiveness. Moreover, according to the complexity of maintenance tasks, Table 7.1 shows how to split preventive and predictive maintenance tasks and the roles responsible for their implementation. An effective implementation is based on the 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 interactions existing among the parties involved and support provided by the manufacturing management

All these activities have a strong impact on the technical, organizational, and cultural dimensions 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 7.9 summarizes how the task lists designed need to be split for maintenance families in order to be allocated to equipment operators

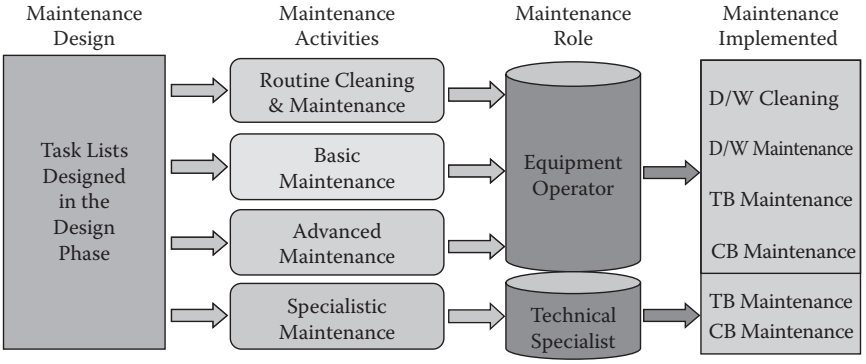


FIGURE 7.9
From task list design to maintenance implementation.

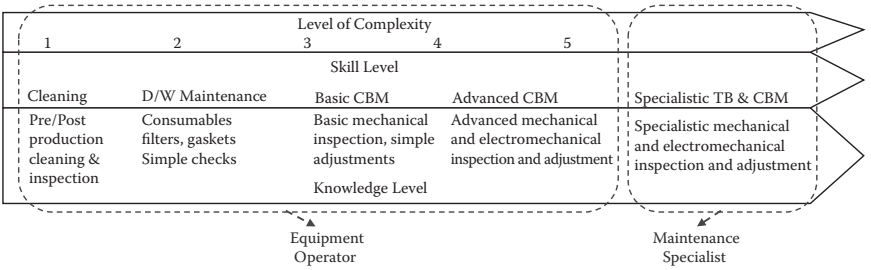


FIGURE 7.10
Level of task list complexity based on skill and knowledge.

and maintenance specialists for their implementation. Daily and weekly (D/W) cleaning and maintenance and time-based (TB) and condition-based (CB) maintenance are implemented by the equipment operators or maintenance specialists according to the complexity of the task list content.[49]

Figure 7.10 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 skill 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 knowledge and experience
- 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 in the 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 nonconformity problems compared 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 7.11, cooperation between operators and maintenance specialists represents a mandatory prerequisite to carry out some maintenance activities where every role alone could experience serious difficulties without the support of the other.

To pursue a real integration between these two complementary roles, it is advisable to enable the operators to implement some maintenance specialist tasks and maintenance specialist to implement some operator tasks. This will produce, as a result, a better awareness of the complexities linked to each role, and the ability to better understand limits and constrictions of the other role and reinforce effective cooperation. Figure 7.11 shows an overlap that represents the area where maintenance tasks can be implemented by both the equipment operators and the maintenance specialist.

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

Table 7.2 shows an example of the checklist to be used for the maintenance task lists designed. The main fields indicate what follows:

- Equipment group/subgroup. This field lists the name of the equipment group or subgroup taken under consideration. This means that the task lists that follow will be referred only to that equipment group.

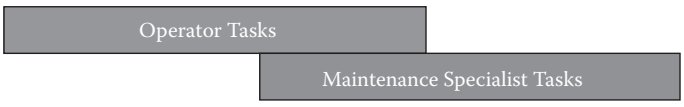


FIGURE 7.11
Overlap between the operator and maintenance specialist.

TABLE 7.2

Checklist Structure

Equipment group/subgroup: 01: Sealing Unit

Section/Description	Action	Role	Documentation	Interval	Average Time (minutes)	Position No.	Result	Notes
Knife integrity	Check/change …	EO-MS	Maintenance manual, p. x	250 W.h	15	10010	Changed	
Inductor profile	Clean/ measure/ replace	EO-MS	Maintenance manual, p. x	250 W.h	10	10011	Cleaned	

- 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 could be check, change, inspect, clean, measure, overhaul, etc.
- Role. The roles identified to implement the specific task list are listed here and 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 indicates 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 could be adjusted, changed, replaced, cleaned, etc.
- 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 templates to be used to carry out each maintenance task, but the most meaningful information is that listed in Table 7.2.

7.3.8 Step 8: Develop Autonomous and Specialist Maintenance Integration

The implementation model acknowledges that the role of the equipment operator is one of the most critical and meaningful for the achievement of sustainable equipment effectiveness. This statement is particularly true in the aseptic liquid food (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. Some crucial cleaning and maintenance activities on sterile equipment can be carried out only by equipment operators. The experience of the machine operator is built on a continuous interaction with the equipment, and this

makes him or her the best person able to pick up on anomalous signals to activate the prevention at the source maintenance policy. According to TPM methodology, 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 a sharp weapon against equipment breakdown. Figure 7.12 shows a full description of the different incremental steps to pursue to implement this methodology in the food industry environment.

1. Initial cleaning. Despite cleaning activities not being generally recognized as professionally qualifying, in the food industry they play a more important role than in other industrial realities. Since cleaning represents a fundamental prerequisite for 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 sequences of operational practices to be put in place.

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 7.12
The route for autonomous maintenance.

Through manual cleaning, operators can detect worn-out parts, moving components that are not moving freely, rollers with surface problems, anomalous residues on mechanical parts, and more generally, failures at their starting phase. The equipment operator gives his or her fundamental contribution to defining the content of good manufacturing cleaning and maintenance practices through OPLs that clearly show the steps of each practice.

2. Eliminate sources of dirt and difficult-to-clean and inspect areas. Among the equipment operator tasks there are the abilities to
   - Discover the reason for dirt
   - Identify a reliable solution for its elimination

   Dirt and residues can be produced by friction and can reveal anomalous behavior of components, but dirt and powder can also be produced by liquid food 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, the equipment operator gives his or her contribution to identify and define the standard contents for cleaning, inspection, and lubrication. No one better than those who are committed to carrying out cleaning and lubrication practices, on daily and weekly bases, can define and improve the relative standards. New ideas on how to inspect and detect potential problems can be properly 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 the company should not serve the standards: standards are important to define the best way to execute a specific activity, and they are essential to avoiding personalisms and uncertainty on how to implement new maintenance procedures.
4. General inspection. Inspection carried out by the equipment operator covers activities not only 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 than the equipment operator can give his or her maximum contribution in this area, and the whole company should promote the operator's involvement in training and participation in improvement team activities.

5. Autonomous inspection. Equipment operator empowerment starts with basic training that enables him or her to know:
   - The working program of the equipment (preheating, sterilization, production, cleaning, etc.), 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 nondestructive) during the production phase and before and after every type of stop
   - How to fix the basic problems regarding short stops
   - How to adjust groups and components to avoid appearance and leakage problems in the final container

   This type of training represents the basic investment that enables the equipment operator to gain standard knowledge of the equipment and how to carry out quality control and basic maintenance. Moreover, to pursue 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 troubleshooting should empower the operator to autonomously fix the basic troubles that produce equipment short stops due to equipment failures or problems in the final package.

   The ability to grow in his or her role and gain a wider possible autonomy depends on stimuli coming from the following:
   - Continuous training
   - Continuous support and dialogue with maintenance and quality specialists

- Continuous participation in the improvement team activities
- Continuous information about his or her 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. Standardization. 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 gray 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 standardize each activity. New ideas to save time, money, or improve safety, quality, and reliability should be regarded not as a disturbance, but as an opportunity to improve the existing standards. Through his or her proactive participation in improvement team activities, the equipment operator can play an important role in defining and improving the company's standards and the standardization process. No one better than him or her can know what to do, how to do it, and when to operate and maintain the equipment effectively.
7. Autonomous management. In the end, autonomous management of the following is carried out by the equipment operator:
   - Equipment operation (pre- and postproduction, production, and cleaning practices)
   - Equipment maintenance
   - Product safety and quality
   - Continuous improvement activities

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

The good manufacturing practices (GMPs) 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 7.13 emphasizes that while the equipment operator is

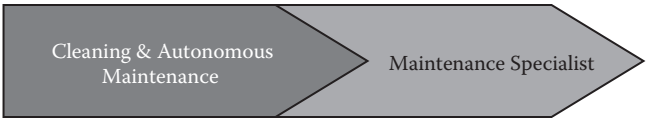


FIGURE 7.13
Synergy between the equipment operator and maintenance specialist.

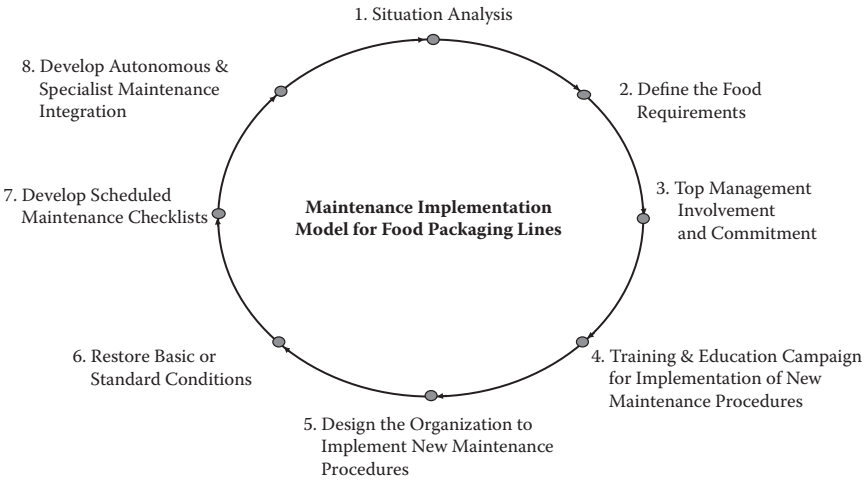


FIGURE 7.14
Maintenance implementation model for food packaging lines.

taking responsibility for cleaning and basic and advanced maintenance implementation, the maintenance specialist is implementing complex preventive and predictive task lists that require higher mechanical and electrical competence.

The task lists implemented under the responsibility of the maintenance specialist should be performed, when possible, together with the equipment operator: this will enable him or her to gain a wider view of the equipment and share his or her experience with the maintenance specialist. Interaction and integration between these two roles represent a fundamental prerequisite to establish a powerful tool for the achievement of the highest food product safety and equipment reliability. The implementation model summarized in Figure 7.14 identifies the main steps that enable the whole company to be committed to an effective implementation of new 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.

7.4 KEY PERFORMANCE INDICATORS (KPIs) TO MONITOR PRODUCTION AND MAINTENANCE EFFECTIVENESS

What performance indicators should be used, and who should be committed to measure maintenance effectiveness? Lord Kelvin (1824–1907) said, "If you can not measure it, you can not improve it." Moreover, in his book on electrical measurements, he said:

> In physical science the first essential step in the direction of learning any subject is to find principles of numerical reckoning and practicable methods for measuring some quality connected with it. I often say that when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind; it may be the beginning of knowledge, but you have scarcely in your thoughts advanced to the state of Science, whatever the matter may be.[31]

The identification of the KPIs that highlight the status of maintenance effectiveness of a food packaging line is discussed in this section with regard to not only technical reliability, but also food quality and safety. Some of the difficulties in gathering measurable information will be highlighted to identify the easiest way to gather and monitor meaningful food packaging line KPIs.

7.4.1 Definitions

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

Actual capacity: The amount of end product produced per hour, during production time, without any stops, e.g., number of filled containers in a filling equipment (including filled containers, bottles ejected or rejected).

Nominal capacity: The capacity of the equipment as stated in the specification. This is the theoretical equipment capacity.

Equipment: The equipment chosen to be investigated, i.e., single machines, part of a production line, or a whole production line.

Approved package/container: A container that has been approved during production (e.g., if an approved container later shows quality problems, it is still to be regarded as approved). The total number of approved containers also includes approved containers taken as samples during production for quality control purposes.

Filled container: A filled container to be regarded as a sealed and closed container, filled with product to intended volume.

Packaging material/container loss: The packaging material or container that has entered the equipment, but does not come out as approved an container sellable in the market.

Manufacturing phases under investigation: The period of time that the equipment is studied; can be divided into the following four phases:

1. Preparation phase. Any working activity or waiting time occurring before production start. The preparation phase starts with the first attempt to prepare, and starts the equipment for planned production and ends when the production phase starts.
2. Production phase. The activity to produce filled containers of food product. The production phase starts with the first attempt to produce containers or packages with the equipment and ends when planned production is done or when for other reasons production is stopped.
3. After-production phase. Any working activity or waiting time that occurs after production stops. 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.
4. Planned maintenance phase. Maintenance and cleaning procedures carried out according to designed criteria and intended to reduce the probability of failure or degradation of equipment effectiveness. The planned maintenance phase starts at the

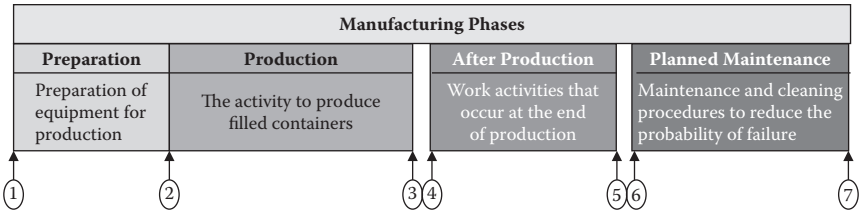


FIGURE 7.15
Manufacturing phases: Preparation, production, after production, and maintenance.

beginning of the first task and ends when planned maintenance has been carried out.

Figure 7.15 shows the four phases under investigation, followed by a short description.

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 have been carried out
6. Beginning of first planned maintenance task
7. Planned maintenance has been carried out

7.4.1.1 Stop Reasons

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

Equipment stops: A stop caused by an equipment failure. An equipment stop can happen during all manufacturing phases. We normally refer to all corrective maintenance activities depending on equipment and due to functional failures.

Other stops: Stops caused by reasons outside the equipment under investigation. Other stop times can happen during all phases. We refer to stop events such as:

- Stop caused by other equipment (different from the one under observation)
- Meals
- Missing information for operating the equipment
- Time necessary to change food product

- Time necessary to change container design, volume, and packaging pattern
- Equipment stopped by the operator for unknown reasons
- Lack of packaging material or containers and other materials
- Lack of services or utilities to the equipment (air, water, steam, electricity, etc.)
- Equipment operator mistakes

This definition is necessary to allocate the stop time to the real source within a packaging line made up of different operating machines.

Time: Figure 7.16 shows the different time segments under consideration, and then a short description highlights the meaning of such definitions. Looking at Figure 7.16, the first consideration refers to the identification of the three main time segments:

- Production phase, which also considers the preparation of the equipment and production
- Other phases, referring to after-production and planned maintenance activities
- Planned downtime, which refers to not working time

Below a short description of different time segments is provided:

- Production time. The working time during which the equipment is performing production of the filled containers delivered to the market.

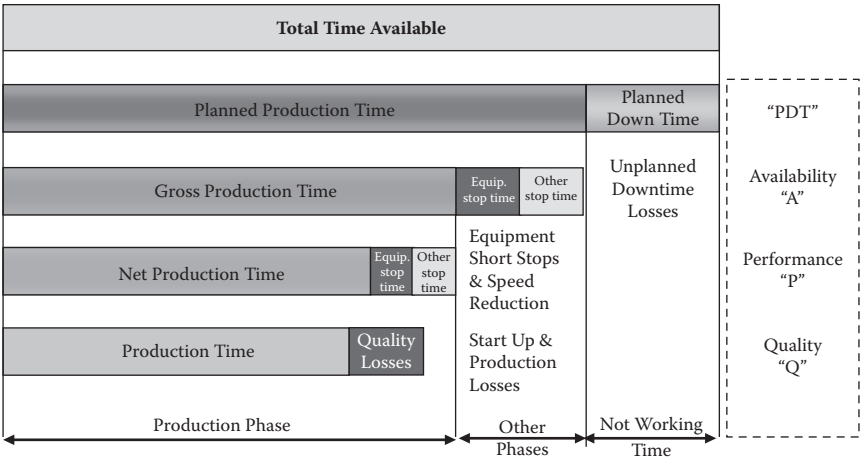


FIGURE 7.16
Total time segments for production activities.

- Net production time. The working time during which the equipment has to carry out production if there are no defects and quality losses during the production phase.
- Operating time. The working time during which the equipment is performing a required function. Operating time can exist during all phases, e.g., production time equals operating time in the production phase.
- Equipment stop time. The time that starts when an equipment stop occurs and lasts until the equipment is back in the same state as it was before the stop occurred. Equipment stop time can exist during all phases.
- Other stop time. The accumulated time interval starting from a stop caused for reasons outside the equipment under consideration and ending when the equipment is back in the same state as it was before the stop occurred. Other stop times can exist during all phases.
- Gross production time. The time during which the equipment would have to perform the required task if there were not equipment stops and other stops due to other reasons, i.e., Gross production time = Production time + Equipment stop time + Other stop time.
- Planned production time. Planned production time = Total time available – Planned down time (Not working time).
- Total time available. The continuous time interval during which the performance of the equipment is considered, for example, 24 h, a week, a month, or a year.
- Planned down time (not working time). The time interval during which the equipment is not used, e.g., when production is not planned. This is time not used for working activities.

7.4.2 Performance Based on Producer View

Producers, differently from people involved in performance analysis of single pieces of equipment, are more interested to identify the utilization of time and capacity available to produce sellable filled containers. The indicators used in this section enable producers to highlight all global factors (technical, organizational, etc.) that influence the performance of the operating packaging line.

7.4.2.1 Total Equipment Utilization (TEU)

Total equipment utilization compares the production time over the total time available:

$$\text{TEU} = \frac{\text{Production Time}}{\text{Total Time Available}}$$

This formula enables us to identify the portion of time effectively used over the total theoretical production time available.

7.4.2.2 Total Time Utilization (TTU)

Total time utilization compares the production time over the planned production time. This formula enables to defines planning, operational, and equipment effectiveness.

$$\text{TTU} = \frac{\text{Production Time}}{\text{Planned Production Time}}$$

Another way to calculate the total time utilization effectiveness is to consider the filled containers produced over the total capacity available in the planned production time.

$$\text{TTU} = \frac{\text{Tot. No. of Filled Containers}}{\text{Planned Production Time} \times \text{Tot. Capacity Available}}$$

7.4.2.3 Gross Production Time (GPT)

Gross production time shows the time used for the production phase. It defines the equipment availability (the one under consideration and other line equipment) for production over the planned production time.

$$\text{GPT} = \frac{\text{Gross Production Time}}{\text{Planned Production Time}}$$

This formula enables us to identify the portion of time effectively used for production over the planned production time available.

7.4.2.4 Production Gross Time Utilization (PGTU)

Production gross time utilization compares the production time to the gross production time. This formula enables us to identify the portion of time effectively used for production over the gross production time available.

$$\text{PGTU} = \frac{\text{Production Time}}{\text{Gross Production Time}}$$

7.4.2.5 Overall Equipment Effectiveness (OEE)

This indicator identifies the real effectiveness of the equipment under consideration, measuring all types of losses that reduce the equipment and production performance.

$$\text{OEE} = \text{Availability} \times \text{Performance} \times \text{Quality}$$

Availability takes into account downtime loss, which includes any event that stops production activity. Among the events we have equipment failures, material shortages, and changeover time (product, packaging material, etc.).

$$\text{Availability} = \text{GPT} = \frac{\text{Gross Production Time}}{\text{Planned Production Time}}$$

Performance takes into account speed loss, which includes any factors that cause the packaging line to run at less than maximum possible speed. This includes equipment wear, poor quality of materials, misfeeds, and operator inefficiency.

$$\text{Performance} = \text{TTU} = \frac{\text{Tot. No. of Filled Containers}}{\text{Planned Production Time} \times \text{Tot. Capacity Available}}$$

Quality takes into account quality loss, which regards packages/containers produced that do not meet quality standards. Quality is the ratio of production time (to produce sellable containers) to planned production time.

$$\text{Quality} = \text{TTU} = \frac{\text{Production Time}}{\text{Planned Production Time}}$$

Quality can be calculated also in this way:

$$\text{Quality} = \frac{\text{Sellable Containers}}{\text{Total Containers Produced}}$$

7.4.2.6 Total Equipment Productivity (TEP)

This indicator enables the producer to evaluate the productive effectiveness of its manufacturing plant considering all technical and managerial factors available:

1. Quality
2. Performance
3. Availability
4. Planning

The formula put together OEE and planned down time (PDT).

$$\text{Total equipment productivity} = \text{OEE} \times \text{PDT}$$

7.4.3 Performance Based on Specific Equipment Focus

The key performance indicators (KPIs) used in this section enable the producer to highlight all technical factors that influence the performance of equipment installed. The formulas used show the efficiency of a specific equipment or part of packaging line under observation.

7.4.3.1 Simple Equipment Efficiency (SEE)

This formula simply defines the equipment efficiency over the production time available. The time segment taken into consideration is the one concerning the production of sellable filled containers to be delivered on the market.

$$\text{SEE} = \frac{\text{Production Time}}{\text{Production Time} + \text{Equipment Stop Time}}$$

7.4.3.2 Mean Time between Failures (MTBF)

This indicator identifies the mean production time existing between equipment failures/quality defects.

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

This formula shows how long (in the production time segment) the equipment is able to produce before equipment failures or quality defects stop the equipment itself.

The production time segment used could be net or gross, and equipment stops considered would be those referred to each specific production time segment.

7.4.3.3 Mean Time to Restore (MTTR)

This indicator identifies the average time necessary to restart the equipment for production after equipment stop.

$$\text{MTTR} = \frac{\text{Equipment Stop Time}}{\text{Number of Equipment Stops}}$$

This formula shows how long the supporting staff is going to take to restart the equipment for production after an equipment failure. This KPI measures the supporting staff effectiveness (supportability) in restoring the equipment for production after an equipment failure. Lack of equipment operators able to implement AM and lack of maintenance specialists could determine high MTTR values, especially when technical service is carried out by a third party coming from a long-distance place.

7.4.4 Performance Based on Containers Used

In this section the containers' (packages, bottles, cans, or containers) performance is measured considering both the utilization and the efficiency.

7.4.4.1 Containers' Utilization (CU)

CU describes the ratio existing between containers at the equipment infeed and the total number of approved containers produced by the equipment.

$$\text{CU} = \frac{\text{Tot. No. of Approved Containers}}{\text{No. of Containers into Equipment}}$$

7.4.4.2 Containers' Efficiency (CE)

This formula describes the containers used to produce filled containers ready for the market. It defines the efficiency of the equipment with regard to the ratio existing between the containers at the equipment infeed and the approved containers delivered at the equipment outfeed. The formula refers to specific equipment taken under consideration and not to other equipment (processing and downstream equipment). The number of containers wasted at another stop refers to the wasted containers produced by other equipment different from that under observation.

$$\text{CE} = \frac{\text{Tot No. of Approved Containers}}{\text{No. of Containers into Equipment} - \text{No. of Containers Wasted at Other Stops}}$$

7.4.5 Examples of Calculation

In Figure 7.17, a practical example of calculation is shown 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):

Preproduction. During equipment preparation, different preproduction program steps must be executed to prepare equipment for production activity; this portion of time is defined as an operating time. The first triangle (on the left) represents a part of preproduction program executed to raise the program at the condition where the equipment 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 (d) segment. If, in restarting 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 executing the last preproduction program steps, to reach the condition where the equipment is ready for production, is the operating time allocated to this group.

Production. Production starts with the first attempt to put the equipment in production to produce filled packages or containers. If, during production activity, represented by the box, allocated

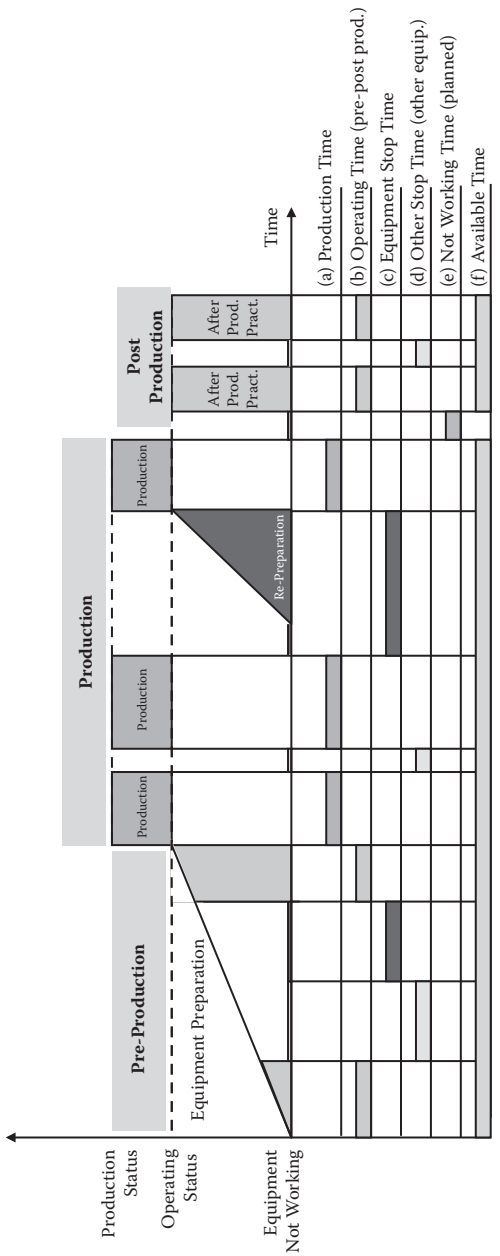


FIGURE 7.17
Production time frames.

to the "production time" group, another short stop is experienced because of lack of compressed air, then this portion of time will be allocated to the "other stop time" group. If, during production phase, the equipment program drops down to the 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."

Postproduction. If, after production activity, the company is not working because of a local holiday, this time, represented by the (e) segment, is stored under the group "not working time." The activities carried out to clean the equipment, after production, are represented by the (b) 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 (d) segment, is stored under the group "other stop time."

The available time, represented by the (f) segment, is the time available for production (preproduction, production, and postproduction) activities without the planned time in which the company is not working.

The correct allocation of every stop time represents a mandatory prerequisite to carry out a reliable performance analysis. The analysis must enable us to identify every source that produces the following:

- Equipment stop
- Setup and adjustment
- Production short stop
- Speed reduction
- Quality defects
- Start-up losses

7.4.5.1 Examples of Data Collected to Calculate the Equipment Performance

1. Production time: 10.5 h
2. Operating time (e.g., preproduction and cleaning activities): 2.5 h
3. Equipment stop time (e.g., containers out of design during production phase): 1 h
4. Other stop time (e.g., missing operator input): 1 h

5. Not working time (not planned): 9 h
6. Available time: 15 h

Number of stops during production phases: 5
Containers into the equipment: 72,347
Containers into the equipment during production phase: 71,670
Containers out (from the equipment): 70,520
Container loss at operating time (2): 575
Container loss at other stop time during production phase (4): 110
Container loss at equipment stop during production phase (3): 465
Total container loss: 575 + 110 + 465 = 1150
Total container loss (containers in – containers out): 71,670 – 70,520 = 1150

Note: The difference between containers in (to the equipment) and the sum of containers out (from the equipment) and loss during production stops is due to containers ejected during the production phase.

7.4.5.2 Calculations Based on Data Collected

Total time utilization (TTU):

$$\text{TTU} = \frac{\text{Production Time}}{\text{Planned Production Time}}$$

$$= 10.5/15 = 0.7 \times 100 = 70\%$$

Containers' utilization (CU):

$$\text{CU} = \frac{\text{Tot. No. Approved Containers}}{\text{No. of Containers into Equipment}}$$

$$= 70{,}520/72{,}347 = 0.9747 \times 100 = 97.47\%$$

Containers' efficiency (CE):

$$\text{CE} = \frac{\text{Tot. No. Approved Containers}}{\text{No. of Containers into Equipment} - \text{No. of Containers Wasted at Other Stops}}$$

$$\text{CE} = 70{,}520/71{,}670 - 110 = 0.9855 \times 100 = 98.55\%$$

Simple equipment efficiency (SEE) during production phase:

$$\text{SEE} = \frac{\text{Production Time}}{\text{Production Time} + \text{Equipment Stop Time}}$$

$$\text{SEE} = 10.5/10.5 + 1 = 0.913 \times 100 = 91.3\%$$

Mean time between failures (MTBF) during production phase:

$$\text{MTBF} = \frac{\text{Production Time}}{\text{Number of Equipment Stops}} = 10.5/5 = 2.1 = 2\text{h } 6\text{min}$$

Mean time to restore during production phase (MTTR):

$$\text{MTTR} = \frac{\text{Equipment Stop Time}}{\text{Number of Equipment Stops}} = 1\text{h}/5 = 12\text{min}$$

Figure 7.18 displays the interaction of indicators such as MTBF, MTTR, and SEE, with the three legs that determine equipment availability:

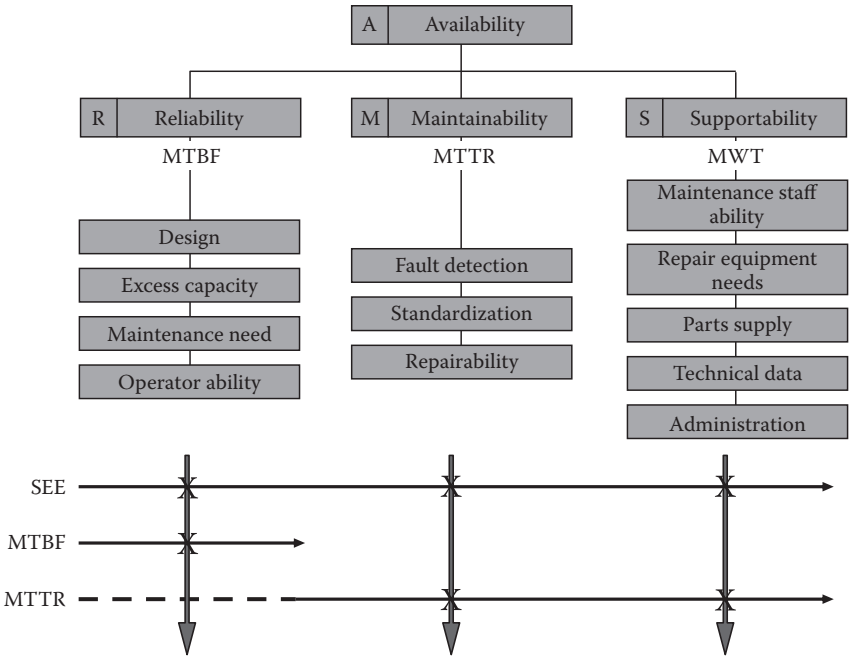


FIGURE 7.18
Equipment availability indicators.

reliability, maintainability, and supportability (ARMS). The 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 the support system available for production activities is also interacting with MTTR.
- Mean waiting time (MWT) 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 a shortage of competency or logistic problems in getting the right competence to carry out equipment troubleshooting.
- SEE is an indicator, referred to as a single equipment performance, that is dependent on the three main availability legs: reliability, maintainability, and supportability.

7.4.6 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 the following:

- Equipment not available when needed because of breakdowns or setup 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 also 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.

$$\% \text{ OEE} = (\% \text{ Availability}) \times (\% \text{ Productivity}) \times (\% \text{ Quality})$$

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.

$$\% \text{ Availability} = \text{Actual production time/Possible production time}$$

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

$$\% \text{ Availability} = (120 - 1 - 7)/(120 - 1) = 112/119 = 94.1\%$$

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 a food packaging line is 40 million packs per year. Last year it produced 37 million packs.

$$\% \text{ Productivity} = \text{Actual production/Optimum capacity} = 37 \text{ million}/40 \text{ million} = 92.5\%$$

The quality rate used in OEE calculations is defined as

$$\% \text{ Quality} = \text{Product produced} - (\text{Scrap and rework})/\text{Product produced}$$

For example, a food packaging line produced 37 million filled containers on a yearly basis, but only 36 million met the commercial specifications on the first pass.

$$\% \text{ Quality} = 37 - (37 - 36)/37 = 37 - 1/37 = 97.3\%$$

$$\text{OEE} = \text{Availability} \times \text{Productivity} \times \text{Quality}$$
$$= 94.1 \times 92.5/100 \times 97.3/100 = 84.7\%$$

Below is another way to calculate OEE:

$$\text{OEE} = \text{Availability} \times \text{Performance} \times \text{Quality}$$

Availability = Planned production time (available time) – Down time/planned production time

Performance = Number of containers produced/Equipment capacity (theoretical) × Production time

Performance takes into account speed loss, which considers any cause that forces the process to run at less than the maximum possible speed or rated speed.

Quality = Number of containers produced – Containers rejected/Number of containers produced

7.4.7 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 food packaging line operation. In this regard a preventive maintenance program represents a real company investment, and the line performance effectiveness is the indicator used to measure the result of this investment. OEE measures the effectiveness of the packaging line, based on line availability, including reduced performance due to speed reduction, and quality of the line (depending on product waste and product quality).

The effectiveness produced by a serious maintenance program will show a positive result on both equipment availability and product quality and safety. In the end, as summarized in Figure 7.19, line effectiveness is the result produced by the equipment availability and product quality.

Moreover, as we are going to see in the next section, a real maintenance effectiveness program should produce added value at a reasonable cost. This means that the added value generated by an effective maintenance design and implementation program will far exceed the cost of maintenance itself.

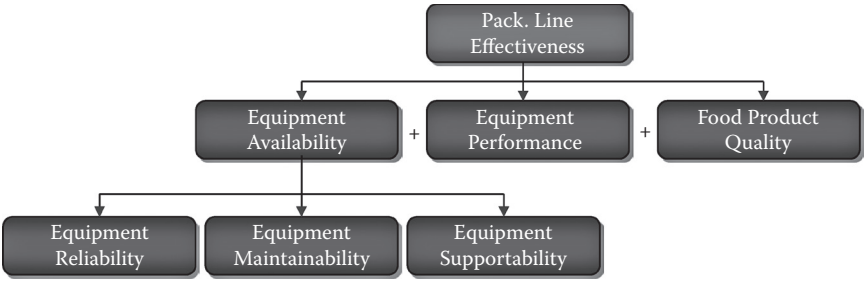


FIGURE 7.19
KPIs to measure packaging line and maintenance effectiveness.

7.5 HOW TO MEASURE MAINTENANCE COST

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 the following:

- 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 quality, line performance, and maintenance cost. Figure 4.43 shows the life cycle profit (LCP) with maintenance cost, which represents the investment that produces an added value measured through the key performance indicators that highlight higher equipment effectiveness and product safety.

- Direct maintenance costs. Direct maintenance costs have to be seen as the investment intended to generate added value in terms of a higher company's competitiveness. These costs normally refer to manpower salaries, spare parts, templates, and technical documentation (necessary to improve equipment supportability).
- Indirect maintenance costs. Indirect maintenance costs are all the costs generated by poor packaging line effectiveness due to lack of maintenance or unreliable maintenance and implementation design. Lack of maintenance affects not only maintenance costs, but also operational and capital costs. In the food industry these costs can be

really heavy and could be due to nonconformity products claimed from the market or, even worse, to product unsterility discovered at the company's warehouse or in the market. Packaging material and product waste represent another source of cost normally produced by a poor maintenance program.

- Loss of revenue. Loss of revenue is produced by the equipment standstill or rejection of products. Every hour of production lost is to be regarded in terms of missing containers sold on the market, and every container rejected represents a damage depending on loss of revenue and waste of money to produce and withdraw the container from the market. This loss can usually be measured through the net profit margin that the company should have earned in selling the packages not produced because of equipment failure. A maintenance program based on a corrective approach only may result in poor equipment availability and unpredicted equipment downtime. Figures 4.44 and 4.45 show the right balance among direct and indirect maintenance costs and loss of revenue.

Below an example drawn from real experience shows the deployment of the indirect costs, loss of revenue, and direct costs of

- Company A, which refused to implement a preventive maintenance program, based on reliability and safety methodologies, with the cost reduction experienced by a similar company.
- Company B, which implemented a preventive maintenance program

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

- Indirect costs of Company A:
  1. Packaging material waste: 4% on 200 million packs/year = 850,000 euro
  2. Product unsterility/year: Two main cases = 35,000 euro
  3. Nonconformity product: 60,000 nonconformity packages = 10,000 euro
  4. Energy loss: Due to equipment downtime = 2000 euro
  5. Chemical loss: Due to cleaning phases following equipment failure = 5000 euro

  Total indirect costs = 902,000 euro

- Indirect costs of Company B:
  1. Packaging material waste: 2% on 200 million packs/year = 423,500 euro
  2. Product unsterility/year: One small case = 10,000 euro
  3. Nonconformity product: 7000 nonconformity packages = 2000 euro
  4. Energy loss: Due to equipment downtime = 1200 euro
  5. Chemical 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 1 year from Company A, compared to Company B, because of equipment inefficiency, is 4 million higher, then the annual loss of revenue of Company A compared 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 the costs of Company B, compared to Company A, were higher than 40,000 euro.

The costs comparison between these two similar companies emphasizes that an investment of 40,000 euro, in a reliable preventive maintenance program (direct cost), has generated the following savings in 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 Company 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 a holistic view of manufacturing reality.

The graphs shown in Figures 4.44 and 4.45 identify the area where an optimum cost balance can be found. A short-term cost view can often be seen as a way to reduce cost, especially during downturn time, but as we saw, it can show terrible effects on indirect maintenance costs and loss of revenue.

Quite often food companies realize the necessity to identify the operational cost for a thousand (or million) filled containers produced.

As shown in Figure 4.46, to identify this cost, in the numerator of the formula used we have to place the following cost elements:

- Spare parts costs
- Service costs (including service carried out by external suppliers)
- Equipment operator costs
- Utility and consumable costs
- Costs of materials/containers waste

In the denominator we place the total number of approved packages/containers that come out from the packaging line.

Because maintenance is sometimes perceived as a disturbance, some manufacturing units consider production as the sole added-value activity that takes place on the shop floor. Where this view prevails, management is characterized by a reactive approach based on short-term problem fixing. As a result, the short-term view of the company's management does not allow the implementation of a competitive maintenance plan (investment) and the realization of the benefits that would come from less operational cost and higher product safety. Below are some maintenance indexes that allow technical managers to show the added value and competitive advantage produced by a reliable maintenance design and implementation.

1. $\dfrac{\text{Maintenance cost}}{\text{Added value}}$

   Maintenance cost includes all costs directly allocated to maintenance activities. Added value means valued production minus expenses due to supply contracts for goods and services from third parties. It measures the incidence of maintenance cost on value added (in terms of increased value that product packed has received at the end of production, minus costs due to third parties).

2. $\dfrac{\text{Maintenance cost}}{\text{Valued annual production}}$

   Maintenance cost includes all costs directly allocated to maintenance activities. Valued annual production is the total production value to the sales price or transfer price (of a company, cost center, etc.) in a year. It measures the incidence of cost of maintenance on product value.

3. $\frac{\text{Maintenance cost}}{\text{Amount produced}}$

   Maintenance costs are all costs directly allocated to maintenance activities. This formula measures the incidence of the cost of maintenance on the quantity produced. It provides guidance on maintenance management, with reference to the volume produced from the plant over the relative period.

4. $\frac{\text{Service hours}}{\text{Amount produced}}$

   This formula measures the incidence of maintenance, in terms of time, on the quantity produced. It provides guidance on maintenance management with reference to the production volume of the plant. It provides a measure of personnel efficiency, equipment and resources used in maintenance, and effectiveness of services done.

7.6 ANALYSIS OF KPIs AND TASK LIST IMPROVEMENT

Once the KPIs used to measure production and maintenance effectiveness have been calculated, the next most important activity concerns a deep analysis necessary to identify critical areas and opportunities for improvement. Among the points to be reexamined we can find:

- A systematic monitoring routine that best suits the food industry environment needs
- The team to be involved in different measuring activities
- The main topics to address during the analysis of KPIs
- The corrective/improvement activities to 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 continuous improvement of 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 conceivable factors that could have a direct impact on effectiveness will be taken into consideration to enhance implementation and maintenance effectiveness.

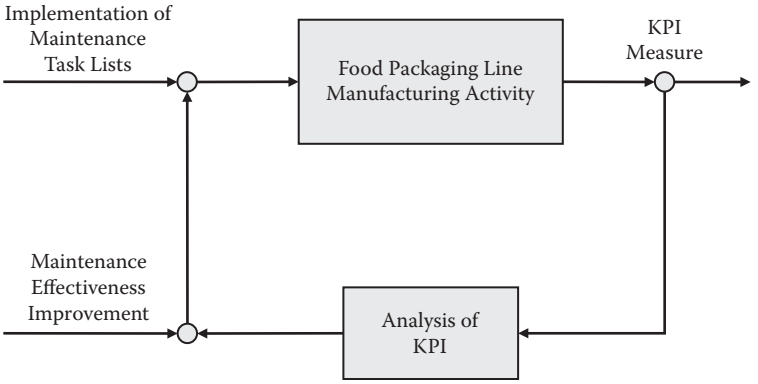


FIGURE 7.20
Analysis of KPIs for maintenance improvement.

As shown in Figure 7.20, analysis of KPIs should always produce, as desired output, some maintenance effectiveness improvement activities. Improvements could regard task list content, the use of further maintenance templates or instruments to improve maintenance reliability, the introduction or change of KPIs, changes in the organization, and so on. If KPIs are not gathered and analyzed to gain a comprehensive understanding of the status of manufacturing and maintenance effectiveness, in order to promote improvement, it is better to avoid gathering them.

7.7 CONCLUSION

In this chapter an analysis of different maintenance implementation models normally used in industry has been done. This analysis produced the identification of the implementation principles to be used in the design of an implementation model proposed for the food industry.

Below is a list of some of the benefits produced by this model:

- It provides a clear pathway to answer the question: How do we avoid losing 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.

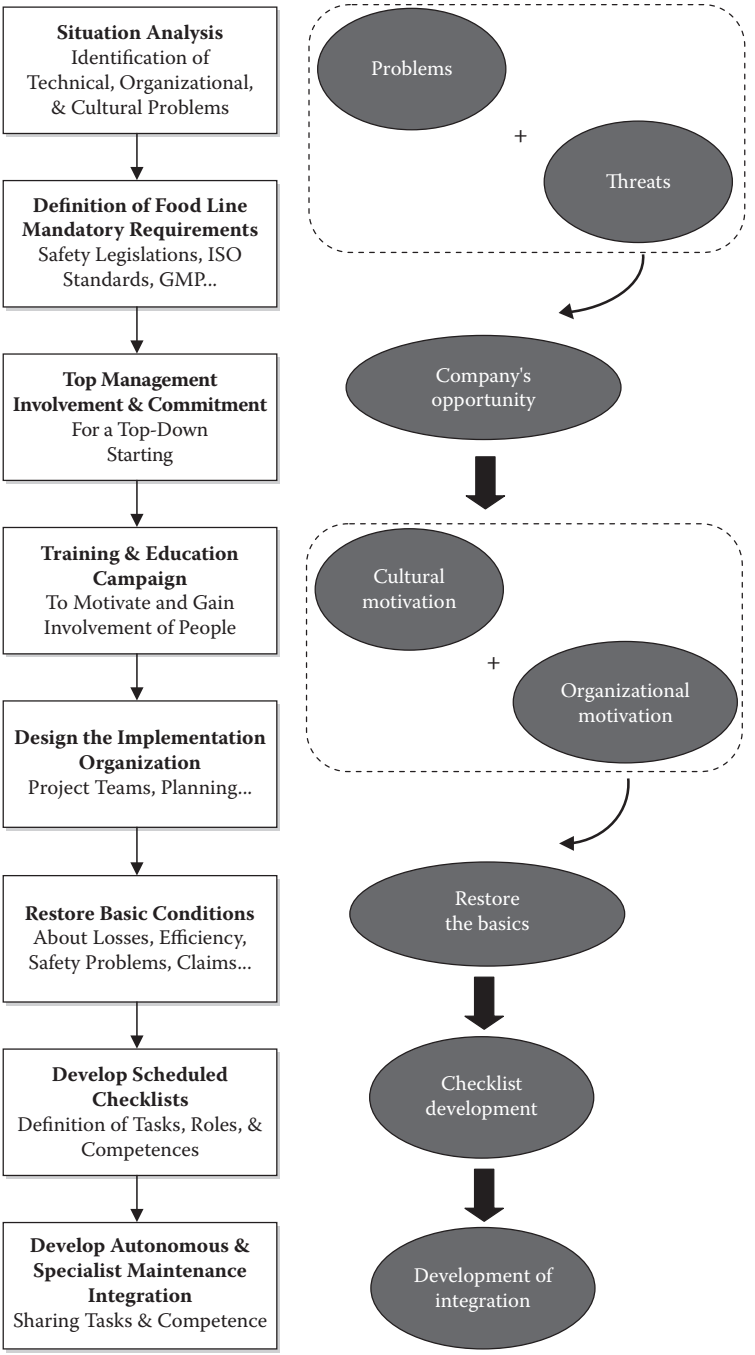


FIGURE 7.21
Proposal of a maintenance implementation model for the food industry.

- 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 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 those tasks.
- It shows the solution for an effective implementation of autonomous maintenance carried out by the equipment operator, that combines all maintenance activities, from cleaning up to inspection and autonomous equipment management.

The model proposed in this chapter and summarized in Figure 7.21 represents an important and original tool to prevent the outcome of the maintenance design phase from being just a good theory without the possibility of delivering real benefits in the real food industry world. Since maintenance represents an investment and not a cost, in this chapter, the different KPIs 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 producer view, and then look at 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, a few basic economical indicators, such as direct and indirect maintenance costs and loss of revenue, were introduced with the scope to provide useful tools to measure the profit and loss (P&L) of the packaging line and to assess if the investment done in maintenance has really produced the expected results.

8

End Product Quality Control

The goal of quality control (QC) is to ensure that materials and food products used in the manufacturing process comply with given specifications. This means that quality control can be done only if quality specifications are clearly established.

Quality control cannot prevent the production of nonconformity products; at best, it can prevent the use or release of such products. Since quality control work is rather expensive, and the confidence level obtained at a reasonable cost is often low, management should implement total quality management (TQM) methodologies in order to rely on quality at the source instead of quality, carried out by QC specialists, on the products, at the end of the production process.

In the food manufacturing process, quality control can be undertaken on

- Raw materials (incoming food products, containers, packaging materials, etc.)
- Intermediate products (products processed: products fed into the heating process and not raw food products)
- End products (product packed and sampled for destructive or nondestructive testing)

Quality control procedures usually concentrate on raw materials and food products used in the manufacturing process, but in this chapter we will examine only quality control procedures carried out on the end products.

8.1 QUALITY CONTROL CARRIED OUT BY THE EQUIPMENT OPERATOR

According to total productive maintenance (TPM) and world-class manufacturing (WCM) methodologies, but in general to TQM principles, the equipment operator plays the most important role in determining the final end product's quality and safety. The effective implementation of good manufacturing practices, regarding pre- and postproduction maintenance and cleaning activities, enables the equipment operator to put under control critical variables such as those regarding equipment sterilization and package integrity. Maintenance tasks, regularly implemented by the equipment operators, allow us to achieve higher equipment reliability with outstanding results on end product quality. Through the implementation of autonomous maintenance (AM) practices and procedures, the equipment operator becomes expert in identifying preliminary signals that may lead to potential or functional failures. His ability to immediately recognize these signals and implement preventive countermeasures to avoid equipment failure produces effective results on end product quality and safety. Quality control carried out on end products allows the equipment operator to monitor the quality performance of his equipment, and then to discover further anomalies and nonconformities, compared to standards, and implement corrective actions to avoid food product quality and safety problems.

8.1.1 Pre- and Postproduction Cleaning and Maintenance Activities on Packaging Machines

Before production can start, the equipment operator needs to execute some important preproduction checks intended to avoid nonconformity problems on product safety and on quality characteristics of the final food product. Among the quality control checks to be executed before production are

- Check and clean the filling section of equipment used for packaging, to avoid product/packaging material residues and dust on filling pipe, on probes, or on floaters.
- Check and clean the forming, sealing, and cutting section to avoid packaging material residues on sealing and cutting elements and sharp residues on forming devices.

- Check and clean the packaging material web components (guide rollers, counter rollers, etc.).
- Check critical parameters of the sterility system: temperatures, pressures, levels of fluids, position of pipes, etc.
- Check the lubrication system, in particular, the effective lubrication of most critical parts or components.
- Check the integrity of product pipe gaskets, seals, gauges, and warning lights.
- Check the level and concentration of chemicals used to sterilize equipment and packaging materials.
- Check safety devices used to avoid incidents and equipment contamination.

Preproduction quality control checks are necessary to establish the highest reliable conditions to start production and avoid equipment stops and nonconformity problems.

8.1.2 Production Quality Control Procedures

During production activity, the equipment operator continues to monitor different critical equipment functions, listening and checking to detect anomalous signals that require a corrective action or further investigation that can be postponed at the end of production. In particular, he regularly checks the following items:

- Weight of filled packages/containers
- Printing information on package/container regarding product packed, its traceability, expiry dates, and other information
- Level and concentration of chemical used as sterilization agent
- Production records are kept updated

Moreover, the equipment operator performs the following quality control checks on filled packages/containers:

Nondestructive quality control. Every 20–30 min, two consecutive packages/containers are taken as samples from the filling equipment outfeed to carry out a nondestructive quality control. The scope of this control is to verify if containers produced comply with quality

specifications. Special attention is normally given to the following parameters:

- Package/container appearance (to avoid package scratches, dents and anomalous ink printing, plastic or glue residues)
- Solid geometry of container (to identify dimensional deviations from standard measures, and potential forming and cutting problems)
- Printing and creasing design (to identify printing quality problems and eventual creasing anomalies)
- Sealing quality and cap tightness (to identify visual nonconformities on container's sealing or on cap tightness)

Destructive quality control. As soon as equipment is stopped or packaging material needs to be spliced or changed, destructive quality control is to be performed on filled containers. The following tests are normally executed on containers produced:

- Package or container integrity is checked through the support of different means, such as air pressure, ultrasonic systems, red ink, and so on. This type of QC allows us to check all critical parameters that may compromise the integrity of containers.
- Container sealing quality (visual inspection, through the support of a magnifying lens, or other media, such as perceptive inks, to identify nonconformities or potential deviations compared to standards).
- Cap/straw/spoon application quality (visual inspection to verify if cap, straw, or spoon has been correctly applied; verify position and glue or sealing tightness).

These types of checks allow the equipment operator to verify if the filling equipment is working according to specifications and to detect potential deviations useful to prevent equipment failures or nonconformity end product problems.

Package/container samples for quality control laboratory. According to the criticality of the product packed and technology used, different sampling methods and quality control procedures can be applied by the quality assurance department.

The standard practice normally allows the equipment operator to sample two or four packages/containers:

- Every 20–40 min
- After packaging material splice or change
- After equipment start or restart for production

Quality specialists can verify if end product conforms to quality specifications such as:

- Package/container dimensions (thickness, rigidity, permeability, etc.)
- Cap, straw, spoon application
- Package/container sealing (longitudinal, transversal, etc.)
- Filled package/container integrity

Quality feedback information provided by QC specialists can enable equipment operators or maintenance specialists to identify potential deviations useful to prevent equipment failure in advance. Effective cooperation among equipment operators, maintenance specialists, and quality experts is an important organizational prerequisite to prevent food safety hazards.

8.2 END PRODUCT CRITICALITIES

A packaging material or container used for packing liquid foods can be made up of several layers of different materials or of plastic, glass, metal, or a combination of them. A package, bottle, can, or flexible container must not only protect its liquid, solid, or semisolid food content against mechanical impact, but also preserve the goodness of its content from biological hazards coming from different environmental sources. For long-life products special care needs to be taken to avoid deterioration of food for the whole shelf life period. Containers must protect their food content during their lifetime and under conditions involving indoor or outdoor storage, transportation, display on the supermarket shelf, and stay in a final consumer residence. Under normal circumstances, containers must protect their food content from:

- External humidity
- Light (artificial and sunlight)
- Oxygen
- Gases
- External bad flavors
- External moisture

Moreover, according to the acidity and content of food packed the materials used in the container may have special features to avoid deterioration

of the food product. Plastic used might be low- or high-density polyethylene (PE), polypropylene (PPP), polythene terephthalate (PET), and PE with a silicon oxide barrier coating (SiO_2). An aluminum layer, normally in the order of a few micrometers, may have a variable thickness according to the concentration of aggressive agents like salt or alcohol mixed in the food product.

One or more of these container characteristics being out of specification may compromise the quality or safety of the product packed. Container nonconformities can be caused either in the manufacturing process of packaging material or in food packaging. While preventive, predictive, and proactive maintenance play a fundamental role in establishing quality at the source, QC needs to be performed to avoid food quality and safety problems. QC activity should primarily be performed by the equipment operator who has full ownership and responsibility of the product packed.

The equipment operator should have at his or her disposal the tools, templates, and measuring instruments (as shown in Figure 8.1) necessary

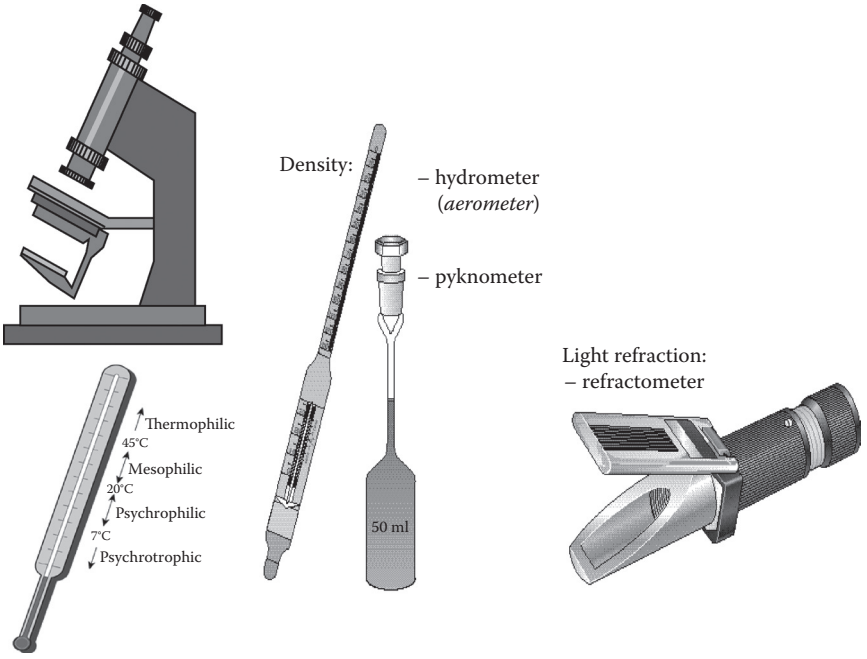


FIGURE 8.1
Quality control tools.

to perform simple and quick quality control checks intended to give him or her good confidence about the quality and safety of the product packed. More complex quality control tests, on containers shown in Figure 8.2, should be performed in a separate laboratory to gain a medium- to long-term quality view of the product packed.

Ultrasonic and laser systems can be used to identify packaging material pinholes, thickness, or dimensional variations. Pneumatic systems, with pressure sensors, and different types of red inks can be used to discover micro-leakages in containers.

Figure 8.3 shows a simple system to verify package integrity or detect leakages in flexible containers like plastic or carton containers. Containers have to be cut and put in an electrolytic solution made by water and salt; the solution used is to be introduced inside the container (on the side in contact with food product) to enable the solution to be in contact with the external and internal sides of the container. An ammeter, able to measure a few microamps, is to be used to check if an electrical conductivity can be established between the two probes. An electrical current of a few microamps will indicate that a small resistance is found, relative to a micro-hole of variable dimensions. The higher the electrical current measured, the larger the size of the micro-hole found.

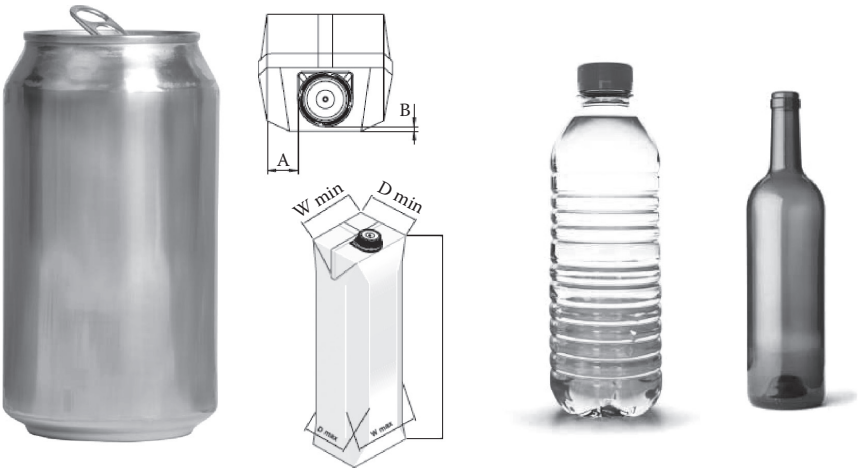


FIGURE 8.2
Different types of food containers.

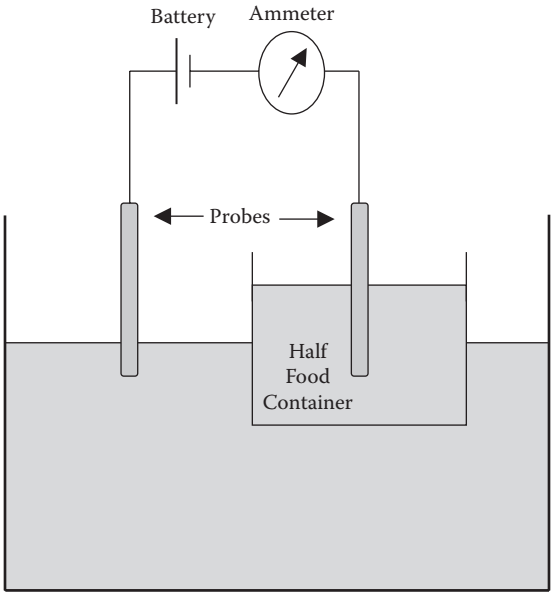


FIGURE 8.3
Electrolytic test.

8.3 STATISTICAL SAMPLING

An ultra-high-temperature (UHT) production line consists essentially of three main elements:

- Raw product
- UHT thermal stabilization treatment
- Aseptic packaging

The procedures used to control the functionality of a UHT food packaging line, including the connection with the filling equipment, refer to a statistical sampling system. There are at least two reasons why a quality control could be performed:

1. To protect the final consumer and the company's reputation
2. To get real knowledge about the effectiveness of the production process

The first reason is, of course, the most important, but the second helps to support the first. Quality control is a management tool to protect the final consumer, and since the result of a statistical analysis will always be in terms of probability, it is a management task to establish such a probability level.

8.3.1 Sampling Plan

A food packaging line producing a single type of food could produce more than 100,000 filled containers for each production shift; despite our target being the achievement of 100% of our quality and efficiency results, we face the problem of detecting a rare event in a large population of containers produced. An appropriate sampling plan can be implemented only if:

1. The prevailing statistical situation is well known,
2. Management's decisions are clearly defined

The statistical laws always take into account all variables introduced into a system; among these we find, for example:

- Raw product characteristics, such as total bacterial count, milk proteins, and fat content
- Characteristics of equipment used for heat treatment intended to stabilize the food product for its whole shelf life
- Packaging line characteristics (equipment, layout, etc.)
- Manufacturing environmental characteristics

The environmental conditions in which production takes place, cleaning, preventive maintenance, and facilities management are some of the factors to estimate the variable of the system. Historical figures on product nonconformities (food quality and safety problems) and equipment and packaging line effectiveness represent important information useful to better characterize this variable.

During the sterility routine checks, we are searching for a rare attribute: the contaminated pack that fortunately represents the exception and not the rule.

The statistical evaluation of a low-frequency attribute is often described and characterized by the Poisson distribution through the graph shown in Figure 8.4.

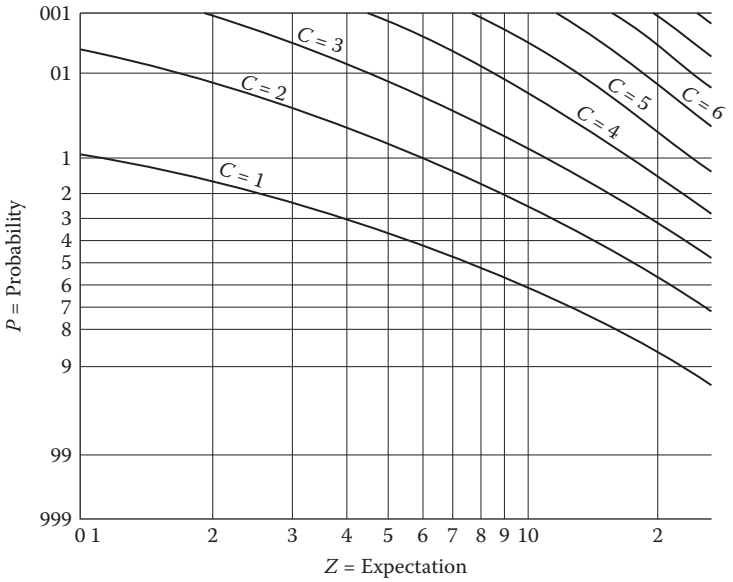


FIGURE 8.4
Poisson probability rate. (From Tetra Pak, *Quality Control Manual*, Issue 8605, 1986.)

This graph highlights that probability P is shown with an event that happens at least C times if the expected number of the event is Z. The number of samples needed is given by the following equation:

$$n = 100 \times Z/\text{defect rate}$$

Implementation of a sampling plan involves the use of statistical methods. The results thus obtained with these methods will be expressed in terms of probability rather than certainty. Since the probability of finding a defective package or container in a batch produced is close to zero, the event is to be considered a rare event, and the Poisson distribution allows us to find the probability that this event may occur. In a continuous probability distribution we find a random variable (X) that is distributed with a mean μ and a given variance. The variance (or standard deviation) is the measure of dispersion of values of the random variable all around the mean μ.

Figure 8.5 graphically illustrates two continuous distributions having the same mean μ value, but with different standard deviations.

As we shall see, X is a discrete variable that can take values such as 0, 1, 2, etc., so that the probability function of X is

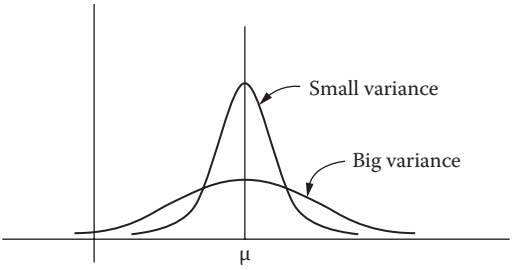


FIGURE 8.5
Two continuous distributions with the same mean value.

$$f(x) = P(X) = \frac{\mu^x e^{-\mu}}{x!}$$

while the mean value μ is the positive constant given by us.

In this type of distribution the number of samples (n) is large and the probability $P(x)$ that an event x (defective package/container) occurs is close to zero.

Table 8.1 contains figures that refer to a sampling system where levels of defect expected are 0.1, 0.2, and 0.5% with a batch of samples of 50, 100, 500, and 1000 units.

Table 8.1 is made up as follows:

- The first horizontal line at the top represents the proportion (p) of defective packages/containers (example: 0.001 = one defective in 1000).
- The second row represents the batch (n) of packages/containers sampled.
- The third line represents the average of defective packages expected in the sampled batch ($\mu = p \times n$).
- The fourth to the eighth row represent the probability that one, two, three, four, five, or more packages are defective in the sampled batch.
- The vertical columns show the probability of finding the defectiveness in a batch of 50, 100, 500, and 1000 packages/containers, with a proportion of defectiveness of 0.001, 0.002 and 0.005.

If we consider the case concerning the probability of finding 2 or more defective packages in a sampling of 500 packs, with the proportion of 1 defective in a 1000, the calculation to be carried out is as follows:

$$P(x > 1) = 1 - [P(x = 0) + P(x = 1)]$$

TABLE 8.1

Probability of Finding One or More Defective Units within a Defined Sample

Proportion of Defectives within the Production (p)	**0.001**				**0.002**				**0.005**			
Number of Units Drawn (n)	**50**	**100**	**500**	**1000**	**50**	**100**	**500**	**1000**	**50**	**100**	**500**	**1000**
Expected number of defective units in sample drawn ($p \times n$)	0.05	0.1	0.5	1	0.1	0.2	1	2	0.25	0.5	2.5	5
Probability that one or more defective units have been found in the sample		0.1	0.4	0.53	0.1	0.18	0.63	0.87	0.24	0.4	0.92	0.99
Probability that two or more defective units have been found in the sample			0.09	0.26	0.008	0.02	0.26	0.6	0.03	0.09	0.7	0.95
Probability that three or more defective units have been found in the sample			0.02	0.09		0.002	0.09	0.33	0.005	0.02	0.45	0.88
Probability that four or more defective units have been found in the sample			0.002	0.03			0.03	0.16		0.002	0.3	0.75
Probability that five or more defective units have been found in the sample				0.007			0.007	0.08			0.11	0.59

According to the formula previously seen, from the Poisson distribution we get

$$f(x)=P(x)=\frac{\mu^x e^{-\mu}}{x!} \quad \rightarrow \quad 1-\left[\frac{0.5^0 e^{-0.5}}{0!}+\frac{0.5^1 e^{-0.5}}{1!}\right]$$

$$P(x > 1) = 1 - [0.606 + 0.303] = 0.0901$$

In the calculation done, $P(x)$ represents the probability of finding a number x of defective packages/containers in the sampled batch, while $\mu = p \times n$ is the mean.

In the example done, the mean μ is calculated as follows:

- n = number of sampled containers
- p = proportion of defective containers in the production
- $\mu = p \times n = 0.001 \times 500 = 0.5$

Below we still consider the case concerning the probability of finding 2 or more defective packages in a sampling of 1000 packs, with the proportion of 1 defective in a 1000.

$$f(x)=P(x)=\frac{\mu^x e^{-\mu}}{x!}$$

$$P(x > 1) = 1 - [P(x = 0) + P(x = 1)]$$

$$1-\left[\frac{1^0 e^{-1}}{0!}+\frac{1^1 e^{-1}}{1!}\right]=1-\left[0.3678+0.3678\right]=0.2644$$

Consider now the case concerning the probability of finding 3 or more defective packages in a sampling of 1000 packs, with the proportion of 2 defective in a 1000. The calculation to be carried out is as follows:

$$f(x)=P(X)=\frac{\mu^x e^{-\mu}}{x!}$$

$$P(x > 2) = 1 - [P(x = 0) + P(x = 1) + P(x = 2)]$$

$$1-\left[\frac{2^0 e^{-2}}{0!}+\frac{2^1 e^{-2}}{1!}+\frac{2^2 e^{-2}}{2!}\right]=1-[0.13+0.27+0.27]=0.33$$

As shown in the previous examples, the data necessary to find the probability that, in a batch of sampled packages, a number of x defectives can be identified are summarized below:

- Proportion (p) of defectiveness over a production span (e.g., 1 in a 1000, 1 in 5000, 1 in 10,000, etc.)
- Number (n) of units sampled
- Number x of defective packages to be discovered in the batch sampled

As the examples previously seen relate to Table 8.1, other tables, with different characteristics, can be established to represent the data that distinguish a specific activity. Obviously, it is not realistic to pick, incubate, and control 1000 samples for each production shift: such an operation, which involves a massive sampling of packages, is recommended only for plant start-up procedures. Once the target efficiency of the entire packaging line has been tested and achieved, quality control will only be done to check the proper functioning of the system, i.e., for monitoring needed to display extraordinary events, rather than the verification of functional features of the plant.

For these two conditions (line start-up and production monitoring) different schemes are proposed. When starting up an aseptic filling system or a packaging line, it is recommended, immediately after installation, to perform three productions of 3000 packages each to check the functionality of the line. During the first three or four production runs, which involve a greater risk, dependent on several new factors, it is recommended to sample 500–600 containers per production shift. Figure 8.6 shows the characteristics of a sampling system built for 500 and 600 samples, respectively.

On the abscissa we find the probability percentage of defective packages (0.5%, 1%, etc., meaning 5 or 10 packages over 1000 sampled), and on the ordinate we have the probability percentage of finding defectives, and curves that relate to batches of 500–600 packs to discover 1, 2, 3, or 4 defective packages. Through a sampling of 500 packs, a defective rate of 1% will be detectable, for example, to 95% (confidence level). Once a daily routine has been established, samples can be reduced down to the levels of 500 to 100 units per production run. Figure 8.7 shows the characteristics of samples for batches of 50, 75, and 100 units for a production run.

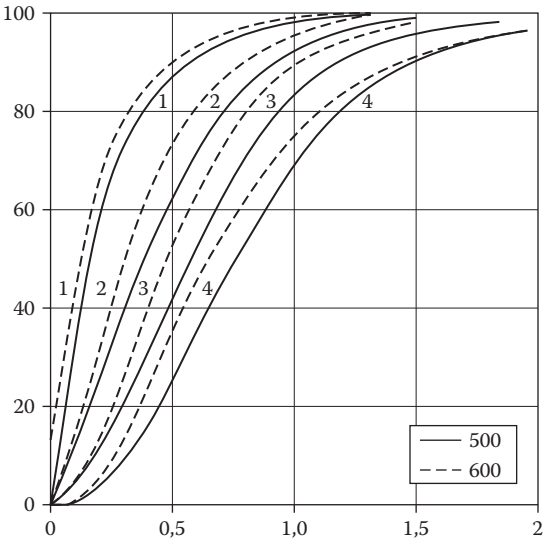


FIGURE 8.6
Sampling diagram for 500 and 600 samples. (From Tetra Pak, *Quality Control Manual*, Issue 8605, 1986.)

These drawings highlight that only a high percentage of defectiveness can be shown. It is therefore necessary to remember that these patterns are not intended to determine the efficiency of a packaging line, but represent a ringing bell alarm in the event of an error or extraordinary fault. Figure 8.8 shows the trend of defective units that may be detected in a sample batch as a function of days of package incubation.

From this diagram it is possible to note that 100%, i.e., the discovery of all defectives, is never reached, and it is also possible to find defectives during the first day of incubation. On the third day about 50% of the total number of defective units can be found. After 5 days of incubation 80–85% of defective units can be discovered.

8.3.2 How and When to Sample Containers

A QC result, with reasonable accuracy, is only possible with a large number of samples, but in order to establish a sampling plan, two parameters must be known:

1. The detection level or the rate of defect to be checked
2. The confidence level or the probability level

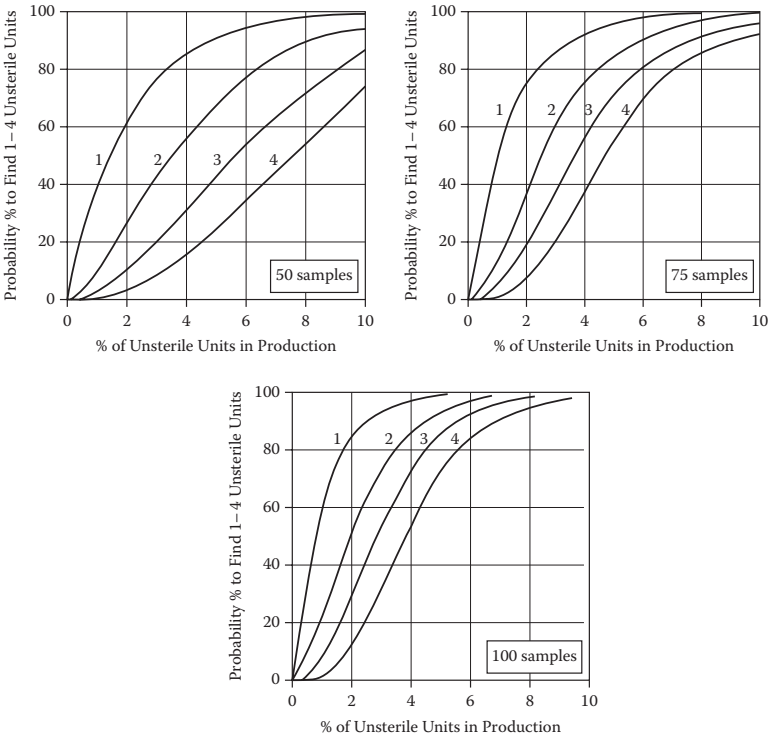


FIGURE 8.7
Diagrams showing sample batch characteristics. (From Tetra Pak, *Quality Control Manual*, Issue 8605, 1986.)

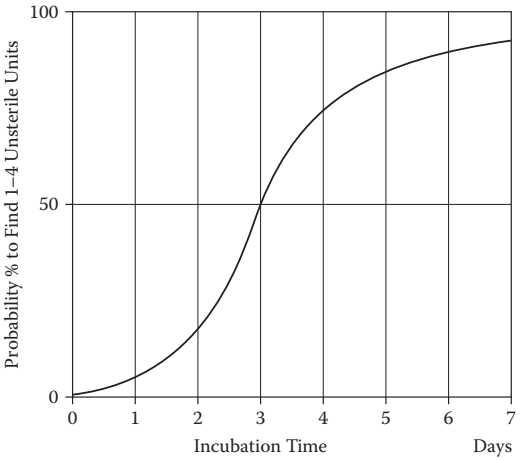


FIGURE 8.8
Trend of defective units on time. (From Tetra Pak, *Quality Control Manual*, Issue 8605, 1986.)

The question that every producer is going to ask is: How many random samples should be taken from a production run? And, moreover, how do we reduce the sample size?

The answer to this question depends on many factors, but among the most important we find:

- The packaging line effectiveness (efficiency and quality) over the time
- The quality and safety of the product packed, as shown by statistical figures taken over the short, medium, and long term

Standard recommendations for the aseptic liquid food industry suggest a minimum sampling scheme of 50–100 samples per packaging line, per production shift. However, even such a sampling will only detect a defective rate of 2–5% with a 90% probability. In these circumstances, one unsterile package could be an indicator of a larger number of defective units in the store.

The following principle applies to Poisson distribution situations:

- The sample size minimum is 10 containers.
- The sample size is less than 10% of the total batch from which the samples are drawn.
- The defective rate is less than 10%.
- The defective units are evenly distributed over the production run.

Just as an example, if 100 containers are sampled from a production run and following a quality control one defective container is found, what is the defective level in the production? In this case, the answer is really simple: 1/100, or 1%.

If we use the graph shown in Figure 8.9 and proceed horizontally along the 100 line until it crosses the 90 and 99% *P* probability lines, these correspond to less than 2.3% at the 90% confidence level and less than 4.7% at the 99% confidence level.

Table 8.2 shows that a large number of sample containers are required if low defect rates have to be found with a high degree of probability. Consequently, if the number of samples is drawn, the probability to find even higher defect rates is low.

Sampling can be done in two different ways: random or aimed. In random sampling schemes every container should have the same opportunity

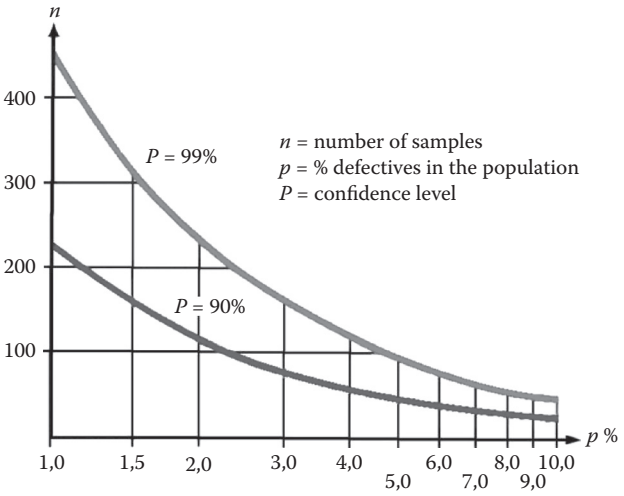


FIGURE 8.9
Sampling graph to find one defective unit.

TABLE 8.2

Packages Needed to Detect Defective Rates

Defective Rate	Risk %	Packages Needed
1:10,000	10	23,000
	5	35,000
	1	46,000
	0.1	70,000
1:1000	10	2300
	5	3500
	1	4600
	0.1	7000
1:100	10	230
	5	350, etc.

to be included in the sample. However, in practice, the production of long-life products is often characterized by an uneven defect distribution caused by a large number of different reinfection possibilities. For practical reasons, a certain number of containers are drawn at regular time intervals. Accumulated sampling will give the average unsterility rate of a production line and will eventually show if a production line fulfills the requirements of the acceptable quality level (AQL) on an average level. AQL for long-life food products is often defined as the maximum

acceptable microbiological defect rate. Aimed sampling concentrates on areas or events where microbiological risk increases. Such situations arise whenever production conditions are changed. In a long-life food production, such functions are as follows:

- Production start
- Change of packaging material reels
- Change of auxiliary materials (longitudinal strip, etc.)
- Change of intermediate product (raw material)
- Change from sterilizer to tank, and vice versa
- Production start or restart after an equipment stop
- End of production

For each production line, areas or events of increased risk have to be identified separately. Since aimed sampling is normally concentrated on functions with an increased risk of defectives, the results obtained will show higher defect rates than the one obtained by random sampling. The goal of aimed sampling is to quantify the contributions that certain risk areas have on the total defective rate.

Normally aimed and random sampling can be mixed together according to the type of food product packed, equipment, and packaging material or container used. If we consider Figure 8.10, showing different production events regarding the production of aseptic milk, as soon as production starts, concentrated sampling (aimed) is suggested to be sure that both product and packaging line conform to standards and specifications. Depending on equipment start-up, product packed, and equipment technology, product sampling for this event can be concentrated, uniformly distributed, or decreasing to zero.

At production start (2) we check if all critical production parameters, like pressures, temperatures, and mechanical functions, comply with specifications.

If a container is formed and sealed in the aseptic filler we have to be sure that the material used and the container design are within specifications, and the forming and sealing sections are running smoothly. If this ramp-up phase is short, then the equipment easily enters in a state of equilibrium, and we can concentrate sampling at the beginning to decrease to zero or to a random sampling scheme as soon as the equipment is permanently stable in production. At production restart (4), after short stop (3), aimed sampling will help detect potential anomalies. As the equipment

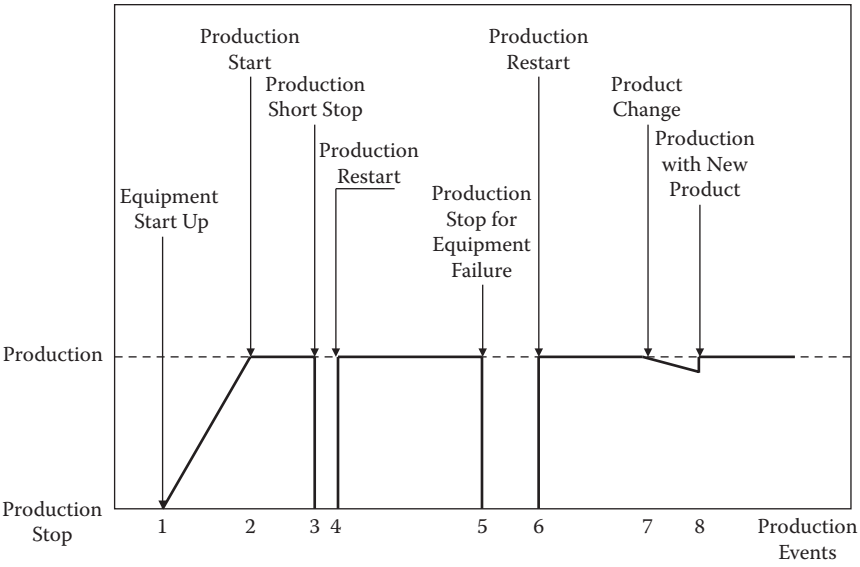


FIGURE 8.10
Production events.

is smoothly running in production, random sampling can be reduced as much as historical statistical figures enable doing so. An even time and quantity sampling could represent a waste of money and be synonymous with a lack of knowledge on equipment and product quality performance. As soon as production stops for equipment failure (5), at production restart (6), the sampling scheme can be changed according to stop time or the type of maintenance activity carried out to fix the equipment failure. When product is changed between events (7) and (8), sampling is done to control the quality of the product over the whole event.

8.3.3 Distribution of Defective Units

The finding of one unsterile package could be an indicator of a bigger problem. If one or more unsterile samples are detected, a resampling plan must be activated. Bacteriological testing should be done on all defective units found to identify the type of bacterial flora growing in the food product. Depending on the food product packed, the time that unsterility takes to develop can be as short as 24 h or as long as 3–4 weeks. Rapid development of spoilage, 24–72 h, may be an indication of an air-waterborne

reinfection. Slow development, 3–4 weeks, may be an indication of process survivors, a cleaning problem, or a container integrity problem. On average, and depending to a certain extent upon the method of evaluation, about 50% of the total number of defectives can be detected after 3 days of incubation in a thermostatic room. This percentage increases to about 75 and 85% after 5 or 7 days of incubation at 30–35°C.

Figure 8.11 shows valuable information that can be gathered from the distribution of defective units over a production run. This type of information can be obtained by plotting the rate or number of unsterile packages against time segments of a single production run. Such patterns are very helpful in identifying possible areas from which the problem may come. The patterns shown in Figure 8.11 highlight:

1. Production starts with no unsterility at the beginning, but bacterial load progressively increases as soon as we approach the end of a production shift. From experience, this progressive growing of a bacterial load is normally dependent on the presence of dirty residues in the filling system. If, for instance, following equipment cleaning, a small dirty residue remains in the filling pipe, this can produce a soft contamination at the production start, with a successive progressive growing of bacterial load.
2. Production starts with a high degree of unsterility at the beginning, but it disappears after some time. This case may be dependent on the presence of a very small bacterial load, due to a cleaning or presterilization problem, that is washed away by the sterile product flowing in the filling pipe.

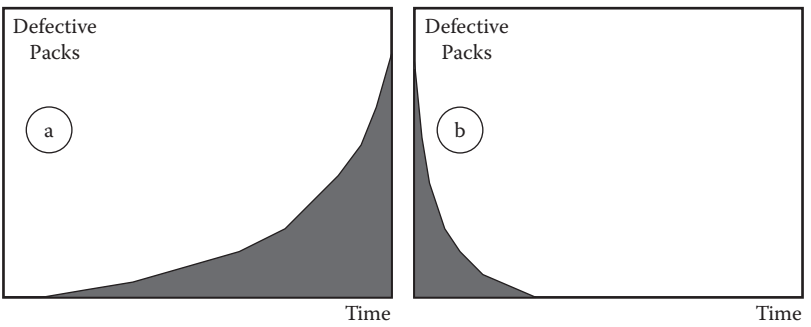


FIGURE 8.11
Distribution of defective units 1 and 2.

Figure 8.12 shows two more unsterility patterns to highlight:

3. Production starts with high degree of unsterility at the beginning, but this is going to maintain a low steady value after some time. This event could be similar to case 2, but with a constant level of unsterility dependent on a small to medium bacterial load remaining in the product filling line.
4. This graph shows regular peaks of unsterility. This trend may be dependent on many different causes, such as a faulty packaging material splice, regular container integrity loss, and so on. A sharp edge of a conveyor guide may cut a flexible container, producing an integrity loss and then an unsterility pattern similar to this.

The patterns shown in Figure 8.13 describe the individual productions during the affected time period. If a pattern of unsterility can be

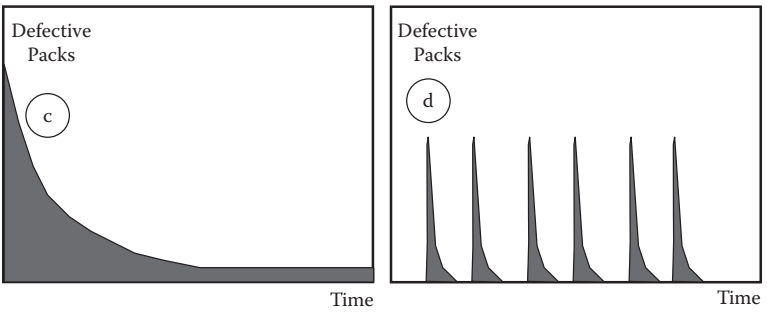


FIGURE 8.12
Distribution of defective units 3 and 4.

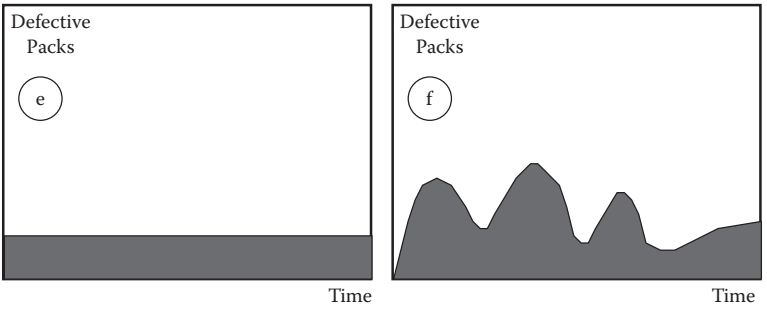


FIGURE 8.13
Distribution of defective units 5 and 6.

established, it can serve as a good indication of the area in which to start looking during troubleshooting.

These patterns show:

5. An even distribution of defective units over the entire production run. This is a stable unsterility that can be due to a low product sterilization efficiency dependent on many causes.
6. High defect rate, but varying in intensity. Contamination peaks need to be examined to better understand the potential causes of unsterility.

The patterns shown in Figure 8.14 highlight:

7. A high defect rate (peak) in the middle of the production run, and then a rapid return to normality. This case might be dependent on a transitory contamination in the filling or in the forming section of an aseptic filler.
8. High defect rate, after some time from production start, that slowly increases over time. If, during production, bacteria living in the air or in the water enter in the sterile environment of an aseptic filler, these can produce this type of contamination distribution.

In order to make equipment operators and maintenance specialists aware of consequences produced by the unsterility cases shown in this section, it is important that quality specialists use their competence to train these two company roles on potential causes that stand behind these

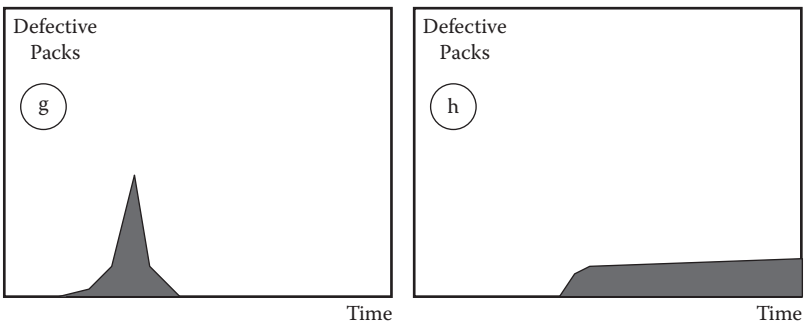


FIGURE 8.14
Distribution of defective units 7 and 8.

unsterility patterns. Equipment operators and maintenance specialists must be involved in the troubleshooting activity necessary to identify the cause of any unsterility case. Experience shows that lack of cleaning effectiveness, dependent on equipment failure or on human error, is often one of the most common reasons for food product contamination. Application of simple productive maintenance procedures, implemented by the equipment operators, can save final consumers and companies from heavy and dangerous consequences.

8.3.4 Why Process Quality Is So Important

Quality control of filled containers is usually based on at least one or more measurable characteristics that are used to specify output quality. These can be analyzed statistically. Once we define some measurable quality performance indicators that enable us to identify the process quality performance of our packaging line, we can then statistically measure the process quality of our manufacturing line. Where the output data show a normal distribution, the process can be described by the process mean (average) and the standard deviation.

A control chart can be used to determine whether the process is in statistical control. The batch of data obtained from end product quality control enables us to measure the output of the process. The more data that are included, the more precise the result; however, an estimation can be achieved with few data points. Quality figures have to be taken from different production runs, including start-ups, equipment stops, production restarts after stops due to equipment failures, and so on. The process mean (average) and standard deviation need to be calculated. With a normal distribution, the tails can extend well beyond ±3 standard deviations, but this interval should contain about 99.73% of the production output.

Normally, most industry manufacturers rate product quality as a key driver of their overall ability to satisfy customers and compete in a global market. Poor product quality, based on objective measures or specifications, is not tolerated. Finished products must comply with the organization's quality standards to minimize costs. While many companies still think of quality in terms of being in specification, the food industry needs to focus on reducing variation to minimize product waste and produce filled containers that consistently perform well over time. For this reason, quality is to be thought of as a function or a result inversely proportional to process variation. This means that as variation increases, product quality

decreases. The standard deviation is a statistical figure that describes the amount of variation in a measured process characteristic. Food manufacturing producers should specify how much a specific measurement, regarding end product quality (food and its container), should be expected to deviate from the mean on average. As shown in Figure 8.15, the larger the standard deviation, the more dispersion there is in the process data.

Statistical sampling and regular analysis of defect rates, and proactive alerts sent to production managers and people involved when quality thresholds are exceeded, enable companies to achieve a true competitive advantage. The two processes shown in Figure 8.15 have the same mean (average), but different standard deviations.

A smaller standard deviation (average dispersion of values around the mean) means:

- Greater consistency
- Greater predictability
- Greater quality

The formula for calculating the true process standard deviation is

$$\sigma = \sqrt{\frac{\sum_{i=1}^{N} (X_i - \mu)^2}{N}}$$

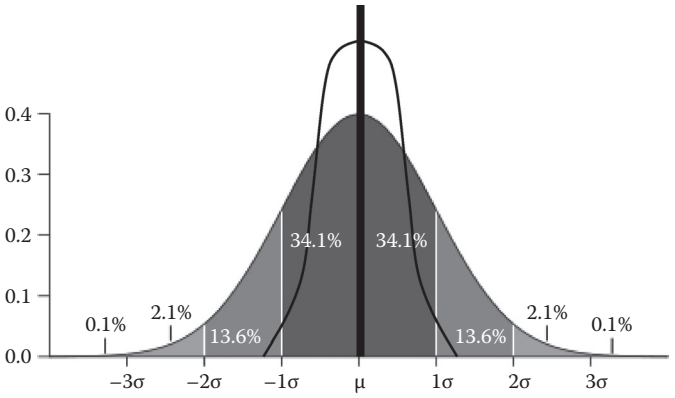


FIGURE 8.15
Standard deviation.

where X_i = the ith data value, μ = the true quality process average, and N = the population size. Essentially, the formula tells us to do the following:

1. Calculate the process average μ.
2. Subtract the process average from each measured data value (the X_i values).
3. Square each of the deviations calculated in step 2.
4. Add up all of the squared deviations computed in step 3.
5. Divide the result of step 4 by the sample size.
6. Finally, take the square root of the step 5 as result.

A simple application is given as an example: A measurable process parameter, like the one regarding package or container forming and sealing, has shown the following measurement results:

46.3, 48.4, 47.1, 45.8, 48.0, 50.1, 46.7, 48.5

The standard deviation of the height process measures is found using the above formula and steps:

1. Calculate the process average μ:

$$\mu = \frac{46.3+48.4+47.1+45.8+48.0+50.1+46.7+48.5}{8} = 47.6$$

2. Subtract the process average from each measured data value (the X_i values);
3. Square each of the deviations calculated in step 2.
4. Add up all of the squared deviations calculated in step 3.
5. Divide the result of step 4 by the sample size.
6. Finally, take the square root of step 5 as a result:

$$\sigma = \sqrt{\frac{\begin{array}{l}(46.3-47.6)^2+(48.4-47.6)^2+(47.1-47.6)^2+(45.8-47.6)^2 \\ +(48.0-47.6)^2+(50.1-47.6)^2+(46.7-47.6)^2+(48.5-47.6)^2\end{array}}{8}}$$

$\sigma = 1.4$

The formula used in the example above to calculate the standard deviation is referred to as the process standard deviation, but practically, since we cannot calculate a real population or a true process average μ, we must estimate it using numerical data coming from a sample size. This means that we can estimate the true standard deviation by using a sample of containers taken from normal production activity. The formula for sample standard deviation (*S*) is slightly different than the formula for process standard deviation: it uses the sample average, and instead of dividing by the sample size (*N*), we divide by (*n* – 1). The formula then is

$$S = \sqrt{\frac{\sum_{i=1}^{n} (X_i - \overline{X})^2}{n-1}}$$

where X_i = the *i*th data value, *x*-bar = the sample average, and *n* = the sample size.

The reason for dividing by *n* – 1 has to do with a concept called degrees of freedom.

Many statistical methods, such as statistical process control (SPC), utilize the standard deviation to estimate variability of a process parameter; sometimes the square of the standard deviation, called the variance, is used. The key point is that the standard deviation is an objective measure of variation. In the numerical example above we see that the average deviation all around the mean is 1.4; ±1.4, as an average value all around the mean, enables the reader or the process analyst to assess if the quality of the process parameter under examination is acceptable or not, and if corrective actions have to be implemented.

To pursue higher quality and customer satisfaction, production, maintenance, and quality specialists should focus their activities on minimizing the standard deviation of key critical process parameters to achieve the narrowest numerical results all around the mean.

8.3.5 Quality Key Performance Indicators (KPIs)

Feedback from the market represents an important source of information that allows manufacturing units to better understand the real quality of their products. This feedback should be spread to all interested parties to

enable them to be aware of field problems and to take proactive actions on production, maintenance, and quality procedures. Some of the most common KPIs to measure quality performance are listed below:

- Overall percentage of defectives. This is the percentage of defectives over the total amount of packages or container produced.
- Number of defectives that reached customers. Defective packages can be found at the company's warehouse or at the retailer's warehouse; this indicator shows the number of defectives found by the final customer or end consumer.
- Value of defective products (euro). This indicator identifies the total value (food product, container, cost of production) of the end defective product.
- Potential cost of recall. This is the cost that the production company must bear to recall defective products.
- Percentage change in quality year over year (quality trend). This indicator allows the company to compare the trend of quality over the years. Results should enable the company to carry out analysis to understand the reasons.
- Top five packaging lines or facilities in quality production. This indicator calls the company to identify the top five packaging lines or facilities that produce better quality results. This allows us to compare quality results and understand the reasons behind positive and negative quality results.

These indicators should be used within the company to challenge people to improve the quality output of the product produced. This information has to be spread within the company's teams to allow a critical review of procedures and practices to find potential room for continuous improvement.

9

Critical Factors to Manage in the Design and Implementation Process

9.1 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 9.1 shows the three main manufacturing dimensions that need to be investigated to avoid potential threats coming from each dimension limiting the achievement of maintenance and manufacturing 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 do we 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 toward a model that provides a way to overcome obstacles and barriers in a structured way.

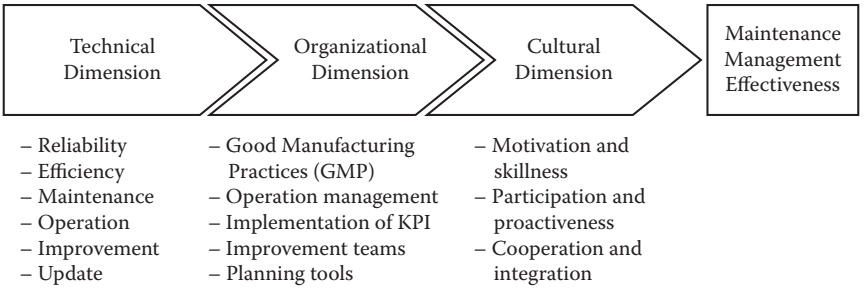


FIGURE 9.1
Technical, organizational, and cultural dimensions for maintenance management effectiveness.

9.2 TECHNICAL DRAWBACKS

By technical drawbacks we refer to

1. Technological or reliability problems of some of the equipment available in the production line
2. Lack of technical documentation available for some equipment of the line
3. Lack of training or service support for the packaging line equipment

9.2.1 Equipment Reliability and Technological Problems

Sometimes equipment shows reliability problems that produce real production line bottlenecks that cannot be overcome by a reliable 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 to an acceptable reliability level. Since reliability design problems cannot be solved through maintenance, as soon as we analyze the equipment, it is very important to identify the inefficiency reasons that produce a poor line or equipment performance.

Normally under this heading we find reasons that could depend on the following subjects:

- Old technology (obsolete equipment)
- Equipment layout (poor packaging line layout reliability)
- Services and utilities (problems dependent on air, water, power supply, steam, etc.)
- 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 trained staff, it is possible to gather numerical figures that highlight the different causes behind production stops. Every type of production stop must be recorded, together with the relative cause, to allow the team to classify the stop time and possibly the reason behind it.
2. Production stop categorization. In order to categorize equipment and stop reasons, production stops related to equipment, practices, or utilities must be split for systems, subsystems, 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.

Problems depending on packaging line layout design and equipment obsolescence must be solved through a new layout design or new equipment installation.

9.2.2 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 or not clear. This lack could be referred to the following missing documentation:

- Operational manual (to identify the operational standards: practices and procedures carried out by the equipment operator)
- Maintenance manual (to identify the mechanical standards: settings and measures)
- Electrical manual (to identify the electrical standards: settings and measures)
- Spare parts catalogue (to identify parts and component specifications)

When this documentation or part of it is missing, the impact on equipment or packaging 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 for poor line effectiveness. Lack of technical training based on reliable documentation, lack of qualified service technicians and service support for equipment upgrade, or lack of a spare parts catalogue could be one of the reasons for 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.
2. Establish a team of company specialists able to develop the standard documentation and support the personnel with the required training activities.

Sometimes because of equipment price competition and immediate satisfactory equipment performance results, technical managers do not verify if the equipment technical documentation is complete and reliable, and if technical and operational standards have been clearly defined by the equipment supplier. In the medium to 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. A lack of clear technical specifications on mechanical and electrical settings will produce an unreliable maintenance approach; on the other hand, a lack of clear standards on operational and quality practices will result in low production effectiveness and product safety. For this reason, the checklist used by the technical managers to assess the equipment suppliers should contain these important requisites.

9.3 ORGANIZATIONAL DRAWBACKS

The organizational model chosen by a food industry can contribute greatly to maintenance effectiveness if some important quality methodologies become the source of inspiration in promoting cooperation and best practices and removing inertia and bureaucracy.

9.3.1 Lack of Autonomous Maintenance Carried Out by the Equipment Operator

The organization in place in some food industry plants shows traditional boundaries among different departments and a narrow definition of roles and functions. Normally equipment operators are not involved in maintenance activities for the following reasons:

- Lack of the necessary skill
- Different company policies

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 emphasizes 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 is an important role: the unavailability of technical and quality specialists to share their competence and experience with equipment operators. Friction among different departments is sometimes another adverse force that leads the departments to limit their cooperation.

To be able to implement maintenance procedures effectively, the role of the 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 hazard analysis and critical

control points (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 the company's roles.

Sometimes autonomous maintenance implemented by equipment operators lacks effectiveness because of poor cooperation and support provided by maintenance and quality specialists. Specialists should be trained to identify the advantages coming from an effective implementation of autonomous maintenance (AM). If equipment operators are supported by maintenance and quality specialists, the following benefits will be experienced:

- Less corrective maintenance and troubleshooting, which allows maintenance specialists to use their time to improve equipment and be involved in more complex technical activities
- Less product quality and safety nonconformities, which allows quality specialists to use their time to improve good manufacturing practices (GMPs) and carry out analysis of quality figures to be shown to equipment operators
- Higher equipment efficiency and less product and packaging material waste
- Improved quality of containers produced and packed
- Improved equipment hygiene, cleanliness, and capacity to discover anomalies
- Better key performance indicators (KPIs) and improved pay-for-performance salaries

Above all, specialists should share their knowledge and give their support to equipment operators for the achievement of the highest possible company competitive advantage. This result is strongly dependent on the relationships existing among different categories of workers: warm and altruistic behavior will save from conflicts, errors, and losses. Managers should lead by example and support the workforce in promoting the better ability of everyone to help and support colleagues in their role.

9.3.2 Lack of Management Commitment and Involvement

Lack of management commitment, due to poor knowledge and awareness of benefits coming from maintenance engineering, represents a problem

that has a strong impact on food industry organizations. 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 the top management. One of the reasons for maintenance implementation failure resides in the inability of management to cope with the complexity of the implementation process. Sometimes managers refuse their own commitment and involvement in supporting the activity of improvement teams, and this often is the reason for poor participation and poor maintenance and production effectiveness. To overcome this problem, it is very important to gain management commitment from the very beginning and design the involvement of management at different levels of the maintenance and production organization. Middle management should be involved in different technical trainings on equipment installed in the packaging line, in operational activities carried out by equipment operators, and in GMPs and HACCP existing in the manufacturing line. They should take part in improving meetings organized by quality circles or improvement teams to give their own support and stimuli. If equipment operators are not fully supported by their managers, company specialists cannot support operators and AM can experience a lower effectiveness or complete failure.

9.3.3 Lack of a Planning and 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 equipment. The maintenance activities designed must be planned and regularly monitored to verify if

- They are regularly implemented
- They are effective, in both quality and time
- Improvement or corrective actions need to be implemented

A common production management drawback resides in the inability to establish a management system based on measure. On the other hand,

a measurement system itself is not enough if the measures obtained are not analyzed and improvement and corrective actions applied. The KPIs used to measure maintenance and production effectiveness should be regularly updated and shared with people involved at different levels. These measures must be compared and contrasted to identify the areas where further improvement can be designed and implemented. Equipment performance must be automatically or manually measured to enable equipment operators, company specialists, and management to be aware of

- Standard performance results
- Results following improvement activities

Equipment operators and company specialists should be involved in the performance analysis activities to discover performance problems and bottlenecks and suggest improvement actions.

9.4 CULTURAL DRAWBACKS

A lack of basic maintenance engineering knowledge quite often does not enable middle management to motivate a company's employees, to support them in overcoming problems during the implementation phase.

9.4.1 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, characterized 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 equipment available today enables reduction of equipment downtime, and that corrective maintenance is the only maintenance approach needed in this context. As a result, the short-term view of a company's management does not allow us to build up a competitive plant: lack of quality methodologies, bureaucracy, and barriers among the departments determine poor equipment efficiency and product safety. Analysis of the culture in place in a food company is an important prerequisite to carry out before maintenance engineering implementation can take place. If the forces that are ranged

against maintenance design and implementation are not examined and managed in advance, implementation failure can be experienced.

As pointed out by Andrew Leigh[29] in the book *Effective Change: 20 Ways to Make It Happen* (1988), the field force analysis (FFA) technique, as shown in Figure 9.2, 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. Often managers in charge of the manufacturing unit tend to limit their role to production planning, cost control, and managing routine daily activities. Their ability to fix daily problems and drawbacks, and to fill planning gaps due to lack of personnel or material, seems to be the most important task for their role. Both equipment operators and maintenance specialists feel instead the necessity to be supported by managers with specific technical skills who can trace the way forward for them. In this regard, it has been said that Napoleon was loved by his soldiers, who were ready to follow him to the head of the world, because in battle he was at their head and not at their tail. If the staff involved in productive maintenance is not led by managers fully convinced and enthusiastic for the project they are responsible for, it is very likely that the project itself will not succeed. Middle managers involved in this project must have or gain an organizational and technical skill that makes them real points of reference for the staff involved. When discouragements or difficulties in the integration process between equipment operators and technical specialists should arise, project managers must be able to motivate staff and influence the proper allocation of duties and responsibilities of a technical nature. Managing conflicts with personnel that are part of

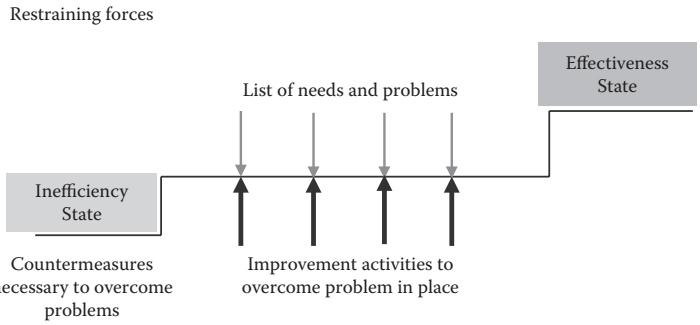


FIGURE 9.2
Restraining forces and countermeasures.

the project is not an easy task, but the value that should guide people who share their convictions must be respect for persons and their opinions. A mother can sometimes harshly scold her child, but this will not offend him because two core values support his relationship with his mother:

- He knows that his mother loves him.
- All she will say is motivated by love for him.

All of us want and expect to be loved; if we can convince our partner that we love and respect him, we will have laid down the foundation for a long and precious relationship.

Managing a project that involves a change means, above all, managing people involved with their expectations, concerns, and disappointments. It is not enough to manage technical, organizational, and economical issues; success of a complex project goes through the proper management of human resources involved in the project.

9.4.2 Workforce Culture

Psychologists such as Maslow, Hezeberg, Adams, and McGregor developed theories that identify human needs and how they affect job performance. Total productive maintenance (TPM) and world-class manufacturing (WCM) workforce cultures 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.[42] 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

MacDuffie[33] argued that HRM is particularly important in determining quality. Japanese employees typically enjoy a much longer-term relationship with their employing organizations, and hence have a much stronger sense of "shared destiny." Work systems are based on teamwork and quality circles, and responsibility for quality lies 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 implementing different TQM projects, the culture is still too much based on strong functional departments that make interdepartmental cooperation difficult. The culture in many European food industries is at present too much based only on short-term company results. The introduction of a pay-for-performance system in a wrong cultural context might determine a concentrated effort of a category of people to achieve their own results, neglecting the other company's objectives. While the definition of KPIs indicates that company's management is based on measurable objectives, in a wrong cultural context these KPIs could be used to achieve personal short-term results disregarding the medium- to long-term effects of decisions. Cooperation between equipment operators and maintenance specialists, and integration of production, quality, and maintenance departments can effectively be achieved only if personnel involved share the same values.

Too often the latest technology, marketing, and commercial issues are considered the sole competitive tools able to produce higher market share. Human resources are a sort of necessary evil, but not a winning factor to manage for higher market share. This suggests particular care in designing a maintenance implementation plan, in defining training programs, and in teamwork formation. The introduction of total quality management principles in a cultural context that is reluctant to change its nature based on bureaucracy, and on lack of integration, may produce a formal application of TQM performance indicators to pursue the achievement of personal results instead of company results. If people involved in different projects are working to achieve their own results and objectives, instead of the company's objectives, the cooperation and integration invoked by the TQM is only apparent and will not produce positive effects on production performance.

The promotion of corporate values allows shifting the focus from the individual to the interests of all workers. Following studies of Herzberg on the characteristics job model, he identifies the intrinsic motivational factors of a job:

- Meaning of work: The ability to perceive the importance of their work.
- Responsibility: Personal commitment in achieving the targeted results.
- Knowledge of results: Being aware of whether the outcomes of their own work are satisfactory or not.

Management by objectives (MBO) defines the objectives assigned to each individual through systematic monitoring and regular evaluation to make the worker aware of the results obtained at every stage of the process. Drucker and White[6] add to a fixed salary a variable salary according to the objectives achieved. The basic steps for the implementation of MBO are

- Identification of shared objectives
- Specification of measurable results expected
- Assigning a target date within which the goal objective is to be reached
- Monitoring the achievement of results at regular intervals

There are two main classes of objectives:

1. Objectives of contribution. They concern the contribution that an employee must provide for the achievement of a targeted result and the conditions for their achievement.
2. Objectives of competence. They concern the acquisition of knowledge and skills aimed at achieving the objectives of contribution.

Human beings are intrinsically willing to pursue the objectives of competence and knowledge to give their contribution for the achievement of a company's results. A mandatory management task is to promote these two objectives, with all personnel, at every level of the organization, to establish the highest level of employee satisfaction and make use of all human resource potential available in the company.

9.4.3 Training for Equipment Operators and Maintenance Specialists

The implementation models suggested by TPM and WCM have been modified to meet the requirements of the food industry environment to embody HACCP methodology, to satisfy both European Economic Community (EEC) legal requirements and maintenance effectiveness requirements. Autonomous maintenance, carried out by those who operate the equipment, must include regular monitoring activities of critical control points (CCPs) of the process. Furthermore, GMPs already in place in many food industry environments suggest some tailoring activity in defining AM procedures for equipment operators. Because of

the low company status suffered by the equipment operators and cultural boundaries existing between production and maintenance departments, strong effort has to be placed in supporting a small group of activities. Most industries today are organized 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 organizational line frequency gets in the way, causing delays and production stoppages. According to Figure 9.3, operators and specialists each have clearly identified skills, and both do only those skills designated as their own.

TPM combines operators and maintenance personnel into a single team that identifies existing tasks that cause delays, create waste, and reduce productivity. Figure 9.3 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 request 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 organizational line requires a tremendous communications effort for the completion of a simple maintenance task. This administrative system consumes much time, promotes inefficiency,

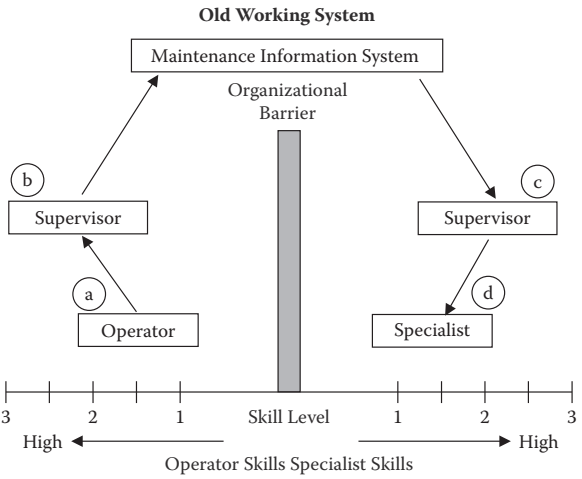


FIGURE 9.3
Old working system.

causes longer downtimes, increases costs, and decreases productivity. The production delays that 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 a result, shows that on an as-needed basis, operators perform some tasks that were once thought to be exclusively maintenance tasks. There is a shared task area where both equipment operators and maintenance specialists can give their contribution in performing the same tasks. This allows a real integration, better participation, and higher equipment availability.

9.5 CONCLUSION

In this chapter the three main company 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 relative inefficiencies. A common denominator that crosses these three dimensions is strongly based on cultural drawbacks depending on the following:

- 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 suggested, but a reliable and lasting solution will depend on the ability to gain a wider participation of people through team activities and strong cooperation. Top and middle managers have a 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, work with others, and give their positive contribution to the teamwork activities is the key ingredient to facilitate bottom-up company change. Figure 9.4 summarizes the technical, organizational, and cultural drawbacks identified in this chapter and the solutions suggested.

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 bottlenecks	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, maintenance, 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 suppliers 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

FIGURE 9.4
Technical, organizational, and cultural drawbacks with relative solutions.

No.	Problem Issues	Note	Solutions Proposed	Result
	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 supports the implementation program
	Management unable 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 supports the project team activities with their participation
2:03	Lack of planning and 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 measurements of production and maintenance effectiveness

FIGURE 9.4 *(Continued)*

No.	Problem Issues	Note	Solutions Proposed	Result
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 defined 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 participation	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 cooperation between operators & specialists	Product safety & equipment reliability management through AM

FIGURE 9.4 ***(Continued)***

10

Conclusions

Here I briefly summarize some of the main findings highlighted in the different chapters to enable the reader to better catch the key issues and use them effectively.

10.1 INTRODUCTION

The different sections of this chapter summarize the main findings based on problems and questions identified in the first two chapters: these emphasized the conclusions highlighted in this book and the relative benefits. The analysis of the background that allows the definition of problems led to the identification of criticalities in the food industry and the need of a maintenance design and implementation process specifically designed for this industry sector. The analysis of case studies produced:

1. Questions that call for a maintenance design and implementation process specifically thought out for the food industry environment
2. Analysis of quality and maintenance engineering techniques
3. Definition of the process to design and implement maintenance procedures for the food industry environment

The critical factors to manage in the maintenance design and implementation 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:

- Problems and questions that arose on the maintenance design and implementation process for the food industry
- Research findings
- Solutions proposed and implemented
- Potential contribution given to the food industry

The critical review of quality, reliability, and engineering principles and techniques allowed the comparing and contrasting of the material available to pursue the development of the process to design and implement maintenance procedures for this critical industry environment.

10.2 CONCLUSIONS ON FOOD PACKAGING LINE PROBLEMS

This section highlights the problems and questions that arose in the first two chapters and the solutions found.

10.2.1 Solutions to Manage the Effects Produced by Equipment Downtime and Failures

We already showed that while in the mechanical industry a machine stop could have a low economical impact on production cost, in the food industry, an equipment stop can have tremendous impact on a company's costs. The analysis of the case studies produced the important questions that highlight the necessity to develop a maintenance design and implementation process to manage and overcome product safety problems and equipment reliability issues. The hazard analysis and critical control points (HACCP) analysis showed that some equipment failures could have serious effects on the quality of the product packed, and eventually on the consumer's health. The solution found to the problems produced by the equipment stops and failures is based on 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, compared to processes used to design

maintenance procedures for other industrial sectors, is based on the 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 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 is the necessity to identify all conceivable critical control points (CCPs) existing in the manufacturing line, and that could influence the quality and safety of product packed. The application of the HACCP and hazard operability (HAZOP) techniques represents the solution for the identification of the equipment and process criticalities that produce biological, chemical, and physical risks of food product packed. Risks have to be weighted to produce a list of priorities that have a direct impact on final food 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 a result, a list of priorities has been developed according to the outcome coming from safety and reliability analysis. The development of maintenance task lists, able to control food packaging line criticalities, is the last design phase necessary to provide a solution to equipment stops and potential consequences on the product packed.

The implementation constrictions coming from a company's three main dimensions—technical, organizational, and cultural—have been analyzed and solved through the deployment of countermeasures coming from the application of maintenance engineering techniques. Top management involvement, training and 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 and specialist maintenance integration is to be 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 food product quality and safety nonconformities, together with unpredictable economical losses.

10.2.2 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
- The preventive maintenance actions to avoid product quality and safety problems

Hazard analysis and critical control points (HACCP) is the production process control methodology selected, as a solution, to

1. Identify and assess specific hazards
2. Estimate risks
3. Establish 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 equipment functions, human errors, and production practices (good manufacturing practices (GMPs)). The design process identifies and quantifies:

- The various types of failures
- The failure distributions
- The component/part lifetime
- The categories of causes
- The link between causes and effects on product packed

Potential and functional failures can be identified, and the effects produced by each failure mode can be scored, together with corrective and preventive measures. Safety and reliability analysis carried out through HACCP and reliability-centered maintenance (RCM) allowed a global evaluation of failure 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 has been designed to answer the specific needs in place in the food industry. This form lists safety and 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 can be designed as a solution to increase resistance to failure, to reduce equipment failure probability, and to establish product safety compliance.

10.2.3 Solutions to Risks Depending on the Human Factor

The findings shown in the previous chapters underline that the risks associated with human behavior can be reduced through the use of condition monitoring systems and sensors to automatically monitor critical parameters normally under human control. To avoid loss of control of critical parameters, such as those linked with machine sterilization or package integrity, mandatory use of online monitoring systems is strongly suggested. 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 us to leave minimum risks depending on human factor.

10.3 CONCLUSIONS ABOUT THE CRITICAL FACTORS TO MANAGE DURING THE DESIGN AND IMPLEMENTATION PROCESS

Figure 9.1 displays the three main company dimensions in food manufacturing companies. The maintenance design and implementation process could suffer from 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 shown in Chapter 9 and are summarized below.

10.3.1 Solution to Technical Drawbacks

One common drawback, depending on lack of technical documentation and standards, is normally referred to as customized equipment. 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 proposed 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 (to identify the stop reasons)
2. Production stop categorization (to identify the different stop categories)
3. Production stop prioritization (to prioritize the equipment stop type)
4. Analysis of priorities (to rate the priorities)
5. Equipment improvement (to improve the present effectiveness)

If the equipment supplier is not available, the above procedures can be implemented by the company's specialists.

10.3.2 Solution to Organizational Drawbacks

The problem found is based on inertia and bureaucracy introduced by traditional boundaries among different departments, based on a narrow definition of roles and functions, which do not allow the equipment operators to be involved in maintenance activities. The concept "I produce and you repair," well established because of a narrow view of the 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 top management's commitment in establishing a new operator role and in leading the whole organization to a wider participation of people in a real integration between equipment operators and company 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, represents some of the tasks under management responsibility.

10.3.3 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 from motivating different categories of employees and supporting them in the design and implementation phases.

10.3.3.1 Solution to Old Management Culture

The solution proposed to overcome problems depending on the reactive approach, on short-term problem fixing, consists in the use of the 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 9.2 shows the basic approach to this solution.

10.3.3.2 Solution to Lack of Workforce Commitment

Chapters 7 and 9 showed that commitment of the workforce can be a problem if the hierarchy of needs that affect job performance and promote employee empowerment, as a key issue to achieve company objectives, is not well established in the company.

The solution proposed 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 the company's organizations and workforce
- A much stronger sense of "shared destiny" among the parties involved

The literature search shows that work systems based on teamwork 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.

10.3.3.3 Solution to Establish a Close Cooperation between Equipment Operators and Maintenance Specialists

Despite the maintenance design and implementation process's call for close cooperation between equipment operators and maintenance specialists, the reality shows that operators and specialists often have rigid patterns of skills, and both do only those activities designated as their own. The solution identified suggested the implementation of autonomous maintenance (AM) and GMPs be carried out by the equipment operators with the support and cooperation of maintenance specialists. The AM activities promote a real integration of these two roles, removing the cultural boundaries existing between the production and maintenance departments.

10.4 CONCLUSIONS ABOUT FOOD SAFETY AND THE EQUIPMENT RELIABILITY PROBLEM

The analysis of the food production environment underlined the importance of maintenance in determining both product safety and equipment reliability. A search showed that no literature is available to address and solve the criticalities of the food production lines through a maintenance process.

The maintenance design and implementation process for food industry packaging lines represents the answer to the equipment stops and to product safety problems 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 a result, the highest end product quality and safety.
2. The integration of some maintenance engineering and product safety techniques enables us to weight product safety and equipment reliability risks.
3. The quantitative and qualitative analysis done allowed us to define the maintenance prioritization necessary to identify maintenance tasks that answer the need for safety and reliability at reasonable cost.
4. The condition monitoring systems and sensors must be 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, is strongly recommended to allow the effective implementation of autonomous maintenance procedures able to address and control the different food criticalities.
6. The key performance indicators (KPIs) used to measure equipment and maintenance effectiveness allow us to measure efficiency, quality, and cost elements that make the process particularly effective for food industries.

10.5 POSSIBLE SOLUTIONS

The application of the mentioned solutions can be done through a set of maintenance procedures to implement maintenance tasks on the food industry packaging lines. A maintenance system is made up of

not only a set of maintenance procedures, but also three other basic components:

1. A software program that prints out the checklists 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 checklists
3. A working team responsible for implementing and improving the maintenance checklist content

Figure 10.1 shows the relationship among the different components that make up this maintenance system.

10.5.1 Software Program

The maintenance tasks designed are normally stored in a software program that enables us to print out the specific checklist for each service and record the service results at each maintenance occasion.

Figure 10.2 shows a FMEHA form referring 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

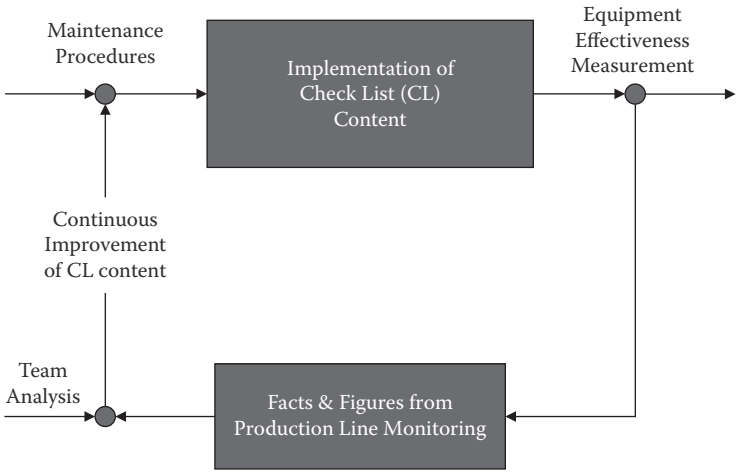


FIGURE 10.1
Checklist implementation and improvement.

Part or Process name						Design/Manufacturing Resp.			
Series No./Dev. Step						Engineering Release Date			
Part/Process Description CCP Description	**Process Purpose**	**Identify the specific Potential Hazards: (B) Biological (C) Chemical (P) Physical**	**Critical Limits for Each CCP**	**Potential Failure Mode**	**Potential Effects of Failure(s)**	**Severity**	**Potential Causes of Failure**	**Occurrence**	**Current Controls**
Sealing Inductors	Package Sealing	B	Electrical (see EM 6.32) Mechanical (see MM 5.20)	(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

	Other Areas Involved			Suppliers & Plants Affected					
	Prepared By			FMEA Date					
Existing monitoring procedures (Frequency)	**Detection**	**RPN**	**Recommended Corrective Action(s)**	**Area Individual Responsibility & Completion Date**	**Actions Taken**	**Severity**	**Occurrence**	**Detection**	**RPN**
Electrical: continuous. Mechanical: W, 1000 work hours	2	64	Daily checks included in the AM check list	Production: Equipment Operator	Definition of: - AM check content - Op. training - Tools	8	4	1	32

FIGURE 10.2
FMEHA form for sealing inductors.

on a daily basis. This improvement action produced an RPN reduction as a result, from 64 to 32.

The maintenance design activities are stored in the software together with the maintenance checklists that show the maintenance tasks identified for each maintenance occasion.

Figure 10.3 shows an example of a checklist 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

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 10.3
Maintenance checklist form. (From Tetra Pak Training Department, Training material on TPMS, 1999.)

As soon as historical information is gathered, statistical figures can be obtained to measure the component lifetime, the maintenance adjustment frequency, for each task, and the average time spent for each service activity.

10.5.2 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

10.5.3 Working Team

A working team, composed of 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 10.4, the activity of the team is spent not only in starting up the system, but also in pursuing its continuous improvement through the constant analysis of production line monitoring indicators.

Figure 10.5 summarizes the main features of a maintenance management system that embodies the three main elements:

- Software program
- Production line monitoring
- Working team

Figure 10.5 shows that:

- Maintenance tasks designed are planned according to checklist content
- A maintenance report, compiled by equipment operators and specialists, contains the service activities implemented
- Service results are stored in the maintenance software program

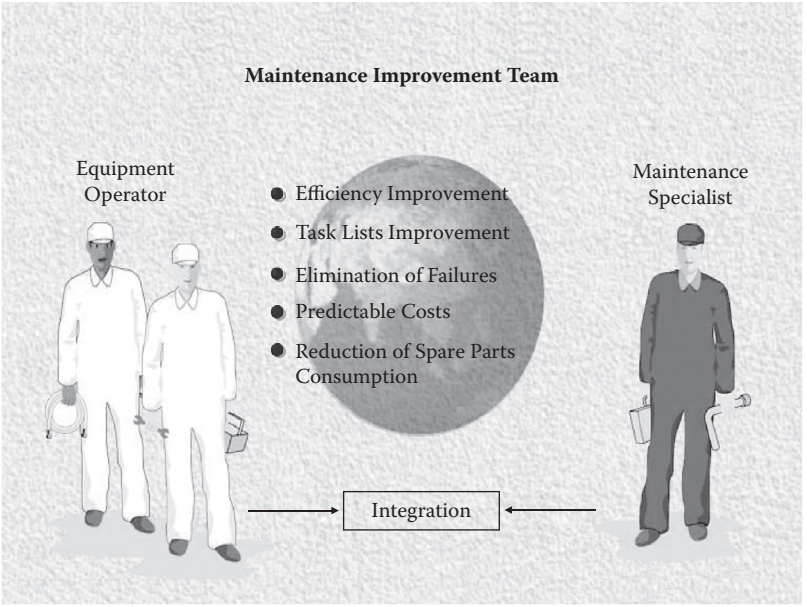


FIGURE 10.4
Working team goals. (From Tetra Pak Training Department, Training material on TPMS, 1999.)

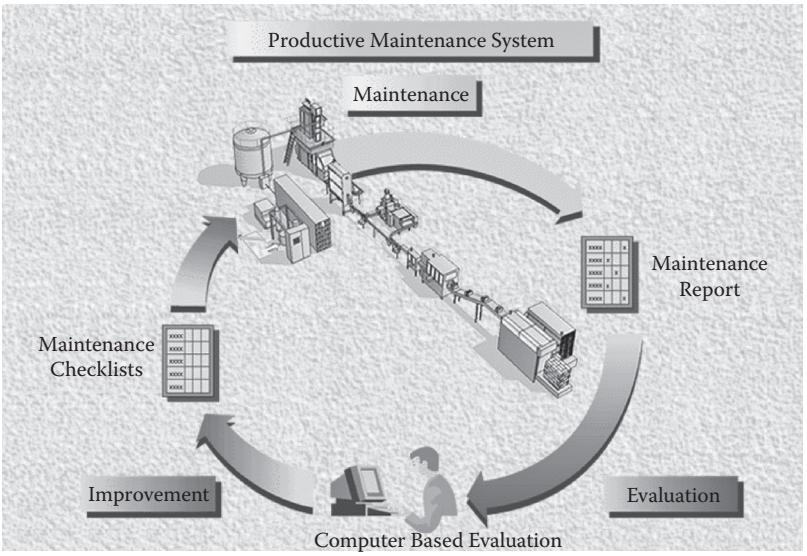


FIGURE 10.5
Maintenance management system. (From Tetra Pak Training Department, Training material on TPMS, 1999.)

- Periodical analysis of KPIs enables the working team to identify the improvement areas where upgrades and updates can be introduced
- Improvements are stored in the system and spread in the checklist content

10.6 CONTRIBUTION OF THIS BOOK TO THE ACHIEVEMENT OF HIGHER PRODUCT SAFETY AND EQUIPMENT RELIABILITY

Following a literature review, this book identified an important gap regarding the lack of a maintenance process able to manage product safety and equipment reliability critical issues of food industry packaging lines. Different books have focused their attention on 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 food industry packaging lines. The analysis of different case studies showed that low maintenance effectiveness could have dramatic effects on final product safety and equipment reliability. The analysis showed that consumer health could be affected by the biological, chemical, and physical risks existing in the food packaging line, which can determine product safety problems. The scope of this book was to explore the gap existing between theory and real maintenance status in the food 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 produced by this book is mainly due to the definition of a maintenance process to design and implement maintenance tasks for the food industry packaging lines. This process allows us to fill this important food industry gap, providing a route map to design and implement maintenance tasks to manage food industry criticalities. The contribution expected is mainly due to the following issues:

1. 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 integrated to identify the equipment

CCPs and their effects on product safety, equipment reliability, and maintenance activities to put CCPs under control.

2. Maintenance implementation based on autonomous maintenance for the food industry environment. Autonomous maintenance (AM) has been designed to empower the equipment operator role to maximize maintenance implementation effectiveness for food industry 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 effective way to implement maintenance tasks designed for food industry packaging lines.
3. 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 us to display the added value of the maintenance process, and the positive effects on product safety and equipment reliability.

10.7 FUTURE WORK ON THIS SUBJECT

This book identified a maintenance design and implementation process for food industry packaging lines. This process has been designed to address and manage the criticalities existing on production lines for packing food products intended for human consumption. Quality techniques have been integrated with maintenance engineering and reliability techniques to define a maintenance design process able to identify product safety risks and design maintenance tasks to put these criticalities under control. The author of this book is strongly convinced that this work shows the way to manage the food industry criticalities, dependent on equipment and operational practices, through a reliable maintenance process. Future activities can be done to continue the integration of maintenance engineering and safety techniques to pursue product safety and equipment reliability goals for different food industry sectors. Future works 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 losing the benefits produced by the design phase and to add value through a proper

definition of roles, tasks, and procedures to be implemented in the food industry packaging lines. Further activities in this area can investigate if the conclusions drawn in this book can be differentiated and customized for different food industry fields. The maintenance design and implementation process draws the way to highlight the role that maintenance can play in determining product safety and equipment reliability. We hope that this work represents a modest contribution to create further stimuli in the reader to pursue further research activities in this important industry field. The intention of the writer is to continue to work and give his contribution in the following future projects:

- A design solution for maintenance tasks for the food industry. This tool should allow us to easily design maintenance tasks according to different types of criticalities under consideration.
- 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 specialists. The definition of roles and activities, and the level of integration between the equipment operator and other company specialists represent other important areas where this work can add further value.

10.8 LIMITATIONS

The content of this book is addressed to the food industry environment; the maintenance design and implementation process has been conceived to provide a reliable answer to the hazards in this industry sector. Biological, chemical, and physical risks of food 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 industry sectors. A maintenance design and implementation process for the 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 equipment and products with other type of risks that require the application of other techniques necessary to better manage the criticalities not taken into consideration in this book.

10.9 SUMMARY

This chapter summarized the main questions and solutions identified at the beginning of this book. The solutions found in the maintenance design and implementation process enable food companies to manage the product safety hazards and reliability problems existing in the food industry 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 ensure a reliable management of biological, chemical, and physical risks of product packed, qualitative and quantitative analyses 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 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 specifically designed for the food industry, and represents a reliable tool to use to put under control the critical variables of the food industry packaging lines. The technical, organizational, and cultural criticalities, identified in the food industry 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 have been 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 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 specialists. The KPIs identified in the implementation process provide a way to measure production line and maintenance effectiveness. In the end, the hope is that the content of this book represents a real answer to the product safety and equipment reliability problems existing in the food industry, and a way to establish better cooperation among the workers.

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Designing Food Safety and Equipment Reliability Through Maintenance Engineering

Existing maintenance engineering techniques pursue equipment reliability with a focus on minimal costs, but in the food industry, food safety is the most critical issue. This book identifies how to ensure food product safety through maintenance engineering in a way that produces added value and generates real profits for your organization.

Integrating food safety techniques with reliability and maintenance engineering techniques, **Designing Food Safety and Equipment Reliability Through Maintenance Engineering** details a maintenance design process that captures all conceivable critical factors in food manufacturing lines. While maintenance engineering normally starts with equipment reliability, this book starts with product safety to identify equipment criticalities and maintenance solutions.

The text examines the problems currently facing the food industry and introduces powerful solutions to help food producers and consultants manage both food safety and manufacturing effectiveness. It presents an innovative tool for weighing food, human, and equipment criticalities and also describes how to maximize maintenance design outcome through the empowerment of equipment operators and their close cooperation with maintenance and quality specialists.

Detailing how to design reliable task lists, the book includes case studies that illustrate the problems that low equipment reliability can create for your customers and your company's image. It outlines key performance indicators that can help producers and suppliers easily identify quality, availability, and productivity gaps. It also highlights critical factors that can help you avoid process bottlenecks.

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