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The Research and Implementation of Maintenance Excellence on Clean Utility Systems in the Pharmaceutical Industry

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**THE RESEARCH AND IMPLEMENTATION OF
MAINTENANCE EXCELLENCE ON CLEAN UTILITY SYSTEMS
IN THE PHARMACEUTICAL INDUSTRY**

By

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ME IN ADVANCED ENGINEERING**

**Thesis Presented for the
Degree of Master of Engineering**

**Thesis presented for the partial fulfilment of the
Degree of Master of Advanced Engineering**

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Course Coordinator**

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Project Supervisor**

October 3rd 2008

DECLARATION

I hereby certify that this material, which I submit for assessment of the programme of study leading to the award of M.E in Advanced Engineering, is my own work and has not been submitted for assessment for any academic purpose other than in partial fulfillment for that stated above. All the published and the unpublished sources utilised has been referenced.

Signed.....

Date.....

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I would also like thank my employers Dalkia Ireland Ltd and Wyeth Biopharma for sponsoring this project and supporting the quest for Maintenance Excellence.

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ABSTRACT

Maintenance Excellence is the implementation of best maintenance practices within industry; it is the balance of performance, risk, and cost to achieve an optimal solution.

This thesis has been structured around the 5 main areas of maintenance excellence; it has documented all the important functions of the maintenance department that contributes towards maintenance excellence. Demonstrating maintenance excellence is a big achievement however demonstrating it on pharmaceutical clean utility systems with strict regulatory controls is a major challenge.

Pharmaceutical production is one of the most heavily regulated industries. With such an emphasis on product quality in the pharmaceutical industry, and with such economical and health consequences of machine failure, the maintenance team plays a critical role in the success of the product. It is the maintenance department's responsibility to ensure the equipment is kept to a maximum operating condition. It must predict and prevent failures and repair any problems, which may already have led to a failure, while adhering to the rules and procedures set out by their respective regulatory bodies

This thesis has explored the regulatory aspects of the business in-dept and presented a number of practical approaches to building in a world-class maintenance program whilst still ensuring the utmost of safety and quality to the patient.

THESIS TABLE OF CONTENTS

DECLARATION.....	I
ACKNOWLEDGEMENTS.....	II
ABSTRACT.....	III
THESIS TABLE OF CONTENTS.....	IV
LIST OF FIGURES.....	VII
SUMMARY OF REFERENCES.....	X
GLOSSARY OF TERMS.....	XIII

THESIS INTRODUCTION.....	1
---------------------------------	----------

CHAPTER 1 – LITERATURE REVIEW.....	6
1.1 Introduction.....	6
1.2 Maintenance Excellence.....	6
1.3 Evolution of Maintenance and current thinking in industry.....	6
1.4 Types of maintenance strategies.....	8
1.5 Maintenance Performance Measurement and Benchmarking.....	14
1.6 Maintenance Management Strategies.....	16
1.7 Computerised Maintenance Management Systems (CMMS) and Maintenance Planning.....	17
1.8 Regulatory requirements for maintenance within the pharmaceutical industry.....	18
1.9 Literature Review Summary and Conclusions.....	20

CHAPTER 2 – LEADERSHIP, MAINTENANCE CULTURE

& PEOPLE.....	25
2.1 Introduction.....	25
2.2 Asset Management Policy and Strategy.....	28

2.3	Outsourcing of the Maintenance Department.....	35
2.4	Operations and Maintenance Synergy.....	40
2.5	Embedding the maintenance & operations teams in new plant & equipment projects.....	44
2.6	Building in Maintenance Awareness with Manufacturing and top level management.....	48
2.7	Chapter 2: Summary and Conclusions.....	50
CHAPTER 3 – MAINTENANCE PROCEDURES AND PRACTICES.....		53
3.1	Introduction.....	53
3.2	Maintenance Compliance in a regulated industry.....	55
3.3	Plant Maintenance Databuild.....	69
3.4	Computerised Maintenance Management Systems.....	74
3.5	Maintenance Planning.....	77
3.6	Chapter 3: Summary and Conclusions.....	80
CHAPTER 4 – RELIABILITY IMPROVEMENT.....		83
4.1	Introduction.....	83
4.2	Condition Based Monitoring (CBM).....	85
4.3	Criticality and single point of failure analysis.....	95
4.4	Reliability Centred Maintenance (RCM).....	100
4.5	Root cause analysis and corrective/preventative actions.....	106
4.6	Chapter 4: Summary and Conclusions.....	110
CHAPTER 5 – MAINTENANCE PERFORMANCE MEASUREMENT.....		113
5.1	Introduction.....	113
5.2	Maintenance Standardisation.....	115
5.3	Maintenance Key Performance Indicators.....	119
5.4	Maintenance Improvement.....	131
5.5	Maintenance Auditing and Benchmarking.....	133
5.6	Chapter 5: Summary and Conclusions.....	138

CHAPTER 6 – THESIS SUMMARY AND CONCLUSIONS..... 141

6.1	Introduction.....	141
6.2	Key areas of research and findings.....	144
6.3	Cost Savings Overview.....	145
6.4	Results Summary.....	146
6.5	Future Thesis Applications and Recommendations.....	148
6.6	Thesis Conclusions.....	149

APPENDIX 1 - MAINTENANCE EXCELLENCE AUDIT ASSESSMENT

**APPENDIX 2 - TECHNICAL PAPER - BUILDING MAINTENANCE
OUTSOURCING EXCELLENCE**

LIST OF FIGURES

Figure 1.1 Growing expectations of maintenance.....	7
Figure 1.2 Maintenance Approach – Expectations.....	11
Figure 1.3 Fishbone diagram used for root cause analysis.....	13
Figure 1.3 Maintenance Categorisation - BS EN 13306:2001.....	14
Figure 1.4 Maintenance Terminology - BS EN 13306:2001.....	15
Figure 1.5 PAS 55 Process Flow Diagram.....	16
Figure 2.1 World Class Maintenance – UK & Ireland.....	25
Figure 2.2 PAS 55 Process Flow Diagram.....	29
Figure 2.3 Wyeth Grangecastle Asset Management Strategy.....	33
Figure 2.4 Wyeth Grangecastle Maintenance Strategy.....	33
Figure 2.5 The Wyeth Biopharma Campus at Grangecastle.....	37
Figure 2.6 Dalkia/Wyeth Organisation Chart for Utilities.....	38
Figure 2.7 Engineering Work Instruction procedures to be merged.....	41
Figure 2.8 Standard Operating procedures to be merged.....	42
Figure 2.9 Projected cost savings from merging EWI procedures.....	43
Figure 2.10 Projected cost savings from merging SOP procedures.....	44
Figure 3.1 Typical validation/qualification process for clean utilities.....	57
Figure 3.2 Reverse Osmosis (USP Water) System.....	58
Figure 3.3 WFI Water Compression Still (WFI Generation).....	61
Figure 3.4 WFI Storage & distribution system.....	62
Figure 3.5 Pharmaceutical specifications for RO & WFI Water.....	63
Figure 3.6 Clean Steam Generator.....	64
Figure 3.7 Clean Steam Generator and distribution pipework.....	64
Figure 3.8 Control system graphic of an Air Handling Unit.....	65

Figure 3.9 Overall schematic showing a clean room HVAC system.....	66
Figure 3.10 Pictures showing a selection of gaskets (left) and diaphragms (right).....	68
Figure 3.11 Maintenance Task List for a WFI Pump.....	71
Figure 3.12 Typical 2 years operational spares listing for a pump.....	72
Figure 3.13 Weibull life distribution for engineering components.....	73
Figure 3.14 SAP CMMS extract: equipment maintenance history.....	75
Figure 3.15 PM:CM ratio results.....	76
Figure 4.1 Typical vibration analysis FFT plot (magnitude Vs Frequency).....	86
Figure 4.2 Wyeth, Grangecastle vibration analysis program.....	88
Figure 4.3 Vibration Analysis (VA) – 2007 program results summary.....	88
Figure 4.4 Thermal Image of a HVAC electrical isolator.....	89
Figure 4.5 Thermal Image survey of utility pipework.....	90
Figure 4.6 Wyeth, Grangecastle thermal imaging program.....	91
Figure 4.7 Thermal Imaging (TI) – 2007 program results summary.....	91
Figure 4.8 Wyeth, Grangecastle oil analysis program.....	92
Figure 4.9 Ultrasonic measurement instrument.....	93
Figure 4.10 Steam loss calculation for failed steam traps.....	94
Figure 4.11 Steam trap survey results.....	95
Figure 4.12 Utilities-Production process map.....	96
Figure 4.13 Utilities criticality assessment results.....	97
Figure 4.14 LPHW Block diagram.....	98
Figure 4.15 End of Line Differential Pressure Transducer (single point of failure).....	99
Figure 4.16 Risk Analysis RCM grid for LPHW system.....	103

Figure 4.17 Troubleshooting guide for humidification steam system.....	107
Figure 4.18 Cause/Effect prioritization matrix.....	109
Figure 5.1 EN13306 Maintenance Classification Model.....	116
Figure 5.2 SAP Maintenance Activity Type Codes.....	118
Figure 5.3 EN13306 / SAP CMMS model.....	119
Figure 5.4 Suite 1 Validated HVAC Systems List.....	120
Figure 5.5 Maintenance Excellence KPI – SAP CMMS Report.....	123
Figure 5.6 Maintenance Excellence KPI – MS Utilities Availability Report...	125
Figure 5.7 Maintenance Excellence KPI Base Data.....	126
Figure 5.8 Extract of the calculated Maintenance Excellence KPI's.....	127
Figure 5.9 Sample of maintenance KPI results from the SAP system.....	130
Figure 5.10 KPI results – No. of Work Orders and Labour Man-hours.....	131
Figure 5.11 Maintenance Excellence KPI benchmarks.....	133
Figure 5.12 Example audit results using PASS-55 Web Chart.....	134
Figure 5.13 Results Summary Table Chart.....	136
Figure 5.14 MS Utility Audit Results 2008 - PASS-55 Web Chart.....	136
Figure 5.15 MS Utilities – Overall weighted results.....	137
Figure 6.1 Results Summary Table Chart.....	146
Figure 6.2 MS Utility Audit Results 2008 - PASS-55 Web Chart.....	147
Figure 6.3 MS Utilities – Overall weighted results.....	147

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High purity water systems - <http://www.Aqua-chem.com>

History of the Irish Medicines Board (IMB) - <http://www.irishhealth.com>

Industrial Maintenance Roundtable (Australian Maintenance Excellence Awards) -
<http://www.sirfrt.com.au>

Introduction to Process Mapping (Lean Six Sigma) – <http://www.youtube.com>

Reliability Web – web community for Reliability and Maintenance Engineers:
<http://www.reliabilityweb.com>

UE Systems Inc. (suppliers of Ultrasonic measurement instruments) –
<http://www.uesystems.com>

Weibull life distribution for engineering components - <http://www.weibull.com>

GLOSSARY OF TERMS

Barg	Bar Gauge Pressure
BS EN 13306:2001	European Standard for Maintenance Terminology
CBM	Condition Based Maintenance
CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practices
CM	Corrective Maintenance
CMMS	Computerised Maintenance Management System
Commissioning	Set of activities aimed in bringing new plant/equipment to a fully intended operating status
DMAIC	Six sigma principles: define, measure, analyse, improve and control
DOM	Design Out Maintenance
ECO	Elastomer (soft parts/gaskets) Change Out
Emissivity	A heat factor which allows for the material type being scanned using thermal imaging
EN15341	European Standard for Maintenance Key performance Indicators
Endotoxin	The secretion and remains of dead bacteria
EWI	Engineering Work Instruction
FDA	Food and Drugs Administration
FFT	Fast Fourier Transform
FTM	Fixed Time Maintenance
Glycol	Also called ethylene glycol, ethylene alcohol. a colourless liquid, C ₂ H ₆ O ₂ , used chiefly as an antifreeze and as a solvent
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Arrestors (sterilising grade filters)
HVAC	Heating Ventilation and Air Conditioning

IMB	Irish Medicines Board
IMR	Industrial Maintenance Roundtable
IQ	Installation Qualification (part of the validation process)
ISO-9001:2000	International Quality Management Standard
JIT	Just In Time
KPI	Key Performance Indicator
LPHW	Low Pressure Hot Water
Microbial	A minute life form; a micro-organism, especially a bacterium that causes disease
MTBF	Mean Time Between Failure
MTL	Maintenance Task List
O&M	Operation and Maintenance
OQ	Operational Qualification (part of the validation process)
P&ID	Piping and Instrumentation Drawing
PAS 55	Publicly Available Specification for Asset Management
PDCA	Plan-do-check-act
PM	Preventative Maintenance
PQ	Performance Qualification (part of the validation process)
PVC	Polyvinyl chloride (material used for insulation of electrical cables)
RAG	Risk Analysis Grid
RCM	Reliability Centred Maintenance
RO Water	Reverse Osmosis (Purified Water System)
RPM	Revolutions Per Minute
RTF	Run To Fail

SAP	Company name SAP provide business software applications and solutions
SAP BI	Company name SAP provide business software applications and solutions, 'BI' is a SAP application called 'Business Intelligence'
SOP	Standard Operating Procedure
SPOF	Single Point of Failure
Synergy	In an industrial context can be defined as “Cooperative interaction among groups, especially among the acquired subsidiaries or merged parts of a corporation, that creates an enhanced combined effect”
TI	Thermal Imaging
TPM	Total Productive Maintenance
TQM	Total Quality Management
VA	Vibration Analysis
Validation	The stage of an equipment life-cycle where new plant/equipment (which is intended for critical pharmaceutical production) is evaluated to ensure that it complies with the requirements and regulations
Weibull Distribution	A set of statistical life data for a number of common machinery components and is commonly used in reliability engineering
WFI Water	Water for Injection - pharmaceutical grade water used in the production of intravenous drugs

THESIS INTRODUCTION

Maintenance Excellence is the implementation of best maintenance practices within industry, it covers every aspect of the maintenance department from management, craft utilization and planning to the reliability of the equipment being maintained. As companies strive to become more competitive they need to optimise plant performance and costs and are now being forced to implement best practices.

Most modern industries are moving towards a 24/7 production schedule, the supporting equipment and systems availability need to keep up. No longer do maintenance departments have the luxury of huge amounts of available downtime in order to carry out maintenance, instead the maintenance function is moving towards a more condition monitoring based approach.

Intrusive maintenance is needed to be at a minimum therefore the most effective maintenance program must be employed.

There are a number of tools and standards which can help the maintenance organisation develop best maintenance practices such as the European maintenance excellence standard EN15341, condition based monitoring technologies and Reliability Centred Maintenance. One of the most difficult things to do is to measure the performance of the maintenance department; EN15341 has tackled this problem and outlined a number of key performance indicators which can highlight reliability problems at an equipment level. These metrics include measurements such equipment downtime, planned Vs unplanned maintenance, mean time between failures (MTBF) and mean time to repair (MTTR). Also the implementation of this standard can help show how effective the maintenance strategy is and also if it is cost efficient. Reliability Centred Maintenance (RCM) which was developed in the 1960's for use in the aircraft industry is now finding its way into modern industry. RCM helps develop a maintenance program where improved reliability is a key concern but it also helps eliminate non-value adding maintenance activities (activities performed that do not add any value to the overall equipment performance). This thesis will explore these tools in detail and provide guidance and practical experience of how they are best implemented on critical utility systems supporting the production of pharmaceutical products.

Another standard PAS 55 „Publicly Available Specification for Asset Management’ looks at the overall strategy of maintenance management and helps setup the goals and objectives of the maintenance department to link in with the overall business objectives. Maintenance reform should be a top down approach and PAS 55 helps this transition. This top-down approach involves looking at the overall organisational objectives and then building the maintenance department objectives around them. This approach helps build consistency into the business where each function is working towards common organisational goals.

Maintenance in the Pharmaceutical Industry

Pharmaceutical production is one of the most heavily regulated industries. With such an emphasis on product quality in the pharmaceutical industry, and with such economical and health consequences of machine failure, the maintenance team plays a critical role in the success of the product. It is the maintenance department’s responsibility to ensure the equipment is kept to a maximum operating condition. It must predict and prevent failures and repair any problems, which may already have led to a failure, while adhering to the rules and procedures set out by their respective regulatory bodies. Unlike other industries the critical utility systems supporting production are strictly qualified with associated documentation is needed to prove that equipment serves its function consistently as per the design.

This often leads to maintenance departments performing more work than is necessary to increase assurance of equipment reliability, even if these extra precautions do not necessarily provide any additional benefits.

During the qualification of these systems the maintenance program is developed and put in place. To change the content of maintenance after this can prove difficult as strict change control procedures need to be followed and full documented justification needs to be provided. With these sort of barriers to prevent changes to the maintenance program it may often be more time consuming and difficult than to just leave the maintenance program un-changed. This can prevent the continuous improvement of the maintenance program.

In recent year’s regulatory agencies such as the Food and Drugs Administration (FDA) and the Irish Medicines Board (IMB) have become more tolerant of emerging modern maintenance techniques. Tools such as Reliability Centred Maintenance

(RCM) and the use of the many sciences involved in conditional based monitoring as a way of improving the maintenance function. This is allowing pharmaceutical companies to become more cost competitive while still ensuring utmost quality to the pharmaceutical products end user: the patient.

Project background

The author has worked in maintenance engineering within the Pharmaceutical and food industries for over 5 years. During this time the author has been involved in setting up start-up maintenance programs in one of the worlds largest biopharmaceutical plants.

Maintenance excellence is implementation of best maintenance practices in the following areas:

- Leadership, Maintenance culture and People
- Planning and Scheduling
- Maintenance Procedures and Practices
- Reliability & Continuous Improvement
- Business Performance

These above categories have been referenced from the criteria for the Inaugural Australian Maintenance Excellence Awards and outline all the important functions of the maintenance organisation.

Project Aims

The project aims to research and document what is required and how best to implement a world class maintenance excellence program. The overall aim for this project is to serve as a practical guide for implementing best maintenance practices in a heavily regulated industry such as pharmaceutical production.

Project Objectives and Goals

Research and implementation of Maintenance Excellence/best practices in the following key areas. During the project the key areas will be benchmarked against industry best practices. These benchmarks will be researched from established best practices data available from well established reliability organisations. The following

outlines the different areas of research and implementation which will be documented as part of this Thesis:

Chapter 1 – Literature Review

The literature review will review the evolution of maintenance within industry and look at some of the emerging maintenance strategies. The review will also seek to answer the question „What are maintenance best practices in modern industry?’.

Chapter 2 – Leadership, Maintenance culture and People

Chapter 2 will look at the use of PAS 55 „Publicly Available Specification for Asset Management’ in order to build the maintenance strategy and definitively outline how the maintenance department operates. Maintenance reform should be a top down approach and the maintenance objectives should influence every aspect of the daily running of the maintenance department.

This chapter will also explore the outsourcing of maintenance activities and the potential benefits to the company.

Chapter 3 - Maintenance Procedures and Practices

Chapter 3 will look at the use of computerised technologies such as CMMS (Computerised maintenance management systems) and how best to utilise CMMS to effectively implement a work planning system, trend historical data and reduce plant downtime. Also this chapter will examine the following key areas in the maintenance function:

- Ensuring maintenance compliance in a regulated industry (i.e. FDA, IMB).
- Setting up a plant asset register and implementation of preventative maintenance programs
- Engineering spares, identification of critical spares required for utility systems and how best to optimise the cost of Spares.
- Planning and scheduling

Chapter 4 - Reliability Improvement

Chapter 4 will look at the use of modern maintenance technologies used to help create an optimal maintenance program which is cost effective and maximises plant uptime:

- Conditional based monitoring (Vibration analysis, thermal imaging, oil analysis, ultrasonic inspection) and how best to use the information found.
- Criticality and single point of failure analysis
- Implementation of reliability centred maintenance
- Continuous improvement through investigations of equipment failures (root cause analysis and corrective/preventative actions)

Chapter 5 - Maintenance Performance Measurement

One of the most important areas is the ability to measure the performance of the maintenance program and to be able to use these measurements to highlights areas which need improvement. Chapter 5 will look at the use of European maintenance excellence standard EN15341 to standardise maintenance classification and performance measurement by implementing Key Performance indicators, maintenance auditing and benchmarking.

Chapter 6 – Summary and conclusions

Chapter 6 will summarise the conclusions and findings from this research and also identify the overall practical outcome of implementing these maintenance strategies. The overall aim for this thesis to serve as practical guide for implementing best maintenance practices in a heavily regulated industry such as pharmaceutical production.

CHAPTER 1 – LITERATURE REVIEW

1.1 Introduction

This literature review will look at what is the current perceived meaning of maintenance excellence and how maintenance has evolved with the emergence of some new and some improved maintenance strategies.

The review will also seek to answer the question „What are maintenance best practices in modern industry?’.

1.2 Maintenance Excellence

According to Campbell et al, 2001, Maintenance Excellence is the balance of performance, risk, and cost to achieve an optimal solution.

In other words the goal of maintenance excellence is to maximise the performance and safety of equipment by implementing a maintenance program that is value adding and cost effective. It is the outcome that can be achieved by using a number structured approaches and tools to help review and implement an effective maintenance program.

1.3 Evolution of Maintenance and current thinking in industry

Over the past 20 years, maintenance has changed dramatically and perhaps more so than any other management discipline. Nearly every service you can think of from air conditioning to the water coming out of your taps, modern services are provided reliably from good equipment design and effective maintenance. In industry, maintenance expectations have shifted with the realisation of the impact equipment failures can have on safety and product quality. The maintenance organisations are now becoming under increasing pressure to achieve high equipment availability whilst striving to reduce costs. This calls for a radical reform of maintenance by implementing „best practices’ in order to compete on cost within similar industries.

Moubary, 1997, describes three generations of maintenance evolution. The first generation covers the period up to World War II. The industry at this time was not highly mechanised, equipment downtime did not have any real consequences. Prevention of equipment failure during this period was not a very high priority in the minds of most managers. During World War II the demand for goods and shortage of

manpower led to increased mechanisation. The machinery became more complex and the industry was beginning to depend on them, unplanned downtime was now a big problem and led to the idea that equipment failures could be prevented. The concept of Preventative Maintenance was born. In the 1960's this consisted mainly of equipment overhauls at fixed intervals. The cost of maintenance was also rising relative to other operating costs which led to the emergence of Maintenance Planning and Control Systems which is now an established part of current best practices. From the 1970's to present, maintenance professionals have started to adopt new approaches to maintenance. Greater automation and mechanisation means that more and more failures can have a direct impact on product quality. Reliability, availability and overall equipment life cycles are now a key part of a modern production facility. The cost of maintenance in modern industry is still rising and is one of the highest elements of operating costs. As a result maintenance managers are implementing maintenance best practices and tools in order to help reduce costs, improve reliability and sustain high product quality.

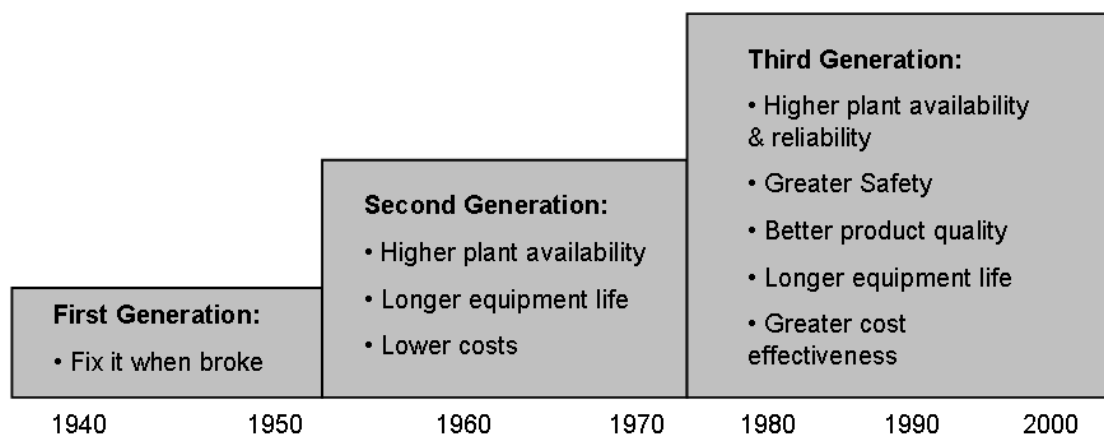


Figure 1.1 Growing expectations of maintenance

Courtesy: Moubray, 1997

As Cooke, 2003, points out that unfortunately many high level managers still consider maintenance as a “necessary evil” and fail to recognise that significant contributions can be made by the maintenance function towards improved productivity.

Research carried out by Cooke, 2003, on British industry shows that maintenance is still not as efficient and effective as it could be. Only in the most recent years maintenance practices has gradually developed into a subject in its own right, linking engineering and management together as the two key aspects in its business process.

1.4 Types of maintenance strategies

There are a great array of maintenance tools and strategies available in order to design the optimal maintenance program:

Preventative Maintenance (PM)

Preventative maintenance (PM) can be described as a fixed time maintenance task scheduled in order to detect or prevent failures before they happen. This is the most common approach to maintenance and usually aligns with the equipment manufacturer recommendations. As equipment can be used in many different applications it is always beneficial to challenge the current PM program frequencies, as equipment history is built there is an opportunity to remove non-value adding tasks. Garg et al, 2006, highlighted the importance of an effective PM program within manufacturing strategies such as Just in Time (JIT) where optimal stock buffers in the production process are setup; preventive maintenance is included in this buffer and allows the equipment to be maintained without holding up the entire process. As more and more companies are now moving towards Lean Manufacturing in which waste in every aspect of the production process is eliminated, preventative maintenance may not be enough on its own and more emphasis is moving towards on-line condition based monitoring which is non-intrusive and can detect potential failures well in advance. This „waste’ term referred to in Lean Manufacturing is not the conventional meaning of the word but rather anything that is non-value adding in the production process, waste could be seen as equipment breakdown which can cause unnecessary delays in production.

Condition based monitoring (CBM)

Condition based monitoring or Predictive Maintenance is a group of emerging scientific technologies that can be employed to detect potential failures that may not be evident even through a PM program. If the failure characteristics of the equipment are known then condition based monitoring can detect the failure well in advance and appropriate actions can be taken in a planned manner. The use of condition based maintenance has dramatically reduced non-value adding maintenance by eliminating the need to unnecessarily shutdown equipment for maintenance checks. The technologies currently used in industry are listed blow:

- Thermography (infra-red imaging to detect abnormal temperatures or hot spots).
- Vibration monitoring (accelerometer instruments can be used to detect abnormal or high vibration particularly in bearings).
- Oil analysis (sampling of oil which is then analysed can detect the deterioration or breaking down of an internal equipment part).
- Ultrasonic measurement (use of ultrasound technologies to detect leaks or blockages on utility systems)

Condition based monitoring is a relatively new Science and has huge benefits in industry, however from the authors experience the tendency can be to sometimes have too much reliance on these technologies. There must be a fine balance between condition based monitoring and conventional maintenance practices.

Mather, 2007, asks the question *„Is Predictive Maintenance a Burden or Benefit?’* condition based monitoring will give maintenance ample warning of a failure but may take the focus away from the actual root cause of the failure. Mather’s, 2007, opinion is that for a truly effective predictive maintenance program an optimum cost should be spent on condition based monitoring based on risk, but also it should only be used a first step into determining why the equipment being monitored is starting to fail and what are the possible contributions. This is where the experienced maintenance professionals are still an important part of the maintenance process.

Corrective Maintenance (CM)

Corrective maintenance is responding to a problem that occurs unexpectedly or has been picked up in the field. Corrective Maintenance is often referred to as „fire fighting’ however not all corrective maintenance is a bad thing. If a good PM program has been setup then big problems that are captured will be completed as corrective maintenance. However, the important difference between PM and CM is that PM is a fixed planned schedule CM is not, this can lead to unexpected costs within the maintenance department. The aim is to have the PM program high and the amount of CM low. The common acceptable industry benchmark is PM:CM ratio of 80:20, as part of implementing maintenance best practices industries are striving to further improve this. Reliability Web, 2007, which is an online community for Reliability and

Maintenance Professionals published a series of „Best Practices Maintenance Benchmarks’ with a PM:CM ratio of 85:15.

Run to fail (RTF)

Run to fail is exactly what it means, there is no scheduled maintenance.

This may seem like a very poor strategy but in many cases it simply may not be cost efficient to maintain a piece of equipment that is cheap to replace and doesn’t really have any immediate consequences if it fails. One of the biggest problems that maintenance engineers have is that they want to execute maintenance on everything believing that there is more benefit than simply doing nothing. The run to fail option should be chosen following a detailed analysis of the system while only implementing the maintenance that matters.

Design out Maintenance (DOM)

If a component or piece of equipment is prone to frequent failure and preventive maintenance is only really placing a plaster on the problem each time, then it may be possible to design the problem out of the system altogether. This is where the Maintenance Engineer and Systems Engineer need to work closely together in order to solve these sorts of problems. By designing out the problems we can improve system reliability and eliminate the need for maintenance.

Reliability Centred Maintenance (RCM)

Reliability Centred Maintenance (RCM) is a structured approach to improving equipment reliability and blends failure and risk analysis with preventative and predictive maintenance. RCM can be considered as being one step away from achieving Total Productive Maintenance (TPM).

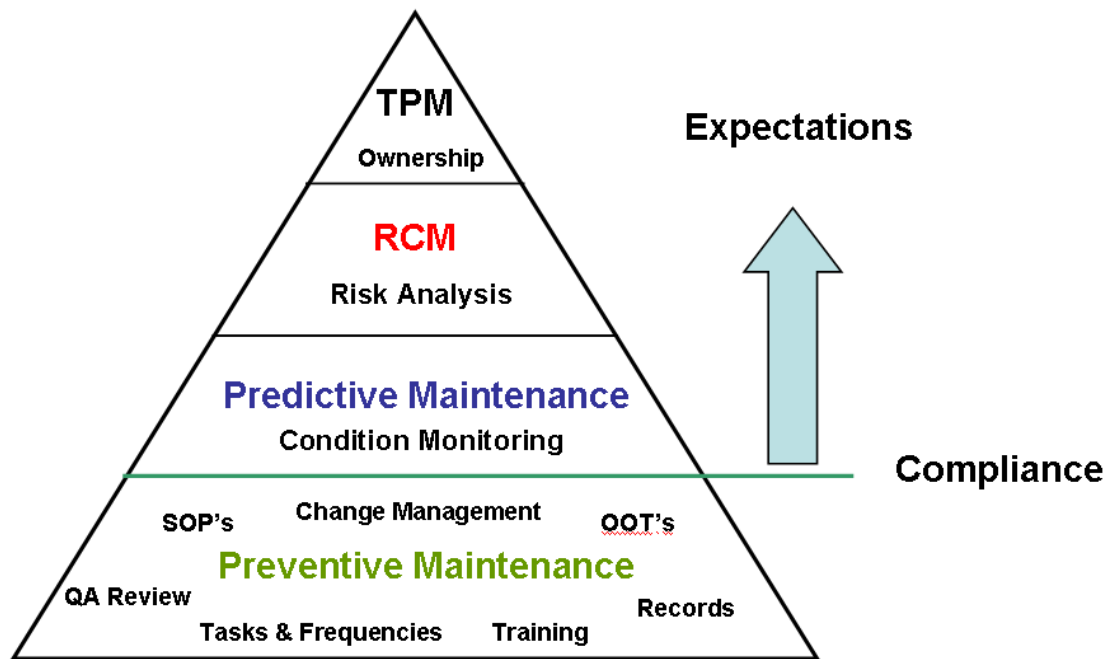


Figure 1.2 Maintenance Approach – Expectations

The above model is applicable to the pharmaceutical industry and shows the current shift in expectations for maintenance strategy. The green line shows the minimum regulatory compliance requirement where a preventative maintenance program is required and has to be documented.

Jones, 1997, defines RCM as „*a method for developing and selecting maintenance design alternatives based on safety, operational and economic criteria by employing a system perspective in its analysis of system functions, failures of functions and prevention of these failures*’.

The RCM approach looks at groups of equipment at a system level, it then analyses all the functions of the equipment, what failures can occur and how these failures affect the end user (manufacturing). When all this information is collected the maintenance program is designed to suit the needs of the end-user.

When designing a maintenance program using RCM the tools detailed previous are all considered in implementing the most effective optimised maintenance program:

- Preventative Maintenance (PM)
- Condition based monitoring (CBM)
- Corrective Maintenance (CM)
- Run to fail (RTF)
- Design out Maintenance (DOM)

RCM is a risk based approach and focuses resources on critical items, it promotes a learning organisation.

The right combination of all the above tools using RCM will contribute towards a truly effective maintenance program that is in line with maintenance best practices.

Garg, 2006, believes that RCM *„Ensures a sound maintenance strategy meeting the dual objectives of minimisation of hazards caused by an unexpected failure of equipment and a cost effective strategy’*

Backlund et al, 2003, comments that when preparing to introduce RCM within an organisation, a long term approach is preferable, so as to increase management and employee commitment. By doing this the desired maintenance performance based on an RCM analysis is far more likely to endure.

It seems as if a lot of industries are realising the benefits of implementing RCM and it links in well with overall quality systems: Hanson et al, 2003, see RCM as an *„effective and efficient maintenance in response to the needs of Total Quality Management (TQM)’*.

Root cause analysis and corrective/preventative actions

The investigation process for equipment failures is of paramount importance for the maintenance department who wish to continuously improve. Each time an equipment failure occurs an investigation is started in order to determine the exact root cause, when the root cause is known suitable corrective/preventive actions are put in place to prevent it from happening again. These corrective/preventative actions may involve updating the maintenance program, introducing conditional monitoring or a design improvement change to the process. Unless the maintenance department fully understand why equipment is failing then it is difficult to design the most beneficial maintenance program.

Madu, 2005, identifies root cause analysis as important part of maintenance strategy: *„Root Cause Analysis is a common terminology in the reliability literature. It is important to understand root causes of any problem in order to avoid future occurrences and perhaps, transfer knowledge gained in product/process design and redesign’*.

Fishbone or Ishikawa diagrams can be used by the investigation team for difficult problems to help try and identify possible root causes. This process looks at the five main categories of possible contributions to a failure: equipment, facilities, people, methods/procedures and materials. These possible root causes can then be scored in terms of likelihood and severity and ranked.

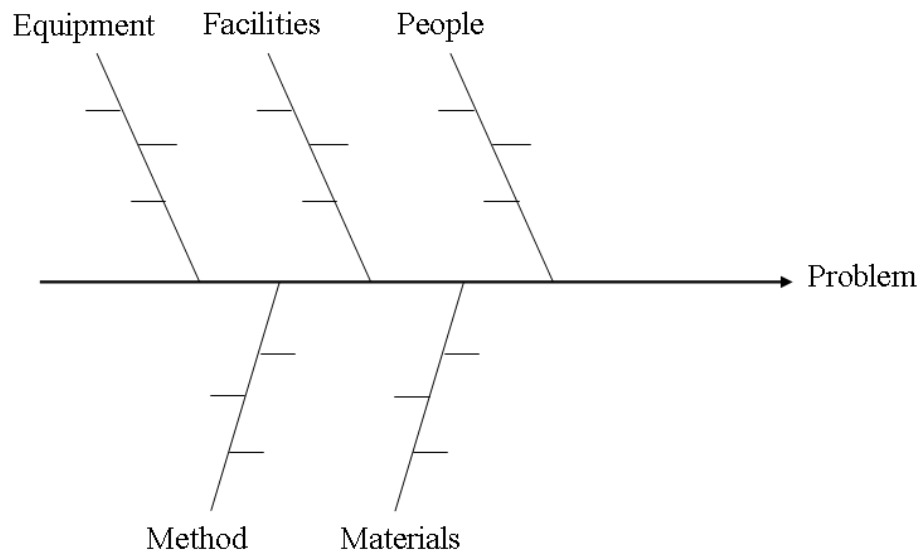


Figure 1.3 Fishbone diagram used for root cause analysis

The historical information obtained from these investigations can be used to develop troubleshooting guides which identify equipment failure symptoms and lists the most suitable checks and interventions. In addition to the investigations the historical information for recorded maintenance should be carried out periodically in order to capture any possible failure trends on equipment.

According to Marquez et al, 2004, „*maintenance records analysis can provide critical information from past experience to improve current maintenance process in a company*’.

The principles of Six Sigma which were originally introduced to address product defects have branched out into other applications and can be used to help improve most processes. For example the Six Sigma principles: define, measure, analyse, improve and control (DMAIC) has been used to improve the maintenance investigation process carried out at Wyeth Biopharma.

1.5 Maintenance Performance Measurement and Benchmarking

Maintenance performance measurement is of key importance and is a way of seeing the benefits of a maintenance program but also highlighting areas that need improvement. Over the past few years a number of standards have been published in an attempt to standardise maintenance terminology and key performance indicators in the measurement of maintenance effectiveness.

BS EN 13306:2001 „*Maintenance Terminology*’ is a recent standard that has been created to define and standardise maintenance terminology, this is leap forward for the maintenance community as it categorises different types of maintenance clearly and will help aid benchmarking between industries in the future.

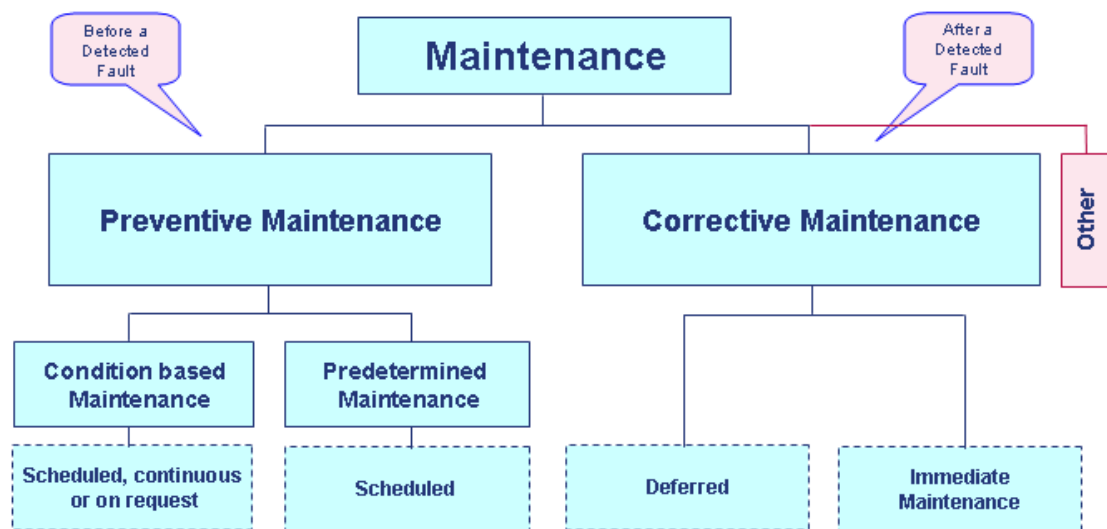


Figure 1.3 Maintenance Categorisation - BS EN 13306:2001

Description	Definition
7.1 Preventative	Maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or degradation of the functioning of an item
7.2 Scheduled	Preventative maintenance carried out in accordance with an established time schedule or established number of units of use
7.3 Predetermined	Preventative maintenance carried out in accordance with established intervals of time or number of units of use but without previous condition investigation
7.4 Condition Based	Preventative maintenance based on performance and/or parameter monitoring and the subsequent actions [NOTE: Performance and parameter monitoring may be scheduled, on request or continuous]
7.5 Predictive	Condition based maintenance carried out following a forecast derived from the analysis and evaluation of the significant parameters of the degradation of the item
7.6 Corrective	Maintenance carried out after fault recognition and intended to put an item into a state in which it can perform a required function
7.7 Remote	Maintenance of an item carried out without physical access to the personnel to the item
7.8 Deferred	Corrective maintenance which is not immediately carried out after a fault detection but is delayed in accordance with given maintenance rules
7.9 Immediate	Maintenance which is carried out without delay after a fault has been detected to avoid unacceptable consequences
7.10 On Line	Maintenance carried out during the time that the item is in use
7.11 On Site	Maintenance carried out at the location where the item is used
7.12 Operator	Maintenance carried out by a user or operator

Figure 1.4 Maintenance Terminology - BS EN 13306:2001

An extension of this standard is EN 15341 „*Maintenance Key performance Indicators*’ which details 70 Key performance Indicators (KPI’s) for measuring reliability, maintenance effectiveness at equipment level and overall department performance.

The KPI’s are listed under the following categories:

- Economical Indicators
- Technical Indicators
- Organisational Indicators

Most of these indicators can be used at different levels depending on whether they are being used to measure the performance of the entire plant, individual systems or individual system components (equipment). With the use of standard maintenance terminology and standard KPI’s we can consistently measure performance and compare with other industries.

Tsang et al, 1999, mentioned that „*maintenance measurement is needed in order to give the maintenance manager quantitative information on the extent to which maintenance goals can be reached and what action is to be taken in order to improve the operations to meet the goals*’.

As part of this thesis both these standards will be implemented for maintenance programs within the pharmaceutical industry.

1.6 Maintenance Management Strategies

Implementation of Maintenance Excellence simply cannot happen if the overall maintenance strategy does not support it. PAS 55 „Publicly Available Specification for Asset Management’ was published in 2004 and has been developed in response from industry for a standard for carry out asset management. It has been contributed and supported by many of the largest industries in the United Kingdom. Its scope is applicable to any business that wishes to implement, maintain and improve an asset management system. PAS 55 has a Plan-do-check-act (PDCA) methodology as per ISO 9001:2000 and has a structure of ensuring that all asset management activities are directed towards achievement of the business plan, at optimal cost and on a sustainable basis.

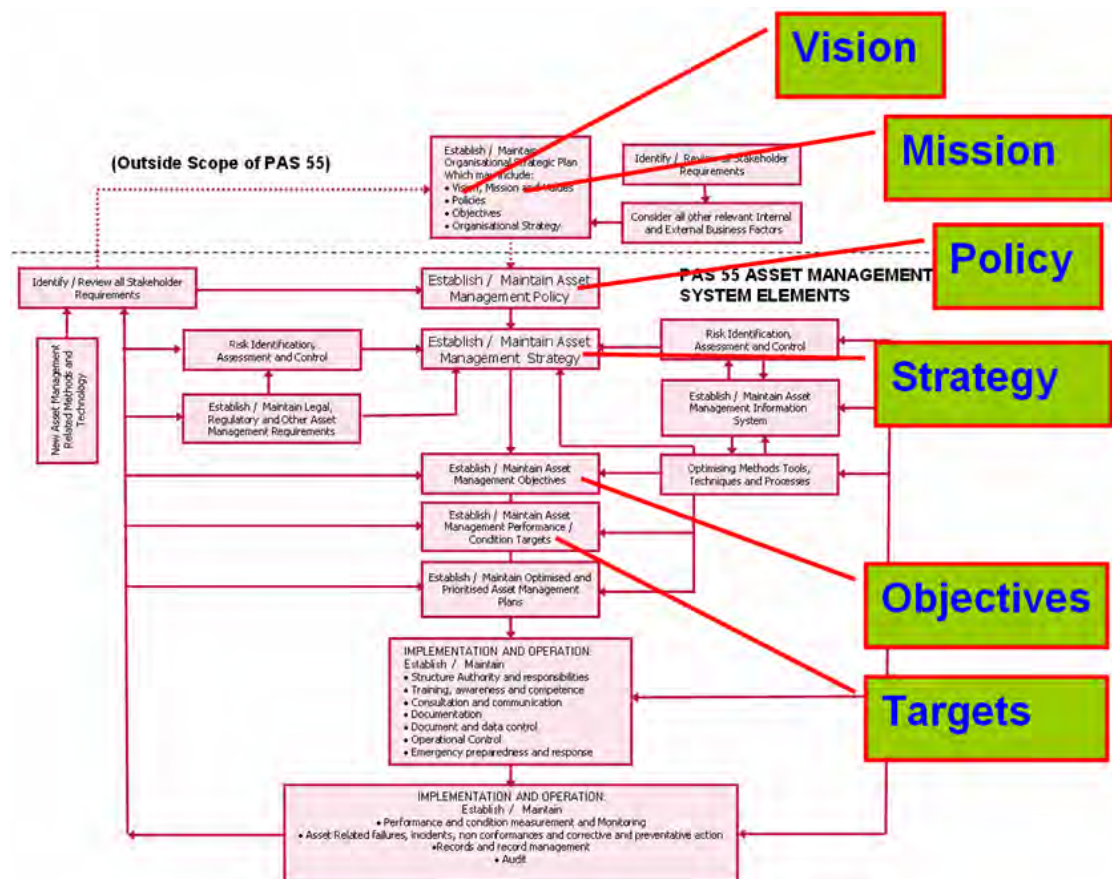


Figure 1.5 PAS 55 Process Flow Diagram

Asset Management: “systematic and coordinated activities and practices through which an organisation optimally manages its (physical) assets and their associated performance, risks and expenditures over their lifecycle for the purpose of achieving its organisational strategic plan.” PAS 55

1.7 Computerised Maintenance Management Systems (CMMS) and Maintenance Planning

Computerised Maintenance Management Systems (CMMS)

In its simplest terms a Computerised Maintenance Management System (CMMS) is a software tool which can be used to schedule and record all maintenance activities. Most CMMS's used in industry today such as SAP or Maximo are hugely powerful and will also take control of spares management, calibrations and resource scheduling. The CMMS has become a critical part of the successful maintenance organisation, the system when implemented correctly can drive the preventative maintenance program by scheduling activities at fixed time intervals, record history of maintenance back into the system, keep track of maintenance costs (labour and spares) and track equipment downtime hours.

Cooke, 2003, defines the objective of using a CMMS is to *“facilitate the management of the maintenance resource, to monitor maintenance efficiency, and to provide appropriately analysed management information for further consideration.*

As described above CMMS systems have an array of tools available, from the authors experience not all of these tools are used, in particular the resource planning function in which detailed man-power requirements and allocation to the maintenance activities are very rarely used. The main reason for this is that most CMMS systems such as SAP and Maximo are overly complicated to use and companies tend to fall back to its primary use which is scheduling and recording maintenance activities. This project will look at the current use of the SAP maintenance management system within a pharmaceutical industry and will explore and help implement potential areas of improvement.

Maintenance Planning

The successful implementation of a CMMS in the maintenance department relies heavily on the role of the maintenance planner. The maintenance planner is the key interface between the CCMS and the maintenance staff executing the maintenance program. The maintenance planner organises the execution of work, plans and co-

ordinates equipment downtime, analyses historical trends and reports the performance of the maintenance department.

The planner is constantly looking ahead to try and effectively utilise equipment downtime and group all outstanding activities such as scheduled maintenance and calibrations so that impact to the end user is minimised.

Evidence from the literature shows that the planning function is not always adequately resourced or the role is not clearly defined. Kister, 2006, suggests the proper ratio of planners to maintenance tradespersons in a very disciplined and mature process is 1 to 20. Kister, also identifies the common misguided application of the planner function in which they often act as fetchers, parts chasers and that these tasks *“detract from the core responsibilities of planning and scheduling, which is to prepare work plans and scheduling for the next week and beyond”*.

Cholasuke et al, 2004, highlights that the lack of planning and scheduling can *“significantly restrict a maintenance operation from meeting its objective of servicing the organisation needs”*. Cholasuke et al, goes on to show that evidence from a number of UK manufacturing firms show that *“proper work planning can lead to high responsiveness, less unplanned work, and less unplanned overtime with consequences of lowering the cost of maintenance”*.

The skill set of the maintenance planner is also important to consider and from the authors experience a person with a good technical ability combined with good organisational and interpersonal skills is needed. This project will examine in detail the role of the maintenance planner within the pharmaceutical industry and how best this role is defined and utilised.

1.8 Regulatory requirements for maintenance within the pharmaceutical industry

It is a regulatory requirement to have a defined maintenance program for Clean Utility Systems feeding pharmaceutical processes.

Clean utility systems are those systems which can have a direct impact on product quality; examples of these types of systems are as follows:

- Clean HVAC (Heating Ventilation and Air Conditioning) Systems: these HVAC systems are used to provide production clean room environments and

are critical to product quality. The HVAC system controls pressure, humidity and temperature in the production areas and filter the in-coming air at a microbial level. A production clean room is an environment which is free from contamination and unwanted micro-organisms, in these clean rooms the product is prepared and may be exposed to the surrounding air.

- High purity water systems: these water systems can be mixed with the product for oral or intravenous use.
- Process Air Systems: this is a compressed air system which may have direct product contact and is filtered at a microbial level.

The regulatory agencies such IMB (Irish Medicines Board) and FDA (Food and Drugs Administration) govern the authorised sale and administration of pharmaceutical products to the patient. The pharmaceutical manufacturers are legally responsible for the Identity, Strength, Purity, Quality and Safety of their products. Research conducted on the FDA website shows that US Government were historically the first to develop and implement tight regulation of medicinal products. Following a number of medicinal product related human fatalities since the early 1900's, the FDA was setup in 1903 in order to strictly control the manufacture and sale of food and medicinal products. The FDA over the last century has developed a number of strict guidelines and regulations to which pharmaceutical manufacturers must adhere to before being licensed to sell medicinal products. Adopting many of these FDA regulations, the Irish Medicines Board (IMB) was established in 1995 (replacing the National Drugs Advisory Board), and now licenses all medicines for human and animal treatment in Ireland.

The following regulations govern the maintenance requirement on clean utility systems:

- EU Good Manufacturing Practices (1998)
“Manufacturing Equipment should be designed, located and maintained to suit its intended purpose”
- EU GMP Annex 1 – Manufacture of Sterile Medicinal Products (2003)

“All equipment such as air handling, filtration systems and water treatment systems (generation, storage and distribution) should be subject to planned maintenance”

- EU GMP Annex 18 – GMPs for Active Pharmaceutical Ingredients (2001)
“Schedules and procedures (including assignment of responsibility) should be established for the preventative maintenance of equipment”
- US FDA 21 CFR 210 and 211 – cGMPs for finished Pharma Products (2004)
“Equipment shall be maintained at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality or purity of the drug product”

All the above regulations document the requirement for a procedural maintenance program to be put in place. The regulations also place strict control on revising procedural content and therefore trying to improve or change the established maintenance program in the pharmaceutical industry can be difficult.

The regulations also place strict controls on the use of Computerised Maintenance Management Systems (CMMS) with regards to the maintenance records, changing its content and access into the system.

This project will explore how best to improve maintenance programs and how to provide enough documented justification in order to stay compliant with the regulatory requirements.

1.9 Literature Review Summary and Conclusions

Maintenance evolution

The literature review has shown that the shift in maintenance expectations has increased dramatically over the past century. In modern times maintenance has evolved to becoming a subject in its own right, currently maintenance practices in industry are most likely at its best to date, however a number of authors point out that there is still room for improvement. This is where the next evolutionary step in maintenance is starting to immerge which is „Maintenance Excellence’ or „World Class Maintenance’ and industries are realising the potential of improved productivity and cost reductions to the overall business by implementing such strategies.

Emerging maintenance tools and management strategies

The review details a great array of maintenance management tools and strategies available to help the organisation and should aid a structured approach to implementing a world class maintenance program. Industry is moving beyond basic preventative maintenance and striving towards Total Productive Maintenance (TPM). Following an equipment failure the maintenance teams now investigate the root cause and puts in place suitable preventative and corrective actions to prevent a re-occurrence, this can be considered as continuous improvement and through design improvement can lead to process improvement.

Industry have come together in order to develop and standardise maintenance measurement so the maintenance department can now evaluate performance.

The literature shows that the introduction of computer technologies such as CMMS are now being widely used to automatically schedule the maintenance and record equipment history. However, in a number of articles it has been shown that these CMMS systems are not being utilised to their full potential. The role of the maintenance planner in conjunction with the CMMS has been shown to be critical in effectively executing the maintenance program.

Maintenance in the Pharmaceutical Industry

The review of the maintenance in the pharmaceutical industry has shown that strict regulation can make it difficult to try and improve the current maintenance program. However, the pharmaceutical regulatory bodies such as IMB and FDA are becoming more open to the uses of emerging technologies and practices in maintenance.

Maintenance management: links with Quality Management

During this literature review the author has noticed that current maintenance management is closely aligned with quality management with areas such as continuous improvement, process improvement, reliability centred maintenance, performance measurement, six sigma and defined management strategies being employed. In fact the three quality guru's (Juran, Crosby, Deming) all supported the concepts of Total Preventative Maintenance and Total Productive Maintenance as part of a successful quality culture. Given the vast amount of literature found which is devoted to maintenance, it shows that maintenance best practices has now become a subject in its own right.

Overall Conclusions

Maintenance excellence is an emerging topic in both theory and practice. Its implementation shows a great potential for cost saving, improved equipment performance and overall productivity by helping implement the most efficient and effective maintenance program. The literature review has provided a good insight into the relevance of this project and shows that maintenance excellence is in line with current industry thinking.

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International Standards

- BS EN 13306:2001 (Mar 2001) „*Maintenance Terminology*’
- BS EN 15341:2007 (Apr 2007) „*Maintenance Key performance Indicators*’

PAS 55-1 (Apr 2004) „*Publicly Available Specification for Asset Management*’

EU Good Manufacturing Practices (1998)

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CHAPTER 2 – LEADERSHIP, MAINTENANCE CULTURE & PEOPLE

2.1 Introduction

World-Class Organisations

The term „World-Class’ in industry refers to the ability to sustain profitable growth in competition with anyone in the world. To achieve a world-class status requires using best practices in manufacturing strategies and techniques; this includes maintenance and is the reason why „Maintenance Excellence’ or „Best Practices’ is an important element in a world-class organisation.

MCP Langcet (Maintenance Management Consultants) in 2007 reported that the breakdown of industry in Ireland and the UK in relation to world-class maintenance is as follows:

UK & Ireland	
World Class	2.5%
Promising	18%
Contenders	40%
The rest	39.5%

Figure 2.1 World Class Maintenance – UK & Ireland

Courtesy: MCP Langcet, 2007

The above data shows that World-Class is a relatively new concept and that although a small percentage are considered to be there, the majority of industries are striving towards this achievement. In ever changing economies we now see countries like India and China competing fiercely with the west on cost. These Asian industries may be winning on cost however their industries, that are growing so fast, are continually plagued with quality problems. This is where the western industries are gaining an advantage as the majority of companies based here have a strong emphasis on quality management and are striving towards World-Class status. This can make high technology companies involved in manufacturing developing cutting-edge technology such as microelectronics and biopharma drugs reluctant to set up factories in Asia. These high technology companies have quite high profit margins on their products, labour costs can be higher but with better skills and a strong emphasis on quality; for

this reason the extra cost can often be tolerated. It is up to all industries operating in both Ireland and UK to adopt the „World-Class’ way in order to survive in harshly competing economies.

After all as the famous quality guru Crosby stated “*Quality is free*”, companies can only really benefit by implementing World-Class which has its foundations based on quality management.

Where Maintenance Excellence fits into the World Class Organisation

A lot of supporting strategies have been developed over the last few decades in order to give guidance to the potential World-Class organisation. Unfortunately these strategies such as World Class Manufacturing (WCM) and ISO-9000:2000 do not place enough emphasis on maintenance and asset management.

Asset Management can account for up to 20% of the organisations costs and for this reason following collaboration with industry the first real maintenance guidance document PAS 55-1 „Publicly Available Specification for Asset Management’ was published in 2004. It is predicted that PAS 55 will soon become a standard in itself and the document is already presented in the style of other ISO documents. If PAS 55 becomes a standard then the document has potential for implementing PAS 55 certification. This will be explored in more detail later on in this chapter.

Outsourcing of the maintenance department

In order to enable the manufacturing company to focus more on their core business, which is making product, it can be very beneficial to outsource the maintenance department to an outside company. This outsourcing structure has become very popular in modern industry and in this chapter the author will explore the benefits of implementing this type of outsourcing and how from the authors own experience this can be successfully achieved.

Operations and Maintenance Synergy

Synergy in the industrial context can be defined as “*Cooperative interaction among groups, especially among the acquired subsidiaries or merged parts of a corporation, that creates an enhanced combined effect*”. The author has recently led a synergy project at Wyeth Biopharma in which the operations and maintenance departments for the two main manufacturing buildings are to be merged. This project has shown

potential cost savings by removing duplication and non-value adding activities whilst actually improving the overall support of maintenance and operations to the client (Wyeth). The project is an important element of implementing maintenance excellence and will be detailed in this chapter.

Embedding the maintenance and operations teams in new plant & equipment projects

The eventual end user of any new plant or equipment is the maintenance and operations teams, however the maintenance and operations team often do not have any involvement in the project phase. At Wyeth Biopharma this was identified as a problem and all too often projects were „handed over the wall’ often leaving a lot of operations and maintenance problems which they eventually would have to pay to get resolved.

In 2006 Wyeth installed a new syringe fill manufacturing building at the Grange castle site. The author led a team of Engineers in this project with the objective of ensuring the project was both designed and installed for ease of maintenance, operations and smooth handover. This project was a success and this key engineering process has now been clearly embedded in all future projects. This process ensures that maintenance are always involved from the start and is an indication of the realisation of the importance of the maintenance function, this maintenance evolution at the Wyeth site will be documented in this chapter.

Building in Maintenance Awareness with Manufacturing and top level management

As mentioned earlier maintenance reform should be a top down approach. Top management need to build maintenance excellence into their key objectives, also from the authors experience the manufacturing department within the pharmaceutical industry see maintenance as a regulatory compliance requirement only. The maintenance schedule is not integrated with the manufacturing schedule and obtaining downtime can become very difficult and often with a negative attitude by manufacturing.

This chapter will explore how to increase awareness among manufacturing and top management as to why we do maintenance and what are the benefits for manufacturing and the overall organisation.

2.2 Asset Management Policy and Strategy

Developing World Class Asset management objectives and targets

Anyone working in a manufacturing industry will be aware of the companies overall policy and objectives for the present and the future. It is very seldom that the Maintenance or Asset management group have a policy and strategy of their own that links into the overall organisations objectives. For this reason the maintenance management teams often don't have clear objectives or strategic directions.

This is the first area in which PAS 55-1 „Publicly Available Specification for Asset Management' looks at. In this top down approach you first need to decide what you want out of your asset management program and then work to deliver it.

PAS 55 defines asset management as “the optimum way of managing assets to achieve a desired and sustainable outcome”. Assets include plant, machinery, etc, that provide a function or service to the overall business.

In 2007 the engineering department at Wyeth Biopharma setup a site wide Maintenance Excellence team of which the author is a member of. The team of 6 people consists of engineering support and maintenance teams from across the site in order to start harmonising the approach to asset management and to improve maintenance across the site. This team was setup with support from top management at both company and cooperate level. Using PAS 55 as a guidance document the first step was to develop an Asset Management Procedure which documents how we do maintenance in line with best practices. PAS 55 directs the following order of activities when building the asset management program:

- Create the Asset Management Vision in line with the organisational objectives
- Determine the mission statement for Asset Management
- Establish and document the policy
- Create the Asset Management strategy
- Establish the objectives
- Decide what are the expected targets for these objectives

The following PASS-55 flow diagram shows this step approach:

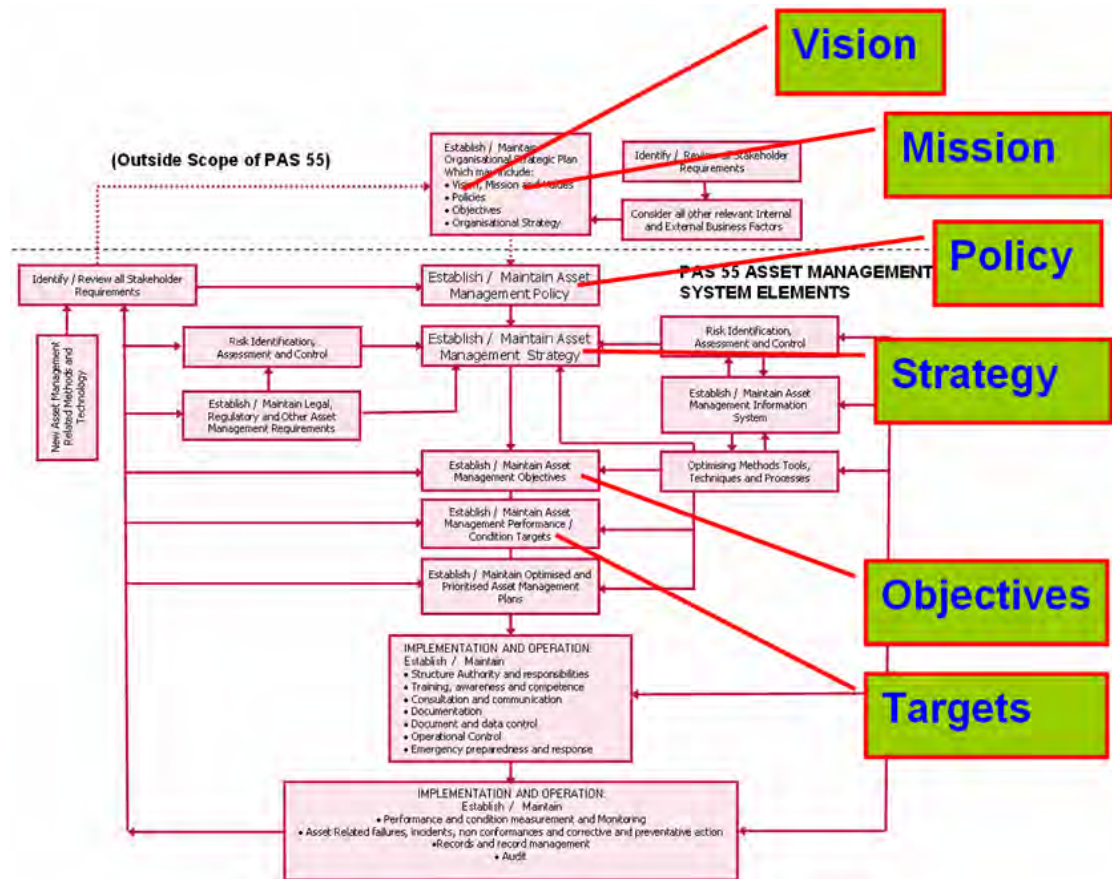


Figure 2.2 PAS 55 Process Flow Diagram

When developing the Asset Management Vision and Mission we first looked at those for the overall site:

Wyeth Grangeacastle Manufacturing Vision:

„To be the most respected Campus for the supply of innovative medicines that significantly improves people’s lives’

Wyeth Grangeacastle Manufacturing Mission:

„We supply quality, high volume, innovative Biopharmaceuticals, Pharmaceuticals and Vaccines to improve patients’ lives.

We maximise Wyeth shareholder value from an integrated manufacturing & development Campus’

The team then developed the Asset Management Vision and mission whilst ensuring that it is line with overall site. If this important activity is not completed correctly then

it is possible to end up with department objectives that conflict with the overall business objectives:

Wyeth Grangecastle Asset Management Vision:

„To be a Team, recognised by everybody on campus, who provide effective, flexible and innovative Asset Management solutions in support of the business’

Wyeth Grangecastle Asset Management Mission:

„Provide Asset Management Services to support the business by Ensuring Plant Availability which is both Cost Effective and Compliant, and to achieve this by realising the potential of team members’

The above asset management vision shows that in order to achieve an overall successful manufacturing plant then key areas such as plant availability, compliance and cost effectiveness need to be of high standard. The mission also recognises the importance of people within the asset management program whose support and continuous development is needed to succeed.

Asset Management Policy:

The term policy within a manufacturing organisation is a set of business rules that need to be followed. Within the pharmaceutical industry these policies are mostly regulatory requirements set out and are of prime importance. When the maintenance excellence team were developing the asset management policy we first needed to understand what the regulatory requirements are and then set them out in a clear and concise way. The following 7 policy statements were created and are in line with regulatory requirements for pharmaceutical production:

- **Maintenance Policy Element No. 1 - Written Procedures**

„There shall be written procedures to ensure that facilities, utilities, and equipment subject to good manufacturing practices (GMP) and food safety requirements are properly secured and maintained.’

- **Maintenance Policy Element No. 2 - Life cycle approach to be taken when planning Asset Management**

„There shall be written procedures for the design, selection, procurement, installation, commissioning, decommissioning and documentation of facilities, utilities and equipment subject to GMP requirements. Appropriate Quality Unit approvals and, if necessary, regulatory agency approvals shall be obtained.’

- **Maintenance Policy Element No. 3 - Maintain as-installed status & performance**

„The primary purpose of the maintenance group on site is to maintain all site assets to their as installed or as qualified status such that the operation and performance of any site asset or equipment item is fit for its intended purpose and does not deviate from its required performance’

- **Maintenance Policy Element No. 4 - Identify all Equipment and Record all Work carried out on it**

„Facilities, utilities and equipment shall have unique identification codes as required. Maintenance activities shall be documented’

- **Maintenance Policy Element No. 5 - Qualified and Approved Personnel only to carry out work**

„Engineering shall ensure that only qualified and approved personnel carry out engineering work on site. Only suitably qualified personnel will be assigned to Engineering positions’

- **Maintenance Policy Element No. 6 - Commitment to continuous improvement**

„A review will be carried out of all maintenance activities within each major location or system on a periodic basis, not less than one per annum, to determine the effectiveness of the maintenance strategy in place and implement any changes where necessary.’

- **Maintenance Policy Element No. 6 - Policy to be visibly endorsed by top management**

„The Director of engineering is responsible for : Ensuring that an engineering quality policy is understood, implemented and maintained within the engineering group; Ensuring that procedures are in place to ensure that engineering activities are in accordance with this quality system; Ensuring that reviews are carried out on the engineering group's compliance to the quality system requirements and to determine the effectiveness of the quality system.’

- **Maintenance Policy Element No. 7 – Spare Parts Management**

„All spare parts will be managed through the Engineering Stores. Spares holding will be decided following a Risk-based Assessment of requirements.’

The above policy statements capture all the important regulatory requirements for maintenance in the pharmaceutical industry. The policies also bring in areas of maintenance excellence practices such as continuous improvement and support from high level management.

Asset Management Strategy:

A strategy is a long term plan of action designed to achieve a particular goal, in asset management terms this is structured in two parts:

- Overall Asset Management Strategy
- Maintenance strategy which links into overall strategy

The overall asset management strategy maps out the key elements of how the desired world class outcome can be achieved:



Figure 2.3 Wyeth Grangecastle Asset Management Strategy

The next part is the maintenance strategy, this details what different approaches to maintenance are to be employed:

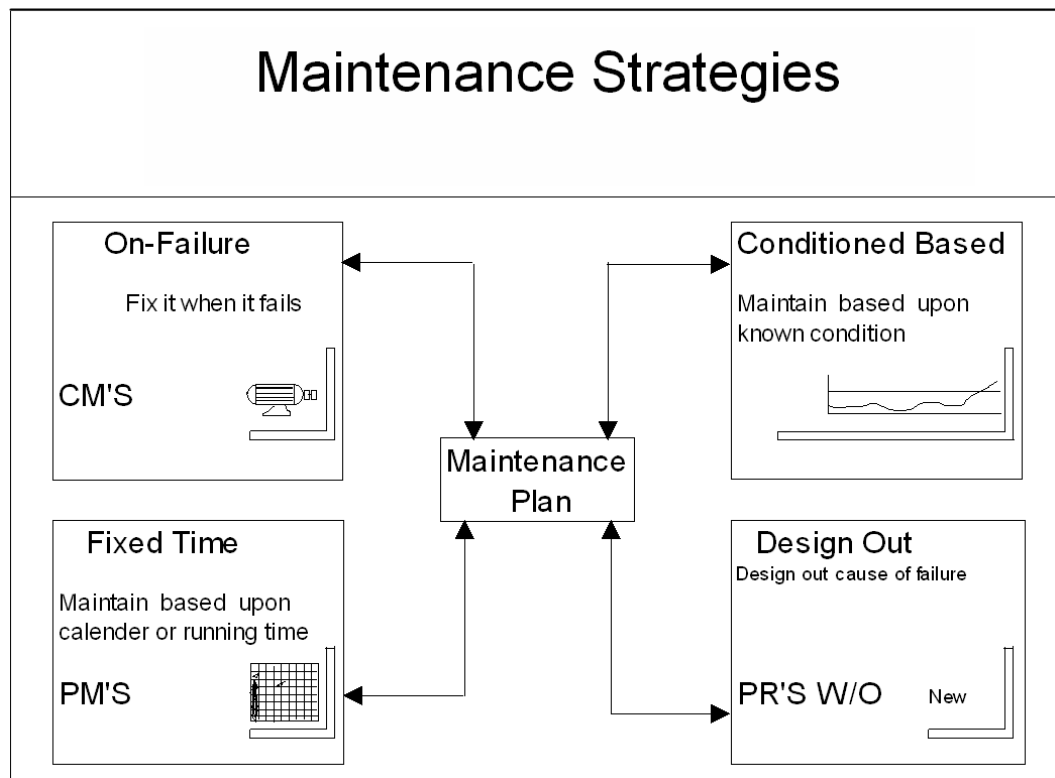


Figure 2.4 Wyeth Grangecastle Maintenance Strategy

The above maintenance strategy shows the four main approaches to maintenance that are employed on site. Each of these approaches are detailed in Chapter 1 and the overall maintenance program will be a mix of these, selection will be based on criticality analysis tools such as Reliability Centred Maintenance (RCM).

Asset Management Objectives:

The next stage of the PAS-55 process flow is to develop and agree the objectives for the Asset Management department. As discussed in the introduction section of this chapter it is of prime importance that the objectives created are in line with that of the overall organisation. The overall objectives for Wyeth are to maintain the success of the business, support the manufacturing processes and to continually improve. To help achieve this, the asset management objectives for 2007/2008 were set out:

1. Operate the Current Maintenance System

- Deliver an effective maintenance program to manufacturing
- Deliver high plant & equipment availability to manufacturing end-users
- Improve site perception of Asset Management and its importance to business success

2. Measure Performance

- Track performance in the areas of Safety, Regulatory Compliance, Plant Reliability and Cost
- Agree and implement set of key performance indicators in order to measure the above areas and report out results to area owners

3. Refine & Develop current maintenance systems and programs

- Improve the safety of systems, equipment and asset management activities
- Improve reliability of systems and equipment
- Improve compliance
- Reduce impact to manufacturing

4. Grangecastle Maintenance Synergy

- Maintenance synergy and consistency across similar utilities and process systems

5. Maintenance & Operations teams to be part of the project life cycle process

- Mobilise a Project/Commissioning/handover team for equipment/system projects sitewide with overall goal to transition any new plant into normal operations

The next step once the objectives have been developed is to agree the targets or desired results, this is an important process, targets need to be both achievable and realistic. The majority of the above objectives will be measured by implementing standard key performance indicators, this project was completed in 2007 and forms part of Chapter 5 „Maintenance Performance Measurements’, this chapter will also explore how to use PAS-55 to benchmark the asset management program against what is considered to be „World Class’. Increased equipment reliability and cost effective maintenance is to be achieved through continuous improvement methods and plant critically analysis, all of which from part of Chapter 4 „Reliability Improvement’.

2.3 Outsourcing of the Maintenance Department

Why is outsourcing maintenance becoming so popular?

According to Jones (1999), it is found that 30 percent of World Class manufacturing organisations will out-source the maintenance organisation, particularly in the area of utility systems. The outsourcing of maintenance is a relatively new trend with as little as 5 percent outsourcing in the early 1990’s.

The main reasons for outsourcing are to allow the manufacturing company to concentrate on its core activities, which is making product. Contracting out the maintenance function can reduce costs by eliminating direct company headcount; management can enforce change quickly, drive continuous improvement and improve service levels. This is possible because the company is the „customer’ and they want the most for their money, for the maintenance contractor the customer is valuable and in many cases they will go to any lengths to ensure customer satisfaction.

By setting out clear expectations and outsourcing to an experienced contracting company, great results can be achieved. Outsourcing should not be mistaken with relinquishing of overall responsibilities, legal aspects such as regulatory compliance for Drug Manufacturing must be closely monitored and the manufacturing company must provide safe systems of work. The manufacturing company should employ people to monitor performance of the outsourced contract and to develop service level agreements.

All the major manufacturing companies in Ireland such as Intel, Wyeth, Hewlett Packard and others have all adopted maintenance outsourcing as part of their business strategy. This has paved the way for a new emerging business sector in Ireland which is industrial services; outsourcing services such as facilities, maintenance and security can all be readily provided. Competition in these areas is fierce which of course drives the standard of service up and the cost down. This is allowing Irish companies to build up expertise in these areas by being able to support large multinational companies who wish to set up in Ireland. This ability of the service companies can help make Ireland attractive to the potential company wishing to setup here.

Wyeth and Dalkia: Building Outsourcing Excellence

In 2001 it was announced that pharmaceutical giant Wyeth was to invest €1.8 billion in a state of the art Biopharma plant at Grangecastle, West Dublin. Later that year the construction of one the world largest biopharmaceutical plant began at Grangecastle. In 2002 maintenance outsourcing began by employing the maintenance expertise of FP2 Ltd (now Dalkia Ireland Ltd) in order to operate plant utilities and to setup maintenance programs for the site. Although we don't see plants of this size being constructed often, perhaps only once every decade, this is the best time to form an alliance partnership with the maintenance outsourcing company, working together from the start.



Figure 2.5 The Wyeth Biopharma Campus at Grangecastle

Dalkia Ireland Ltd are part of the French company Veolia Ltd which employ over 14,000 people world wide through a large portfolio of businesses operating in the service sector. Dalkia in Ireland employ 600 people and provide maintenance outsourcing, utilities and energy solutions for industry. One quarter of Dalkia's employees in Ireland are based at Wyeth, Grangecastle and support Wyeth's 1000 strong employee force to effectively provide utilities operations, maintenance and facilities services.

Since 2002 to present Wyeth and Dalkia have evolved to form one of the best examples of outsourcing excellence in Ireland today. From the authors experience there are a number of key areas that have contributed to this success:

Dalkia: A self-managed Service

Dalkia have a high degree of ownership when it comes to operating and maintaining utility systems. In each manufacturing area the contract is overseen by one Wyeth cost centre owners who monitor performance of the contract and spending. This structure is beneficial to Wyeth and they don't need to get involved in the day to day running of the Utility Systems. Through the cost centre owner Wyeth management have a good visibility of the performance of the contract and the areas that may need to be addressed. Performance is measured through areas such as availability, planned work V's actual, safety and regulatory requirements. For clean utility systems (which are

qualified systems and feed manufacturing areas directly) high level compliance is ensured through Wyeth subject matter experts and the Quality Assurance group in each area. Wyeth has overall responsibility for the safety of their products and this structure needs to exist. The following chart details the type of organisational structure that has been set up for the outsourcing of utility systems in manufacturing areas:

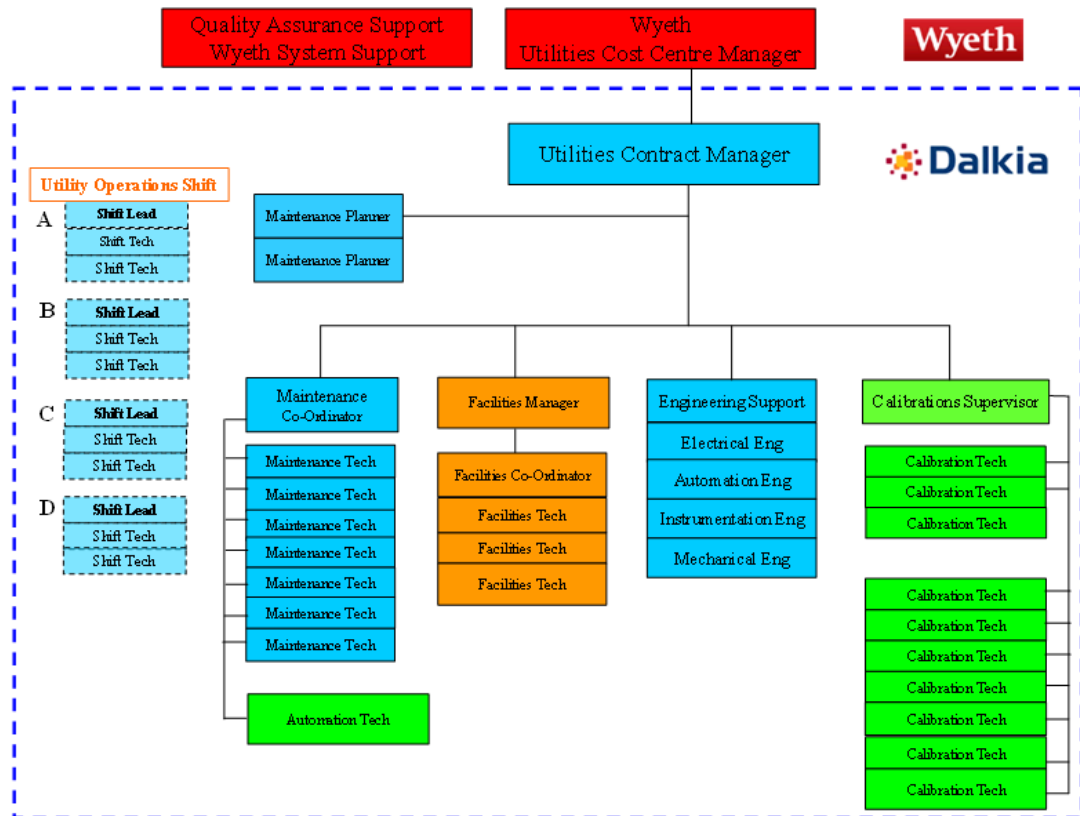


Figure 2.6 Dalkia/Wyeth Organisation Chart for Utilities

One of the key advantages of this structure is that the outsourced company can be measured directly against the equipment/system uptime that is being provided; this is because they own every activity within the maintenance organisation. In some outsourcing situations only certain tasks are contracted, also known in industry as „body shopping’; in this scenario it can be difficult for the company to achieve full accountability from the contractor for systems performance. Where the outsourced company has a high degree of ownership of systems then continuous improvement is a natural evolution, this should be supported and encouraged by the client company.

The service level agreement sets out clear expectations and tasks to be performed by the outsourcing partner. The manufacturing company's measurement of the contract is important; company's can't manage what they don't measure so this is where key performance indicators (KPI's) have a part to play. The KPI's are structured in terms of plant availability, scheduled work completion, safety and compliance with specific targets. In the Wyeth-Dalkia contract, penalty clauses are employed for performance targets that are not met, this approach creates a mutual gain „win-win' (i.e. both share the risks and rewards) environment in which all parties see the benefit of high performance.

By creating the outsourced maintenance function as a separate entity it means that whatever is happening in production, good or bad, the utility equipment/systems performance is not compromised. In cases where the maintenance function is in-house the company departments have tendencies to abandon the maintenance function temporarily in order to sort out problems in production which can ultimately lead to system performance and regulatory compliance suffering due to lack of focus.

Dalkia & Wyeth: An „Alliance Partner' not „Contractor'

Dalkia play an important role in the day to day operation of the Wyeth plant in Grangecastle and for this reason high recognition is given to the outsourced company by treating Dalkia as if they were their own employees. For example, Dalkia receive the same training, are involved in the same social events, instead of being „housed away in the back-yard', Dalkia operate along side Wyeth on a daily basis.

The term „contractor' is very rarely used when referring to Dalkia, rather an „alliance Partner' with Wyeth. In many plants the outsourced company are often referred to as „those mnaintenance people' and this stigma creates an „us versus them' relationship which can inhibit improvement, hinders trust and can have a negative effect on overall plant performance.

All of the above approaches by Wyeth creates a true partnership between the client and the outsourced partner, and the relationship is based on mutual trust and mutual gains.

Dalkia & Wyeth: Building for the future

At present Dalkia and Wyeth are in the process of negotiating a 10 year long term contract in which Dalkia will purchase the utility services at the plant and take over full ownership. The utility services are then sold back to Wyeth at a unit cost. This sort of contract arrangement is set to become the future for outsourcing of utilities.

Again this is a „Win-Win’ situation for both parties, on one hand Wyeth the manufacturing company receive an immediate influx of capital and then allows them to set long term fixed budget costs for each year in return for the supply of utility services. For Dalkia the outsourced company, an operational profit is made over the term of the contract, and investment can be made for the long term development of its people without the fear of losing them through loss of short term contracts.

With a long term fixed price contract, it is within Dalkia’s own initiative as the outsourced company to continuously improve in order to gain a higher profit margin on high availability utilities being sold back to the client.

2.4 Operations and Maintenance Synergy

What is Synergy?

As mentioned earlier in the chapter, „Synergy’ in the industrial context can be defined as *“Cooperative interaction among groups, especially among the acquired subsidiaries or merged parts of a corporation, that creates an enhanced combined effect”*. By merging similar areas and standardising activities, reduction in duplication and non-value adding activities can be achieved. This means cost savings and improved performance levels by adopting a standard consistent approach in all areas which can improve together. This sort of project has close links with „Business Process Re-engineering’ which is a similar management approach aimed at improving the efficiency and removing duplication of business processes.

In 2007 the author led a Synergy project at Wyeth Biopharma to merge the operational and maintenance functions for the two manufacturing buildings on site. The following documents the key areas of implementing such a project:

Identifying areas of potential improvements by implementing synergy

At Wyeth plant there are two main manufacturing buildings, Drug Substance (DS) plant which produces bulk biopharmaceutical product and the Manufacturing Suites (MS) plant which fills the product and packages it for ready for sale. All buildings of the new Wyeth plant was originally designed and constructed by the same company „Jacobs Engineering’ and for that reason both buildings (DS and MS) have very similar utility systems. The utility systems for both these buildings are operated and maintained by two separate groups of people and was identified as an area for potential synergy. At the start of the project the areas that would be synergised as part of this project were identified:

Operational and Maintenance Procedures (Merging and training)

- Merge all operational and maintenance procedures for common Utilities across MS & DS
- Train the teams up the new combined procedures

Engineering Work Instructions procedures (EWI)

System Name	Drug Substance	Manufacturing Suites	Proposed combined MS/DS
Domestic Hot Water	Operation of the Drug Substance Domestic Hot Water System	Operation of the Drug Product Domestic Hot Water System	Operation of the MS and DS Domestic Hot Water System
	Operation of the Pilot Lab Domestic Hot Water System		
Chilled Glycol	Operation of the Drug Substance Chilled Glycol Generation and Distribution System	Operation of the Drug Product Chilled Glycol Generation and Distribution System	Operation of the MS and DS Chilled Glycol Generation and Distribution System
Low Pressure Hot Water	Operation of the Drug Substance Low Pressure Hot Water System	Operation of the Drug Product Low Pressure Hot Water System	Operation of the MS and DS Low Pressure Hot Water System
	Operation of the Pilot Lab Low Pressure Hot Water System		
WFI System	Normal Operation And Draining Of The Drug Substance Water For Injection (WFI) And Clean Steam Systems	Normal Operation and Draining of Drug Product WFI Distribution Loop	Normal Operation Draining and Steaming of MS and DS WFI Storage and Distribution
	Operation of the Pilot Lab Water For Injection Steaming in Place	Draining & Steaming Of WFI Distribution Loops And Storage Tank	
Process Waste	Operation of the Drug Substance Process Waste Systems	Operation of the MS Process Waste System	Operation of the MS and DS Process Waste System
	Operation of the Pilot Lab Process Waste System		
Plant Steam & Condensate	Operation of the Drug Substance Steam and Condensate Return System	Operation of the Drug Product Steam and Condensate Return System	Operation of the MS and DS Steam and Condensate Return System
Reverse Osmosis	Normal Operation And Draining Of Drug Substance Ro Distribution Loop	Normal Operation and Draining of RO Distribution System	Normal Operation and Draining of the MS and DS RO Distribution System
Waste Water Recovery	Operation Of The Waste Water Recovery System	Replacement Of 5 Micron Filters On Ro Waste Water Recovery Skid	Operation Of The MS and DS Waste Water Recovery System
		Operation of ro waste water recovery skid 03-xp78215-01 in the manufacturing suites building	
		Operation Of The Manufacturing Suite (Dp), Reverse Osmosis Water Recovery Clean In Place System	
Total No. of EWI's	12	11	8
	Total EWI's before Transition	23	
	Total EWI's after Transition	9	
	% reduction	61%	

Figure 2.7 Engineering Work Instruction procedures to be merged

Standard Operating Procedures (SOP)

System Name	Drug Substance	Manufacturing Suites	Proposed combined MS/DS
Reverse Osmosis	ENGR-0001-03 Operation of the Drug Substance Reverse Osmosis (RO) System	ENGR-0008-06 Operation of the Manufacturing Suites Reverse Osmosis (RO) System	ENGR-0008-06 Operation of the MS and DS Reverse Osmosis (RO) Systems
	ENGR-0039-03 Operation of the Drug Substance Reverse Osmosis Water Clean In Place System	ENGR-0050-01 Operation of the Drug Product Reverse Osmosis Water Clean In Place System	
	ENGR-0040-00 Drug Substance Reverse Osmosis Water Pump Steaming In Place	ENGR-0051-00 Drug Product Reverse Osmosis Water Pump Steaming In Place	MS and DS Reverse Osmosis Water Pump Steaming In Place
Clean Steam	ENGR-0002-02 Operation of the Drug Substance Clean Steam Generation and Distribution System	ENGR-0009-04 Operation of the Manufacturing Suites Clean Steam Generation and Distribution System	Operation of the MS and DS Clean Steam Generation and Distribution System
Water for Injection	ENGR-0006-03 Operation of the Drug Substance Water For Injection (WFI) System	ENGR-0007-04 Operation of the Manufacturing Suites Water For Injection (WFI) System	Operation of the MS and DS Water For Injection (WFI) System
	ENGR-0045-01 Procedure for Drug Substance Water For Injection (WFI) Pump Steaming In Place		MS and DS Water For Injection (WFI) and Reverse Osmosis Pumps and Vessels Steaming In Place
	ENGR-0047-00 Procedure for Drug Substance Water For Injection (WFI) Storage Vessel Steaming In Place	ENGR-0049-00 Drug Product Water For Injection (WFI) Pump Steaming In Place	
HVAC	ENGR-0026-01 Operation of the Drug Substance HVAC Unit	ENGR-0084-01 Operation of the Manufacturing Suites HVAC Units	Operation of the MS and DS Validated HVAC Units
	ENGR-0076-01 cGMP Alarm Response for HVAC Systems in the Drug Substance Building Grange Castle Campus	ENGR-0092-02 cGMP Alarm Response for HVAC Systems in the Manufacturing Suites Building Grange Castle Campus	cGMP Alarm Response for HVAC Systems in MS and DS Buildings
	ENGR-0029-00 Operation of the Drug Substance Validated Air System	ENGR-0030-00 Operation of the Drug Product and QA/QC Validated Compressed Air System	Operation of the MS, DS and QA/QC Validated Compressed Air System
Misc	ENGR-0131-00 Integrity Testing of Vent Filters in Drug Substance Utilities Area	ENGR-0126-00 Integrity Testing of Utilities Hydrophobic Filters in Drug Product	Integrity Testing of Utilities Hydrophobic Filters in MS and DS
Total No. of EWI's	11	10	9
	Total SOP's before Transition	21	
	Total SOP's after Transition	9	
	% reduction	57%	

Figure 2.8 Standard Operating procedures to be merged

The above figures 2.7 and 2.8 detail the operational and maintenance procedures to be merged, during this project through synergy the number of procedures used by utilities was more than halved. The project included training up all the staff on the newly merged procedures giving both teams the ability and knowledge to operate plant effectively in both buildings thus increasing the flexibility for utilities.

Shift Operations Synergy

The shift operations teams operate utility systems in both buildings on a 24/7 basis. This part of the project was to enable cross-building monitoring and support by implementing the following:

- Utility control systems access for both operating shifts to be upgraded to cover both buildings
- Combined system monitoring setup so each shift crew can view the operational status of utility systems for both buildings

The above shift synergy now gives the ability for shift teams across both buildings to support each other in times of need and allow resources to be assigned to the most important areas at any given time.

Maintenance Synergy

A similar approach of synergy was implemented for the maintenance teams:

- Structured approach to review of maintenance content across similar systems (eliminate duplication and reduction in Man-hours)
- Maintenance focus groups setup between both buildings so that shared learning of solutions to common problems could be achieved
- Implementation of a combined organisational and reporting structure across both buildings

Projected savings obtained from the utilities synergy project

Before commencing this project the key benefits needed to be highlighted, increased support to the client was immediately apparent, also the following cost savings were made:

Operational and Maintenance Synergy

- Standardising of procedures, maintenance and operational cross-functionality
- Maintenance reduction

		Man Hours
Total EWI's before Transition	23	2139
Total EWI's after Transition	9	837
% reduction	61%	
Man Hours Reduction	1329	
Cost reduction @ €50/hour	€ 66,450.00	
Admin Training man-hours reduction (0.25 man hours per document) @ €50/hour	€ 5,425.00	
Savings on Biennial reviews (2 man hours per document) €50/hour	€ 700 / Annum	
Total Savings	€ 72,575.00	

Figure 2.9 Projected cost savings from merging EWI procedures

		Man Hours
Total SOP's before Transition	21	1953
Total SOP's after Transition	9	837
% reduction	57%	
Man Hours Reduction	1143	
Cost reduction @ €50/hour	€ 57,150.00	
Admin Training man-hours reduction (0.25 man hours per document) @ €50/hour	€ 4,650.00	
Savings on Biennial reviews (2 man hours per document) €50/hour	€ 600 / Annum	
Total Savings	€ 62,400.00	

Figure 2.10 Projected cost savings from merging SOP procedures

- Total savings for EWI's and SOP's synergisation = **€135k / year**
- MTL reduction across both buildings of 900 man-hours, this equates to **€30K**, which would be used to absorb extra tasks or drive more efficiencies.
- Full integration of shift teams for MS & DS allowing reduction of 4 shift staff through natural employee turnover = **€570K / Year**
- Total saving made **€735K**, and **€705K** per year thereafter.

The synergy project highlights major benefits for both daily operations and cost saving and shows the importance for companies to review their processes continually for areas of potential improvement.

2.5 Embedding the maintenance & operations teams in new plant & equipment projects

Considering maintenance at the project stage

Earlier in this chapter the importance of embedding the maintenance and operations teams in new equipment/plant projects was highlighted. In 2006 Wyeth installed a new syringe fill manufacturing building (called „Suite 3') at the Grangecastle site. The author led a team of Engineers in this project with the objective of ensuring the project was both designed and installed for ease of maintenance, operations and smooth handover. This section highlights the key areas of ensuring success in this

type of project and the expected cost benefits that can be achieved. This type of interaction between new projects and the maintenance and operational teams forms a key part of a true maintenance excellence culture (i.e. this process ensures that maintenance are always involved from the start).

Setting out the maintenance objectives for a new project

At the start of the new manufacturing building (Suite 3) project the first step was to identify what the maintenance group really want to achieve by embedding themselves in the project. The following key objectives were identified:

- Smooth transition of new utility systems into normal Operations
- Implement lessons learnt from the original construction of the Wyeth plant at Grangecastle
- Safe energisation (start-up) of new utility systems and no impact to the existing business
- Equipment that is accessible, maintainable and operable
- Utility systems that are „fit for purpose’

The above objectives set out all the areas that good design for maintenance and operation should achieve. The new manufacturing area was being constructed along side areas on site that were already in full production, for this reason there needed to be no impact to the existing business.

Safe energisation of all Utilities to Suite 3 with no impact or disruption to the business

As the utilities team that was embedded in the project they were largely familiar with the existing plant the team were in a good position to oversee energisations of the new systems. The team during this project supervised and approved most of the intrusive systems work and protected the interests and safety of the existing manufacturing areas. This structure was a success and no impact or disruption was experienced throughout the project.

Process setup to identify access issues, safety concerns and operational design during construction phase

One of the team's main objectives was to ensure that new equipment was safe and easily accessible for maintenance. This was one of the harsh lessons learnt during the original Wyeth plant construction which started back in 2001, at this time there were little or no maintenance personnel on site so there were limited opportunities to address access or safety concerns during construction. Wyeth ended up paying a large price for this by having to spend a lot of money to 'put things right' and make the plant safe for all people operating in it.

During the Suite 3 project the following key areas were highlighted and resolved at construction stage at minimal cost ensuring Wyeth did not incur any additional costs at the end of the project:

- 20 access platforms for maintenance were identified by the authors team and constructed during the project
- 10 major design change requests for utilities equipment were accepted and implemented during the project

The above items ensured that the utility systems being handed over to normal operations were easily accessible, safe and fit for purpose.

Building up utility systems knowledge at project stage

By embedding operations and maintenance teams in the Suite 3 project allowed a great opportunity for the eventual owners and maintainers to become familiar with the new systems, prepare maintenance and operational procedures and train the eventual end users over manageable timelines.

The net result was that the systems were handed over to utilities maintenance and operations teams very smoothly, and because they were already trained and familiar with the new systems then operations and maintenance activities could start straight away. This allowed immediate seamless supply of utility services to the new Suite 3 Manufacturing areas.

Suite 3 Maintenance spare parts project

Often when a new plant is constructed, the new systems are handed over and normal operations begin. After a short time it is then suddenly realised that each time something fails or needs to be maintained spare parts are not available and due to large delivery lead-times this could have a detrimental effect on the production schedule. This is another lesson learnt from the original Wyeth plant construction that needed to be put right at an additional cost.

During the suite 3 project spare parts for all systems were identified and purchased under the Suite 3 project budget, and then these spares could then be used during early commissioning. At the end of the project, the maintenance and operations teams would have stores full of all the spares they needed to maintain the plant. This prevented duplication of spares purchased for commissioning which are eventually discarded and then more spares being purchased after project handover. This is the best time for maintenance professionals to identify spare parts requirements as during construction and commissioning the equipment vendors are on-site and the information can be easily obtained. By implementing this spare parts project there were huge cost savings made for Wyeth.

Suite 3 Project: Cost Savings Analysis

By embedding the maintenance and operational teams in the Suite 3 Project the following cost savings were made along with a smooth transition to normal operations:

- Suite 3 Maintenance spares project, estimated savings ~ **€200K**
- Suite 3 Access platforms for maintenance: Approx annual saving on scaffolding required per year for operations = **€59,985 / Year**
- Water Systems drain points identified and installed, eliminating the need for extra storage materials and labour during maintenance shutdowns, estimated saving **€15,000 / Year**
- Drip tray and waste path for chemical pump in interstitial areas, potential savings to repair ceilings = **€12,000**
- Venting of pressure safety valves on plant steam system identified during project, cost of a potential building evacuation (**€84,000 / hr**) and cost to install during normal Operation = **€10,000** was eliminated

Along with the benefits to the eventual end users (Maintenance and Operations Teams), the above shows the huge cost savings that can be made by implementing standard maintenance practices at the early stages of a construction project.

2.6 Building in Maintenance Awareness with Manufacturing and top level management

Approach to increasing manufacturing's awareness

The Wyeth Grangecastle vision that was developed states:

„To be a Team, recognised by everybody on campus, who provide effective, flexible and innovative Asset Management solutions in support of the business’

In order for Maintenance Excellence to be successful it needs buy in from top management, one of the most difficult groups historically to accept maintenance as a key part of the business is manufacturing. Manufacturing from the authors experience often see maintenance as a necessary evil and something of an extra hassle that conflicts with their ideal production schedule (which is no interruption for maintenance).

Maintenance is a necessary function to keep the plant up and running and everything the maintenance team do is for the overall benefit to manufacturing. To make our vision a reality it was decided that manufacturing management's awareness of the importance of maintenance needed to be improved. The ultimate goals are as follows:

- Manufacturing and maintenance planning groups working closely together to deliver high equipment reliability.
- Integrated production schedule, which includes maintenance.
- Manufacturing departments to accept that occasionally equipment does breakdown due to unforeseen circumstances, but with a proactive maintenance group everything is put in place to ensure it cannot happen again.

In order to work to achieve the above it was planned to get all the manufacturing area top management for a presentation and discussion on maintenance, this is really a first for Grangecastle. Rather than the maintenance group themselves presenting this it was decided to get an outside maintenance professional to come in, this would be a person

with an unbiased approach and to present the facts from a general industry perspective.

Building the presentation content

In collaboration with the maintenance consultancy group „MCP Langcet’ the presentation content was drafted and agreed, it covers all the main areas in which to target the manufacturing groups awareness of maintenance:

Presentation Audience: 3 Manufacturing Heads (Company Directors), 3 Operations Associate Directors.

Presentation Duration: Approx one hour for presentation and 30 minutes for questions.

Scope of Presentation:

1. What is Asset Management?
2. Present day comparison with 10 years ago.
3. Importance of top down approach and the need for top level support.
4. Importance of integrated maintenance planning. This point needs to be pushed home.
5. Success factors for maintenance best practices.
6. Features of poor asset management & effects.
7. Benefits of best practice asset management.
8. Features of a continuous improvement asset management program.

Theme: High level cost / benefits of best practice asset management with a heavy slant on the maintenance planning side.

As can be seen above the attendees of this presentation are top management (company directors and associate directors), as Maintenance Excellence should be a top-down approach this is an important level to build in awareness. One of the main focuses is on maintenance planning because they are the link between maintenance and manufacturing and the people most likely to be involved and in implementing combined maintenance and production schedules. The presentation was delivered on

the 13 March 2008 and all manufacturing areas accepted the invitation. The manufacturing groups were approached about this presentation and surprisingly feedback was good, self-admittedly the manufacturing groups didn't really have a full understanding of the maintenance function and seen this presentation as a good opportunity to increase their awareness.

This presentation is an important step for the maintenance groups across site and should help build better working relationships with the manufacturing groups.

2.7 Chapter 2: Summary and Conclusions

This chapter has highlighted the importance of „Maintenance Excellence’ or „Best Practices’ as part of a successful world class organisation. Research carried out by MCP Langcet has shown that World-Class is a relatively new concept but it is vital that manufacturing companies strive towards this achievement in order to compete on cost and quality of products with similar industries operating around the world.

“Quality is free” and by implementing best practices the potential benefits are clear to be seen. The introduction of PAS-55 „*Publicly Available Specification for Asset Management*’ has given maintenance managers specific tools in order to develop their overall asset management programs in line with maintenance best practices. The standard includes guidance on creating maintenance objectives and strategies in line with the overall business objectives. The PAS-55 is set to become a standard in its own right and is a major step for the maintenance community to progress within companies striving towards world-class status.

Following research and from the authors own experience the area of maintenance outsourcing has been identified as a major part of modern industry. As discussed earlier the main reason for manufacturing companies to outsource maintenance is cost reduction and to enable them to concentrate on core activities which is making product. However this is only the baseline of possibilities, so much more can be achieved by approaching outsourcing correctly such as high degree of ownership by the outsourcing partner, continuous improvement and a Win-Win culture which promotes open/honest communication.

The future for outsourcing is moving towards full ownership of utility systems through long-term fixed contracts which have shown clear benefits for both parties involved.

To stay in line with a true maintenance excellence culture, maintenance need to „involved from the start’. From the experiences shown at Wyeth; companies can pay a heavy price for not considering this. During the construction of the new Suite 3 manufacturing plant at Wyeth, huge benefits were achieved by implementing a relatively simple concept at the beginning of the project that is to involve the maintenance function at the start. This approach has now been embedded in all future projects at the Wyeth plant.

The results show clearly that maintenance should be on the early agenda for any company wishing to construct or install new plant and equipment.

By adopting programs such as Business Process Re-Engineering, improvement of the overall efficiency of the business can be achieved. Results from the Wyeth synergy project detailed in this chapter show that there are major benefits to be achieved, not just on cost, but can give the ability for simultaneous and consistent improvement in different areas of the plant, and increased flexibility to enable faster response to aiding the business needs at any given time.

Overall, this chapter has provided a good insight into successful management approaches to implementing Maintenance Excellence. In getting this right it will pave the way for all other areas to follow suit in the quest for World-Class status.

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CHAPTER 3 – MAINTENANCE PROCEDURES AND PRACTICES

3.1 Introduction

Many consider the maintenance function to be about „fixing things’ or „responding to problems’, however the modern maintenance department are now more geared towards preventing or detecting failures before they occur. This sort of approach relies more heavily on tools such CMMS (Computerised Maintenance Management Systems) and the function of maintenance planning.

Maintenance is much more than just fixing equipment and it is the background scheduling, planning and inventory management processes that heavily contributes towards maintenance excellence. In chapter 5 the area of maintenance auditing and benchmarking will be explored, it is interesting to see that when using the PASS-55 „Publicly Available Specification for Asset Management’ auditing tool, the areas of management, procedures, planning and work scheduling covers a large proportion of the overall content. This would suggest that these areas are of key importance to the running of a successful maintenance department.

Maintenance Compliance in a regulated industry

When striving towards maintenance excellence people must not forget that maintenance is a regulatory requirement for clean utility systems feeding manufacturing areas. This must always be kept in mind, an improvement to the maintenance program that might make sense based on cost and plant efficiency may not always be compliant and in some case may bring about a hidden risk to the qualified processes and product. This chapter aims to set out the requirements of the maintenance programs on clean utilities systems in the pharmaceutical industry. If improvements are sought how can they be implemented whilst ensuring no potential impact to product? In short, if a company is serious about implementing maintenance excellence improvements, what are the practical steps that need to be followed?

Plant Databuild

Plant databuild is the starting point for any maintenance department, it involves collecting information on plant & equipment, researching the equipment, authoring suitable maintenance tasks and loading this information on to the CMMS in order to

automatically schedule the maintenance program. This databuild process can be quite a time consuming process & laborious but getting this wrong can have severe consequences, this chapter will show why. There are a number of practical guides available detailing how to approach this process, because of the importance of databuild new companies often get specialist vendors to come on site to complete this task. The author has been involved in two major plant databuild projects at Wyeth Biopharma, the first one being the newly built campus at Grangecastle, Clondalkin. A number of years later the same and improved databuild techniques were used on the start-up of a newly constructed manufacturing building at Wyeth Biopharma. This chapter aims to map out the databuild process from a newly constructed plant to a fully functional maintenance program.

Maintenance Spare Parts

Spare part inventory management is considered to be a subject in its own right. This chapter will look at equipment spares from a maintenance perspective. Identification, quantifying and setting up of plant spares is an extension of the plant databuild process. Following an unplanned equipment breakdown, not having the required spare part could stop production. The misguided approach would be to carry spares for „everything’; this is not practical and could be hugely expensive. Identification, quantifying and purchasing of spare parts is a closely balanced approach between risk, delivery lead times and maintenance experience. The subject area „Spare Parts Excellence’ has emerged over the past number of years and has now become an integral part of the overall maintenance excellence strategy.

The author has previously led a spare parts project for the newly constructed Wyeth Biopharma Campus; this chapter aims to map out the spare parts databuild process.

Computerised Maintenance Management Systems (CMMS)

CMMS are used widely in industry to automatically schedule maintenance tasks and record equipment history. From the literature review it was shown that these CMMS systems are not being utilised to their full potential. This chapter will explore what a plant can expect to achieve from utilising a CMMS. The pharmaceutical industry relies heavily on CMMS systems to archive important plant data and to demonstrate regulatory compliance to preventative maintenance schedules, for this reason from the author’s experience the CMMS is often designed to fulfil this need and very little

else. This leaves out the true potential of the CMMS system by using it as a „compliance tool’ and not a „maintenance tool’.

At Wyeth Biopharma after 3 - 4 years of the CMMS system being used on site, the maintenance teams are only now starting use the system to obtain useful equipment performance data. The use of hybrid systems (i.e. both paper & computer records being used side by side) is an area of concern for the pharmaceutical industry in general; this is duplication of work and information at the grandest scale. This chapter will explore why this is the case and how the regulatory agencies and the pharmaceutical industry are currently working together to eliminate this sort of practice which hinders a true world class approach.

Maintenance Planning

The daily activities of the maintenance crew is precisely planned and scheduled by the maintenance planner, the planner also groups planned work activities in order to best utilise equipment downtime. The literature review showed that the successful implementation of a CMMS in the maintenance department relies heavily on the role of the maintenance planner. This chapter will seek to accurately define the role of the maintenance planner in a maintenance excellence environment, identify the skill set best suits the job and outline procedural steps that should be followed in this role on a daily, weekly, monthly and yearly timeframe.

3.2 Maintenance Compliance in a regulated industry

Validation and Qualification of Clean Utility Systems

Before delving into the maintenance requirements for clean utility systems, the terms „validation’ and „qualified status’ of utilities equipment must first be clearly understood and exactly where maintenance fits in. Another important term is „current Good Manufacturing Practices’ (cGMP) which is a collective term for all pharmaceutical regulations; cGMP affects everything that the maintenance department does on clean utility systems such as documenting maintenance activities and providing full equipment history.

The term validation in pharmaceutical production refers to documented evidence that a system (in this case clean utilities) operates within a defined set of parameters

consistently. The validation process is carried out by engineering and quality groups on a utility system following initial installation and commissioning of a new system or piece of equipment. It involves testing and documenting the operation of the system in order to prove that it can deliver a utility to required operational specifications again and again. When the equipment is validated to operate within the established parameters then its status is known as qualified. Validation consists of the following key stages for a clean utility system prior to being deemed as „qualified’:

- 1. Installation Qualification (IQ):** The equipment or system installation is rigorously checked & verified so that it meets the original design (e.g. electrical wiring, piping welds, filter specifications etc.)
- 2. Operational Qualification (OQ):** The operation or working of the system is checked & verified so that it meets the operational parameters set out by regulatory agencies (e.g. High purity water systems need to operate within certain temperature and flow ranges).
- 3. Performance Qualification (PQ):** The operational performance of the system is checked and verified, this stage may also involve microbial & contamination sampling (particularly for clean room air conditioning and high purity water systems).

Maintenance requirements for the utility systems are setup during the validation phase and once the system is deemed qualified changes to the maintenance content needs to follow strict documented change control procedures.

The chart below details the typical validation/qualification process for a new piece of equipment/clean utility system:

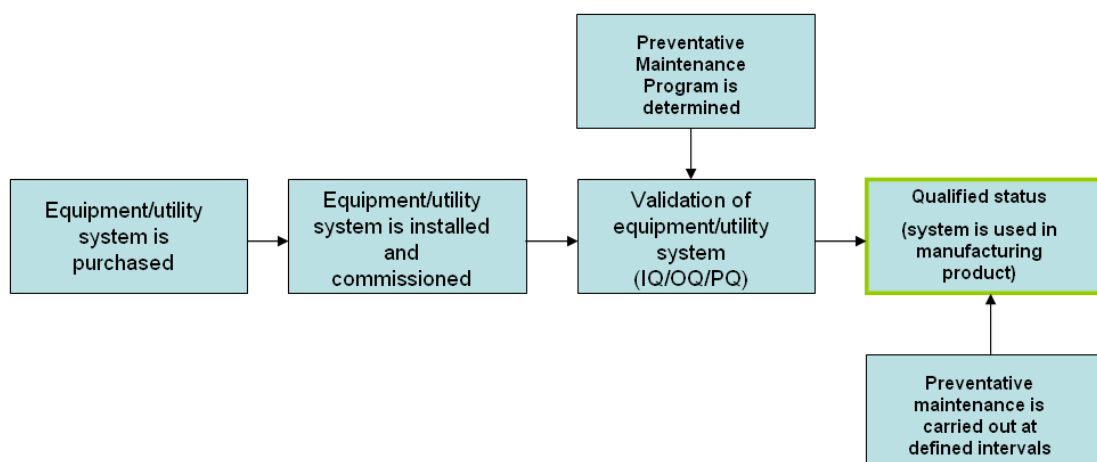


Figure 3.1 Typical validation/qualification process for clean utilities

As shown above in Figure 3.1 the maintenance requirements have been setup during validation, once the system becomes qualified the preventative maintenance program is fixed and must be carried out at the agreed intervals. Deviating from this agreed maintenance schedule is considered to be a breach of regulatory compliance. For the reasons stated above this is exactly why the changing of the maintenance program can be so difficult, in extreme cases some modifications to the system for maintenance purposes may require the whole validation process to be carried out again (this can be hugely time consuming and expensive).

Maintenance requirements for Clean Utility Systems

The following describes the operation of the main types of clean utility systems and identifies some important maintenance requirements to ensure regulatory compliance. These maintenance requirements can be considered as the basic or „must have’ maintenance to ensure regulatory compliance:

➤ **Reverse Osmosis (RO) Water System – Generation & distribution**

The Reverse Osmosis (RO) water system is a high purity water system that is used in pharmaceutical industry, RO water is commonly used as a mixing or washing agent in the manufacture of oral drugs such as tablets and medical devices. The purpose of the RO system is to convert softened town water into water which complies with the US/EU Purified Water Specification or USP Water. The process must remove a specified range of natural chemical impurities which is contained in normal council

water and also must ensure that no microbial contamination exists. The RO distribution system which pipes the water to and from the manufacturing areas must be continuously circulated hot at around 80°C.

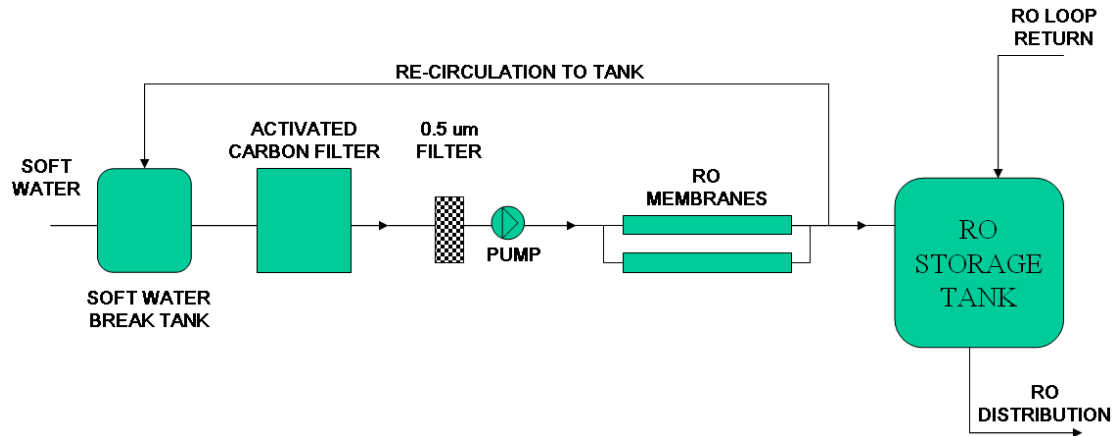


Figure 3.2 Reverse Osmosis (USP Water) System

Figure 3.2 above shows the basic outlay of an RO Water system, the system contains 6 main stages which are detailed below along with some important regulatory maintenance requirements:

1. **Soft Water Feed:** The soft water feed shown above is council water which has gone through a process to remove any natural water hardness. By softening the feed water it reduces problems such as scaling of pipework and blockages.

Maintenance requirements: There are no strict regulatory requirements for maintenance of the feed water system, general inspections for leaks etc. may be carried out by the maintenance teams.

2. **Activated Carbon Filter:** The carbon filter in the system (which contains activated charcoal) which removes chlorine and some carbon based organics from the water. The system is backwashed automatically every 24 hours in order to remove any contaminants or impurities.

Maintenance requirements: The out-feed water of the carbon bed filter is microbial and chemically tested on a weekly basis. Elevated trends

here may require additional backwashes to be carried out. The activated carbon charcoal bed will be replaced every year.

3. **0.5µm filter:** The 0.5µm filter removes particulates from the water and protects the RO membranes from blockage/build up of particulates further up-stream.

Maintenance requirements: The differential pressure across the filters will be checked daily through rounds and readings and replaced if deemed to be blocking or damaged.

4. **RO Water Pumps:** The RO Water pumps on the system are specifically designed for use on high purity water systems. Internal pump impellers are electro-polished pharmaceutical grade stainless steel and the internal mechanical seals of the pumps are continuously flushed to prevent contamination. The pumps provide the main water pressure for the system.

Maintenance requirements: These pumps are subject to routine maintenance checks on a monthly, quarterly and annual basis. Annual maintenance includes an overhaul of the pump with inspections for scores, damage or rouge (deposits or build up of iron oxide on stainless steel) on the pumps internals. Replaced parts need to be acid cleaned prior to installation.

5. **RO Membrane:** The RO membrane consists of thin films of polymer which have molecular perforations which only allow water molecules (known as solvent) to pass through, all other impurities (known as solute) are prevented from passing through the membrane. This process occurs in nature with plants where the solvent by natural osmosis passes through a cellular membrane to the solute. The RO system reverses this process by applying external pressure (from the pumps) onto the membranes. Hence, the name „Reverse Osmosis’.

Maintenance requirements: These RO membranes are subject to frequent alkaline and acid cleans to bring their efficiency back up. The quality of purified water from the membranes is also analysed to

determine if a replacement of the membranes is required (typical replacement frequency is 5 years).

6. RO Storage & Distribution: The RO storage tank (which in Wyeth is 30,000 Litres) stores the purified water coming of the RO membranes. The RO water is then pumped from the tank through distribution pipework around the plant to manufacturing and other users. The storage tank and distribution pipework are constructed with pharmaceutical grade stainless steel. The RO water is continuously circulated to and from the tank, this prevents stagnant or dead legs of water which is then prone to microbial contamination. The temperature of the water in the storage and distribution system is maintained at approximately 80°, at this temperature pharmaceutical regulations deem this water to be 'self-sanitising' reducing the risk further of microbial contamination. Online chlorine analyser and conductivity instruments sample the water continuously and if the system does not remain within defined parameters the manufacturing end users will be locked out from using the water.

Maintenance requirements: Annual inspections of the tank and 6 monthly testing/replacement of tank vent filters are required. There has yet to be specific regulations on maintenance of soft parts such as gaskets, good practice to prevent deterioration of soft parts is a replacement schedule of 2 years.

➤ **Water for Injection System – Generation & distribution**

The Water for Injection (WFI) water system is a high purity water system that is used in the pharmaceutical industry, WFI water is commonly used as a mixing or washing agent in the manufacture of intravenous drugs such as vaccines. The WFI system specifications are that of water free from contamination that can be safely injected into a vein of the patient without any adverse effects. This is one of the most critical systems in a pharmaceutical factory and is heavily regulated. The WFI distribution system which pipes the water to and from the manufacturing areas must be continuously circulated hot at approximately 80°C.

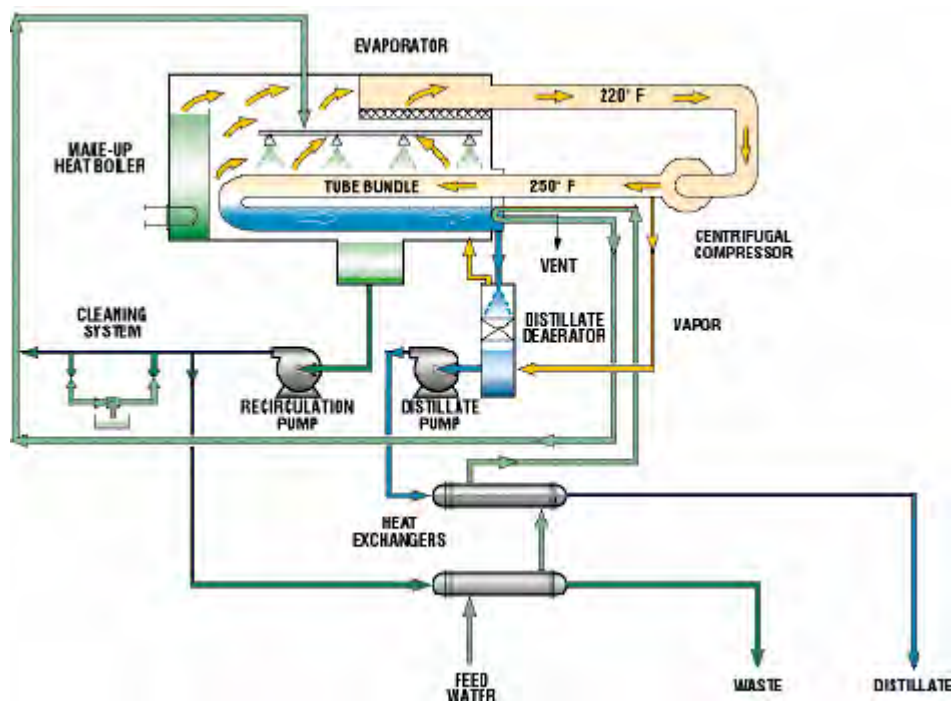


Figure 3.3 WFI Water Compression Still (WFI Generation)

Courtesy: Aquachem water systems corp. product brochure, 2008

Figure 3.3 above shows the basic outlay of a WFI Water System. The process operates by distilling RO feed water, compressing the water vapour and then condensing the vapour to obtain WFI quality water. In this process because the water is heated up and vaporised it leaves any impurities behind which are continuously flushed to drain. It is considered to be WFI quality because the process incorporates a full phase change (i.e. Water → Water Vapour → Vapour condensed back to „WFI’ Water). The water in the system is de-aerated to remove any non-condensable gases which can affect the quality of the WFI water especially if it is used as feed water for Clean Steam generation systems.

Maintenance requirements: Vent filters on the WFI Stills are subject to integrity testing and replacement. Correct operation and checks of the de-aerator is required, general internal pipework condition should be inspected and internal tube bundles must be completely sealed from the outside environment. The WFI water distillate is fed to a WFI storage system and online chlorine analyser and conductivity instruments sample the water

continuously and if the system does not remain within defined parameters the filling of the storage system will be locked out.

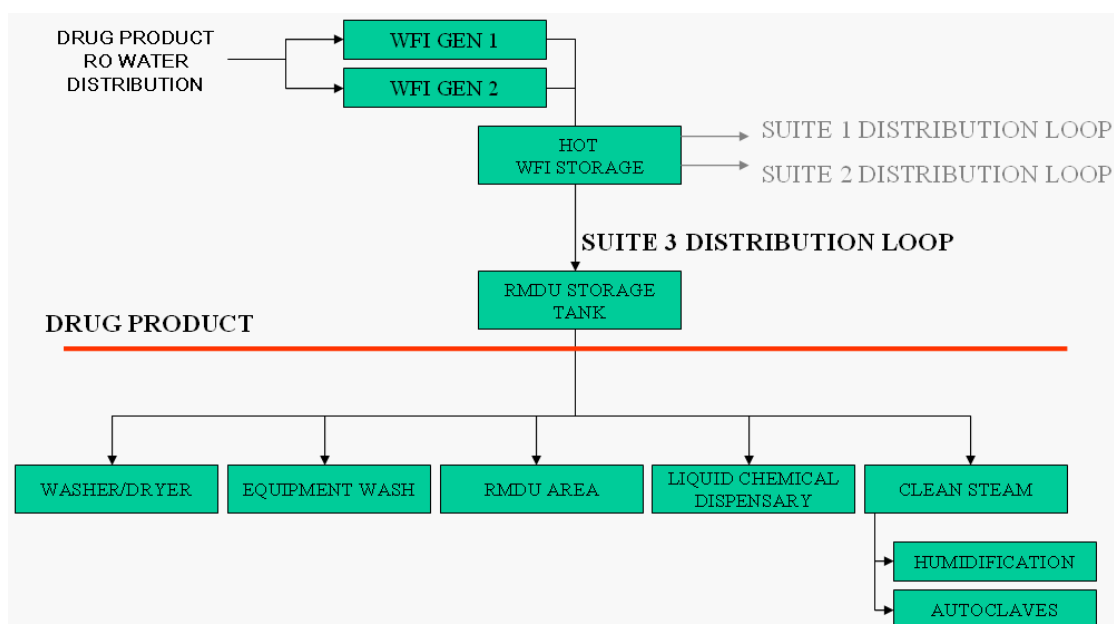


Figure 3.4 WFI Storage & distribution system

Figure 3.4 above shows the basic outlay of a WFI distribution system. As shown above the RO water is used as a feed to WFI generation system, the newly generated water is then sent to WFI hot storage tanks from which it is circulated through the building to a number manufacturing users at approximately 80°C. Manufacturing end users may further cool down the water temperature in order to use safely for specific processes. The WFI storage tanks, pumps and pipework distribution are all constructed from pharmaceutical grade stainless steel.

Maintenance requirements: Similar to the RO system annual inspections of the tank and 6 monthly testing/replacement of WFI tank vent filters are required. There has yet to be specific regulations on maintenance of soft parts such as gaskets, good practice to prevent deterioration of soft parts is a replacement schedule of 2 years.

➤ **Comparison of RO Water and WFI Water specifications**

Current US Pharmacopoeia Standards		
	Purified Water	Water for Injection
Organics (TOC)	<0.5 ppm	<0.5 ppm
Conductivity	<1.3 microsiemen at 25°C	<1.3 microsiemen at 25°C
Endotoxin	No specification	<.25 EU/ml
Bacteria	100 cfu/ml	10 cfu/ml

Figure 3.5 Pharmaceutical specifications for RO & WFI Water

Figure 3.5 above compares the operational specifications of RO and WFI water quality. As can be seen the specifications are similar with exception to „Endotoxin’. Removal of endotoxin (endotoxin is the secretion and remains of dead bacteria) can only really be guaranteed by WFI water quality. Endotoxin although it does not contain living micro-organisms can still have an adverse affect on the patient when injected intravenously. This is the main reason why RO Water is only commonly used for oral medications applications and not intravenous.

➤ **Clean Steam Generation and Distribution Systems**

Clean steam systems can use either RO or WFI quality feed water to a boiler to provide a clean steam supply which can be used for product preparation processes such as autoclaving and vessel steaming. Its quality specification required is that of WFI water. Clean steam distribution systems are pressurised at around 3 – 4 barg at a temperature of approximately 144°C which is considered self-sterilising.

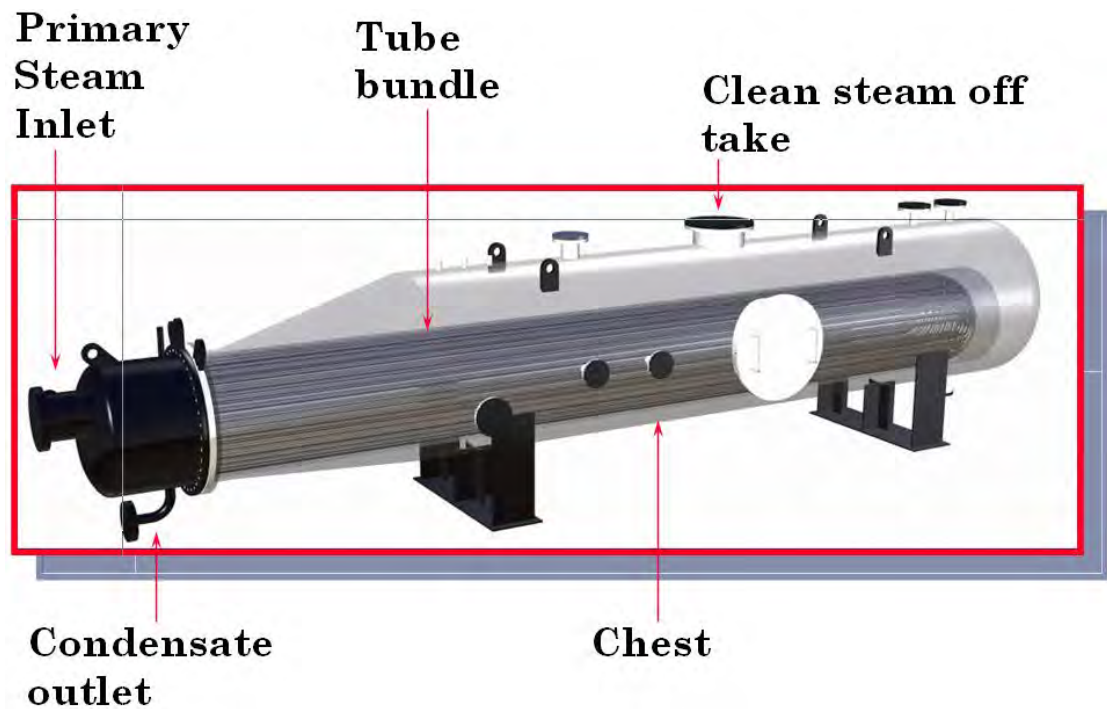


Figure 3.6 Clean Steam Generator

Courtesy: Spirax Sarco, 2008

Figure 3.6 above shows the basic outlay of a clean steam generator. Normal/primary plant steam is fed in through tube bundles in order to generate heat, RO or WFI water is fed into the chest and then boils off from the heat of the tube bundles. Clean steam is then taken off at pressure of around 3 barg and distributed to users around the plant.



Figure 3.7 Clean Steam Generator and distribution pipework

Figure 3.7 above shows the outside of the clean steam generator along with associated distribution pipe work. The generator and distribution pipework are primarily constructed from pharmaceutical grade stainless steel.

Maintenance requirements: Annual inspections internal of the system for rouge (deposits or build up of iron oxide on stainless steel) and scaling are required. The clean steam chamber must be sealed from exposure to primary steam and a number of large gaskets on the system are subject to deterioration and leaking. There has yet to be specific regulations on maintenance of soft parts such as gaskets on the distribution, good practice to prevent deterioration of soft parts is a replacement schedule of 2 years.

European guidelines require annual quality testing of the steam for non-condensable gases, dryness fraction and superheat.

➤ Clean Room Heating Ventilation and Air Conditioning (HVAC)

HVAC systems are used to provide production clean room environments and are critical to product quality. The HVAC system controls pressure, humidity and temperature in the production areas and filter the in-coming air at a microbial level. A production clean room is an environment which is free from contamination and unwanted micro-organisms, in these clean rooms the product is prepared and may be exposed to the surrounding air.

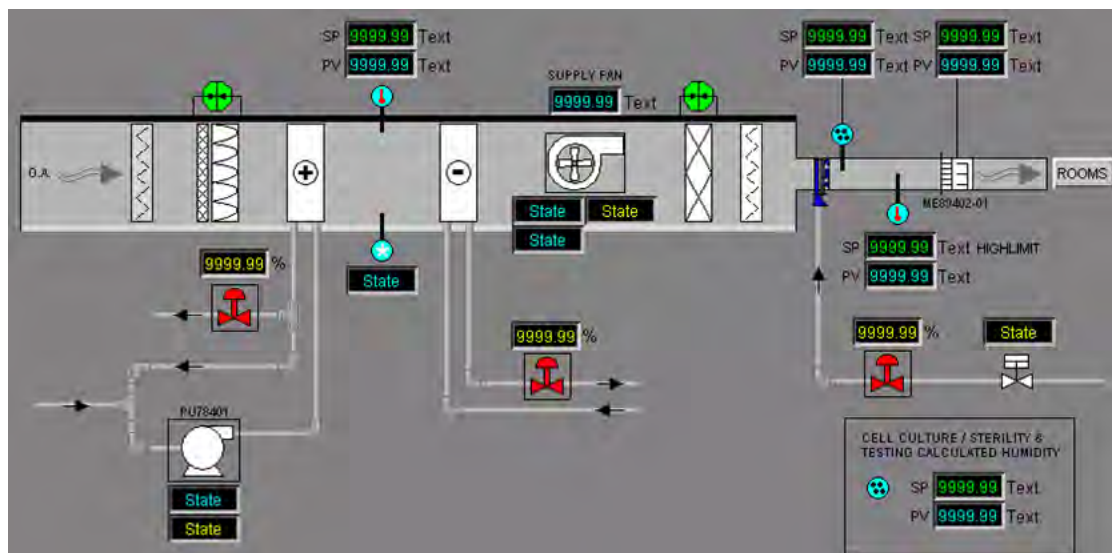


Figure 3.8 Control system graphic of an Air Handling Unit

Figure 3.8 above shows a control system layout of an air handling unit. This is the first stage of HVAC; the air handling unit based in the plant room takes a mix of fresh

air and re-circulated air and filters, heats/cool and humidifies the air to provide the desired conditions in the room.

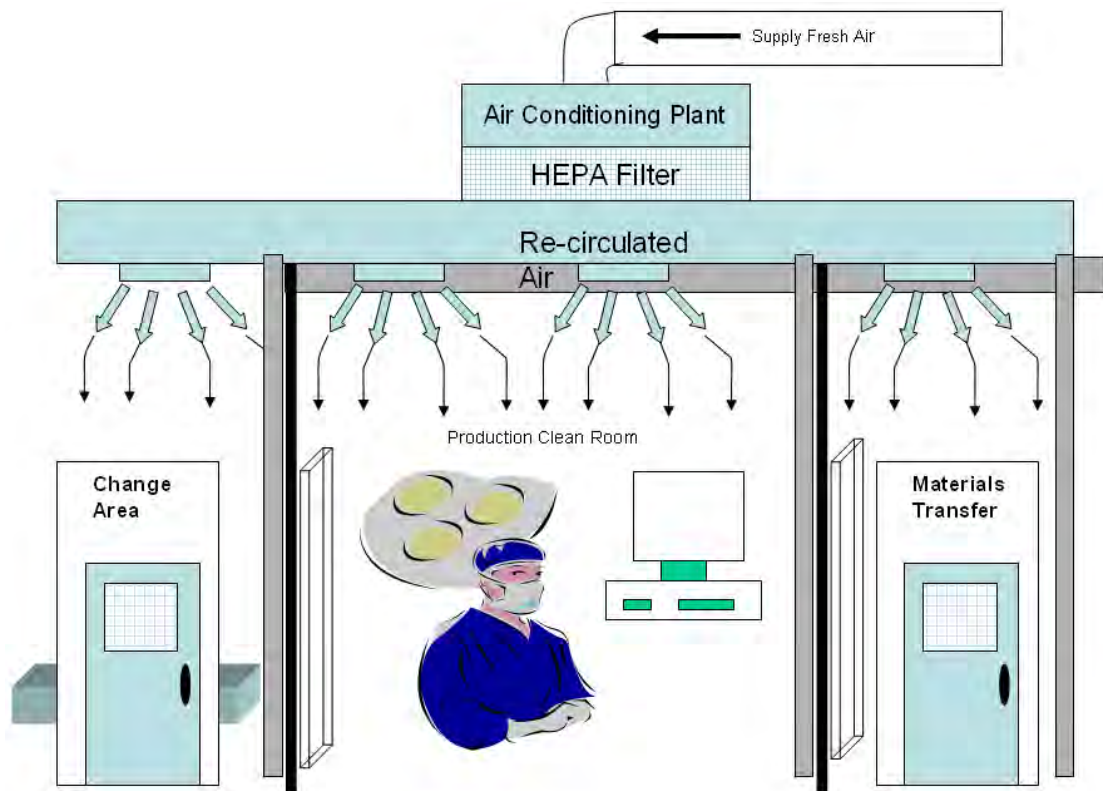


Figure 3.9 Overall schematic showing a clean room HVAC system

As Figure 3.9 above shows the air is then filtered again through terminal HEPA filters before the air enters the room. HEPA filters which stands for High Efficiency Particulate Arrestors are sterilising grade filters and remove 99.97% of all airborne particles 0.3 μ m diameter in size. Pressure cascade systems are used in cleanroom environments in which the most critical areas are kept at a higher air pressure to other areas to ensure contaminants are kept out from less clean areas.

Maintenance requirements: Regulations require strict maintenance programs for cleanroom HVAC systems. For the most critical areas of the clean room where product can be exposed to the surrounding air 6 monthly re-certification is required, re-certification involves testing of the HEPA filters and verifying that all room pressures, velocities and airflow patterns are as per the design. For less critical or „closed process areas’ where the product is not exposed a 12 monthly similar re-certification is required.

Changing the maintenance content for Clean Utility Systems

The purpose of previous section is to provide the reader with a good understanding of clean utilities systems and an appreciation of the tight regulation of maintenance requirements. When seeking to change the maintenance content for improvement purposes some areas can simply not be touched, other areas where maintenance regulation is still quite vague can be subject to maintenance content improvements providing that a full justification and product impact assessment is carried out.

This section is going to document a project carried out by the author at Wyeth Biopharma in 2007 to move the frequency of soft parts changeout on high purity water and clean steam systems from 12 monthly to 24 monthly. Elastomer change out is hugely expensive on both labour and materials and there were significant savings to be made, the following will detail the practical steps involved in order to achieve such a major maintenance change:

➤ **Soft parts change out improvement project**

Change description: To amend the ECO (Elastomer Change Out) frequency on Manufacturing Suite WFI and Clean Steam system as follows:

1. ECO for WFI and Clean Steam gaskets and manual diaphragms to be moved from 12 monthly intervals to a 24 monthly interval.
2. ECO for non-continuous use actuated diaphragm valves on hot WFI to be moved from 12 monthly intervals to a 24 monthly interval.
3. ECO for hot WFI continuous use actuated diaphragm valves to be moved from 12 monthly intervals to a 6 monthly interval.
4. ECO for all RO system soft parts to be moved from 12 monthly intervals to a 24 monthly interval.
5. RO Water Generation soft parts to be removed from routine maintenance and can be considered run-to-failure.

In summary the above identifies a small portion of soft parts 'continuous use actuated type' on the WFI water system that are prone to failure over short periods; the maintenance for this type is increased to 6 monthly intervals. All other soft parts

which are approximately 90% of the system (which have long service life) have been pushed out to a frequency of 24 months. By approaching the change in this way the reliability of the system has actually been increased while still eliminating a huge amount of labour and parts costs by only replacing the bulk of soft parts on the system every 24 months. The clean steam system does not contain diaphragm valves so all ECO was pushed out to 24 months. Considering that the RO water system is only used as pre-treatment feed, all soft parts changeout has been pushed out to 24 months. The RO water generation system which is operated at ambient temperatures does not experience harsh degradation of soft parts so everything is changed to run-to-failure.

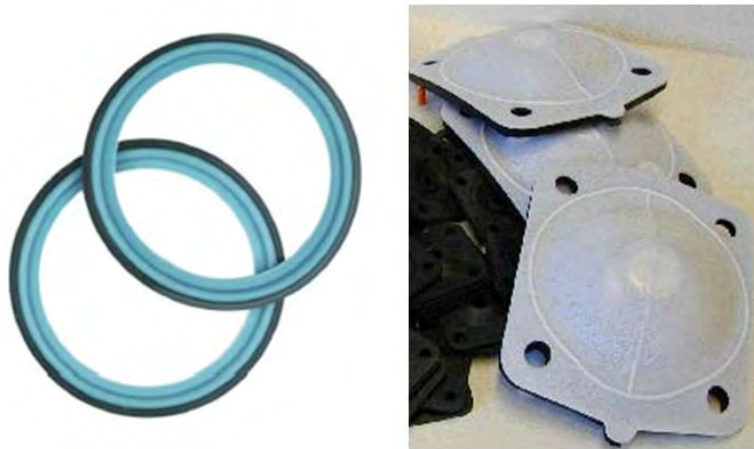


Figure 3.10 Pictures showing a selection of gaskets (left) and diaphragms (right)

Change justification: The main part of this proposed change that required robust data and justification was the clean steam and WFI systems, these systems are used directly by manufacturing. Visual inspection of gaskets, manual valve diaphragms coming out service following ECO carried out in 2005 and 2006 showed no significant deterioration for periods in excess of 12 months. Visual inspections and photographic records has also been carried out on a selected number of soft parts deliberately left in the system for periods up to 24 months. These soft part inspection points were selected due to their strenuous operating conditions (worst case). These inspections were carried out every 3 months up to a period of 24 months and were found to be in excellent condition with no significant deterioration or wear noted. The above shows full justification to move out similar soft parts on the systems to a 24 monthly replacement frequency.

Change proposal result: The above proposed change was documented and brought for approval by all relevant manufacturing and quality groups. The change was approved in December 2007.

Cost Savings: The following documents the approximate overall cost savings obtained for each year that full soft part changeout was not required.

Clean Steam soft parts approximate cost	= 25k
WFI Water soft parts approximate cost	= 75k
RO Water soft parts	= 10k
ECO Labour cost	= 65k
Total savings made every 2 years	= €175k

3.3 Plant Maintenance Databuild

As mentioned in the introduction, plant databuild is the starting point for any maintenance department, it involves collecting information on plant & equipment, researching the equipment, authoring suitable maintenance tasks and loading this information on to the CMMS in order to automatically schedule the maintenance program.

The author has been involved in a number of large scale databuild projects and this section aims to document the practical steps involved in initial plant databuild and the common mistakes to avoid. To get this initial maintenance databuild process right in a pharmaceutical environment is important, given the difficulty and work required to change maintenance content once a system is qualified it pays to get this right first time.

The plant databuild process can be categorised in the following four categories:

1. Compiling equipment records
2. Authoring the Preventative Maintenance Task Lists (MTL's)
3. Scheduling the MTL's
4. Spare parts identification and required stock levels

Compiling equipment records

The first stage in databuild is to identify the equipment to be considered for maintenance and involves reviewing system drawings, walking down the plant, gathering all required nameplate information and then loading this system on to a CMMS. This will create what is known as an „Equipment Birth Cert’ and is the maintenance starting point for new equipment. The equipment register should contain some or all of the following information with the objective of making the equipment uniquely identifiable:

- | | |
|-----------------------|-------------------------|
| - Equipment ID Number | - Technical Description |
| - Location ID | - System ID |
| - Manufacturer | - Model Number |
| - Serial Number | - Year of purchase |

Authoring the Preventative Maintenance Task Lists (MTL’s)

Once all of the equipment in the plant has been compiled the next activity is to determine suitable maintenance programs in order to prevent failures. This can be a difficult process because it is new equipment and therefore there is no maintenance or operational history to analyse. Authoring of the maintenance program at this early stage is a combination of vendor recommendations and the authors own experience with similar types of equipment. Not following specific vendor maintenance recommendations can sometimes have warranty implications. The person carrying out the maintenance databuild should have experience on the type of equipment they are reviewing and have a strong maintenance background. There is a structured approach to determining maintenance requirements and the following areas should be considered.

- **Review Operation and Maintenance manuals (O&M):**

At this stage the databuild technician needs to review all relevant O&M manuals and gain in-dept knowledge of the equipment. An important part here is know the application of the equipment as maintenance requirements can vary depending on things like projected run time of the equipment, operating pressures, temperatures, surrounding environment, actual equipment capacity and if there is a back-up (duty/standby arrangement). Also if the equipment is considered to be critical to manufacturing then its maintenance content will be more intense.

- **Author the maintenance task lists:**

When all the above has been taken into consideration the databuild technician authors the maintenance task list under the following categories:

- Equipment checks when in service (what checks can be done when the equipment is running)
- Equipment checks when out of service (maintenance that requires a complete shutdown of the equipment)

Once the maintenance content has been finalised it should be determined if the actual maintenance content can be completed in-house or needs to be outsourced to a specialist vendor. If a vendor is required then the contract or call-out agreement should be setup at this stage. Estimated maintenance man-hours should also be collected for each task, this information is important for future planning/scheduling of maintenance workloads and estimating equipment downtime needed. The following extract shows a typical set of 1 Monthly preventative maintenance operations performed on a WFI Water System Pump:

Task list	1051	1	WFI RECIRCULATION PUMP
	Strategy		ConstType
	Usage	4	Status 4
GC52	Plant		
CAUTION: Never run the Pump dry in the hope that it will prime itself. SERIOUS DAMAGE TO THE MECHANICAL SEAL WILL RESULT.			
	Work center		
DPUTTECH	Control key		
PM01	Number of persons	1	
	Work	30.0	
MIN	Duration	0.5	HR
Operation	0010	PM: EQUIPMENT IN OPERATION	
	30.1 While pump is Running:		
	30.2 Check bearing condition Trends.		
	30.3 Audibly Check Motor / Pump Bearings and Couplings for abnormal Noise.		
	30.4 Report any Abnormal vibration levels and where necessary request a follow up vibration analysis.		
	30.5 Audibly check pump for cavitations.		
	30.6 Carry out Electrical Checks.		
	30.7 Check Motor Amps and compare against Nameplate FLA.		
	% Speed		
	R _____		
	Y _____		
	B _____		
	30.8 Record Discharge Pressure and compare to previous figures.		
	Discharge = Bar.		
	30.9 Visually Check Pipe Work, Seals, Glands and Flexible Bellows for any leaks or Deterioration. Report / Repair as required.		
	30.10 Check flow rate and temperature of the seal flush water.		
	Flow rate _____		
	Temp _____		

Figure 3.11 Maintenance Task List for a WFI Pump

Scheduling the MTL's

Once the maintenance content has been finalised the next step is to load this information on to a Computerised Maintenance Management System (CMMS) or equivalent. The CMMS system needs to be instructed on the frequency of the maintenance task and also the proposed start date at which time automatic scheduling will start.

Spare parts identification and required stock levels

For a typical new plant start-up the spare part requirements are based on 2 yearly operation of the equipment. This information is usually provided by the equipment vendor, experience comes in to play here as equipment vendors will often over specify parts that need to be held as spares in order to gain good after sales. The identified spares to be stocked and actual quantity required should be a mix of vendor recommendations and the databuild technicians own experience. From a cost and labour perspective it may not be always be the best option to carry individual equipment spare components, instead the databuild technician may opt to purchase a complete spare. For example: Pump spares include seals, impellers, motor etc., if the pump is cheap it could be easier to just purchase a complete assembled spare pump that can be „swapped’ out when needed.

The following extract shows a typical 2 years operational spares listing for a pump:

	Company		KECOL PUMPS IRELAND LTD (JN9974)		SCHEDULE OF RECOMMENDED SPARES		
	After Sales Contact	BILL ASPIL	01-4566750				
	JLL PO Numbers Issued to Vendor.	3044					
SHEET					1	OF	1

Fields Required							
1	3	4	6	7	8	9	
Line Item	EQUIPMENT VENDOR PART NO.	DETAILED DESCRIPTION	EQUIPMENT TAG NUMBER	QUANTITY	UNIT PRICE IN EUROS	LEAD TIME IN DAYS	RECOMMENDED 2 YR SPARES
	PVDF PUMP(625.0002 x 1)						
1	P300/795-0006	COUPLING	06PU-76557	1	€ 22.04	2	5
2	P300/740-0005	SNAP RING	06PU-76557	1	€ 4.15	2	5
3	P300/780-0005	CLAMPING SLEEVE	06PU-76557	1	€ 1.42	2	5
4	P300/790-0016	BALL BEARING	06PU-76557	2	€ 10.07	2	10
5	P300/740-0002	DISTANCE LINER	06PU-76557	1	€ 4.38	2	5
6	P300/790-0041	AXIL FACE SEAL CPL(HC)	06PU-76557	1	€ 58.07	2	5
7	P300/790-0018	LIP SEAL	06PU-76557	1	€ 12.80	2	5
8	P300/840-0060	O-RING SET KALREZ	06PU-76557	1	€ 254.54	2	5
9	P300/740-0012	IMPELLER - R (ETFE)	06PU-76557	3	€ 26.31	2	15
10	P300/740-0014	PLAIN BEARING	06PU-76557	1	€ 18.72	2	5

Figure 3.12 Typical 2 years operational spares listing for a pump

Where the lifetime of a component is not known then a resource known as the „Weibull Distribution’ can be used to estimate change out frequencies and stock level requirements. The Weibull distribution is a set of statistical life data for a number of common machinery components and is commonly used in reliability engineering. The „Eta Values’ ‘Typical’ column gives the expected life of the component (in hours) under normal operating conditions:

Item	Beta Values			Eta Values		
	(Weibull Shape Factor)			(Weibull Characteristic Life--hours)		
	Low	Typical	High	Low	Typical	High
Components						
Ball bearing	0.7	1.3	3.5	14,000	40,000	250,000
Roller bearings	0.7	1.3	3.5	9,000	50,000	125,000
Sleeve bearing	0.7	1	3	10,000	50,000	143,000
Belts, drive	0.5	1.2	2.8	9,000	30,000	91,000
Bellows, hydraulic	0.5	1.3	3	14,000	50,000	100,000
Bolts	0.5	3	10	125,000	300,000	100,000,000
Clutches, friction	0.5	1.4	3	67,000	100,000	500,000
Clutches, magnetic	0.8	1	1.6	100,000	150,000	333,000
Couplings	0.8	2	6	25,000	75,000	333,000
Couplings, gear	0.8	2.5	4	25,000	75,000	1,250,000
Cylinders, hydraulic	1	2	3.8	9,000,000	900,000	200,000,000
Diaphragm, metal	0.5	3	6	50,000	65,000	500,000
Diaphragm, rubber	0.5	1.1	1.4	50,000	60,000	300,000
Gaskets, hydraulics	0.5	1.1	1.4	700,000	75,000	3,300,000
Filter, oil	0.5	1.1	1.4	20,000	25,000	125,000
Gears	0.5	2	6	33,000	75,000	500,000
Impellers, pumps	0.5	2.5	6	125,000	150,000	1,400,000
Joints, mechanical	0.5	1.2	6	1,400,000	150,000	10,000,000
Knife edges, fulcrum	0.5	1	6	1,700,000	2,000,000	16,700,000
Liner, recip. comp. cyl.	0.5	1.8	3	20,000	50,000	300,000
Nuts	0.5	1.1	1.4	14,000	50,000	500,000
"O"-rings, elastomeric	0.5	1.1	1.4	5,000	20,000	33,000

Figure 3.13 Partial extract of the Weibull life distribution for engineering components

Courtesy: Weibull.com

3.4 Computerised Maintenance Management Systems

Using Electronic records in the pharmaceutical industry

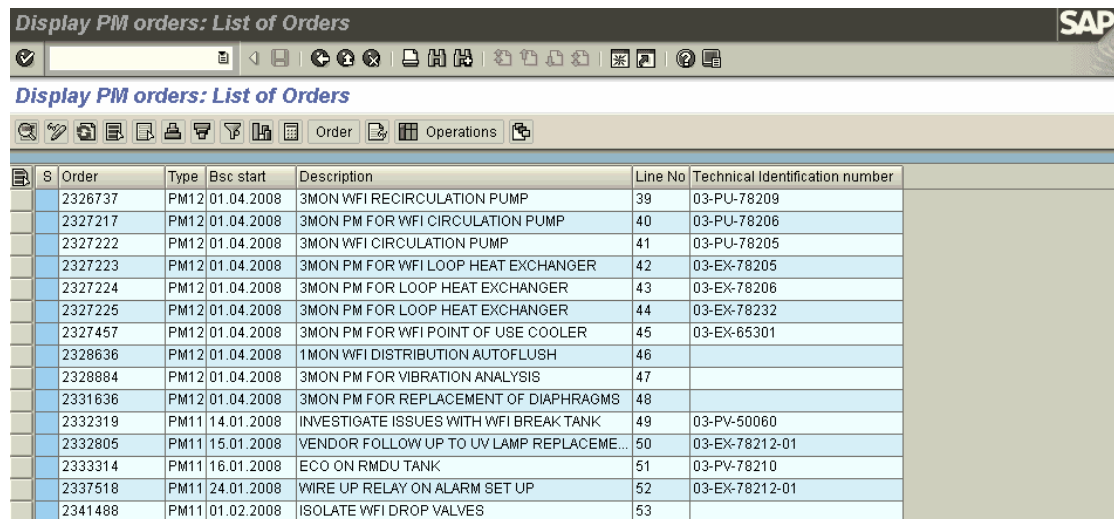
CMMS systems which are used in the pharmaceutical industry are validated in the same way that critical equipment is. Paper based systems in this GMP environment rely on handwritten signatures which can be traceable back to the originator and approvers. Over the past 20 years computers are being used more and more to store critical information such as batch records and alarm histories, unfortunately this is almost always duplicated on a paper based system. In order for the computer based system to provide the same level of traceability as hand written signatures a regulatory standard was created by the US Food and Drugs Administration in 1997. This standard is known as '21 CFR Part 11 Electronic Records, Electronic Signatures' which states that an electronic signature in a regulatory environment can be defined as:

"An electronic process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record."

21 CFR 11 uses computer login ID's and password confirmations when entering or approving records and is seen as equivalent to a handwritten signature. This has allowed CMMS computer systems to store and schedule maintenance records without breaching regulatory guidelines. In order for this process to be safe login ID's and passwords are strictly controlled, fraudulent attempted accesses to systems are heavily protected against. Although this may seem like a perfect opportunity to move towards a 'paperless office' the vast majority of pharmaceutical companies still use hybrid systems where the electronic and paper records co-exist. This gives extra insurance that nothing is missed and all supporting data is traceable. As major software companies are realising the business potential there are more and more custom electronic solutions now available for a wide range of pharmaceutical processes. This new software technology is helping the pharmaceutical industry get rid of paper records for good.

SAP Computerised Maintenance Management System

The SAP Computerised Maintenance Management System (CMMS) was designed with the pharmaceutical industry in mind, the system allows itself to be validated and incorporate functions such as electronic signatures and electronic audit trails. The SAP CMMS uses database technology to store records and schedule maintenance tasks. The process is set up by loading equipment data and maintenance task lists on to the system, the scheduling information then links the two together in order to create a maintenance plan. The maintenance plans will schedule the required maintenance task at the desired date intervals and when the maintenance task is completed the information is then loaded back on to the system. The SAP extract below shows an equipment history search for the WFI Water system over a specific time range:



The screenshot shows the SAP CMMS interface for 'Display PM orders: List of Orders'. The table contains the following data:

S	Order	Type	Bsc start	Description	Line No	Technical Identification number
	2326737	PM12	01.04.2008	3MON WFI RECIRCULATION PUMP	39	03-PU-78209
	2327217	PM12	01.04.2008	3MON PM FOR WFI CIRCULATION PUMP	40	03-PU-78206
	2327222	PM12	01.04.2008	3MON WFI CIRCULATION PUMP	41	03-PU-78205
	2327223	PM12	01.04.2008	3MON PM FOR WFI LOOP HEAT EXCHANGER	42	03-EX-78205
	2327224	PM12	01.04.2008	3MON PM FOR LOOP HEAT EXCHANGER	43	03-EX-78206
	2327225	PM12	01.04.2008	3MON PM FOR LOOP HEAT EXCHANGER	44	03-EX-78232
	2327457	PM12	01.04.2008	3MON PM FOR WFI POINT OF USE COOLER	45	03-EX-65301
	2328636	PM12	01.04.2008	1MON WFI DISTRIBUTION AUTOFLUSH	46	
	2328884	PM12	01.04.2008	3MON PM FOR VIBRATION ANALYSIS	47	
	2331636	PM12	01.04.2008	3MON PM FOR REPLACEMENT OF DIAPHRAGMS	48	
	2332319	PM11	14.01.2008	INVESTIGATE ISSUES WITH WFI BREAK TANK	49	03-PV-50060
	2332805	PM11	15.01.2008	VENDOR FOLLOW UP TO UV LAMP REPLACEME...	50	03-EX-78212-01
	2333314	PM11	16.01.2008	ECO ON RMDU TANK	51	03-PV-78210
	2337518	PM11	24.01.2008	WIRE UP RELAY ON ALARM SET UP	52	03-EX-78212-01
	2341488	PM11	01.02.2008	ISOLATE WFI DROP VALVES	53	

Figure 3.14 SAP CMMS extract: equipment maintenance history

The above equipment history search can give useful information such as recently completed work, recent failures and associated equipment ID's. Behind each line item is a detailed record of comments made in the field by the technician carrying out the maintenance task.

The SAP system is based on database technology and for this reason it can be quite complicated to get meaningful maintenance performance data from the system such as PM:CM ratio, Mean Time Between Failure etc without using an outside tool such as Microsoft Excel to compile all the different sets of data, this is not ideal. In 2007 the Maintenance Excellence Team (which the Author is a member of) at Wyeth issued a

number of maintenance Key Performance Indicators (KPI's) to the SAP group requesting they provide a solution to enable the SAP CMMS system to run these reports automatically. In doing this, useful maintenance performance data could then be easily extracted from the system. The results back from the SAP group were good; a reporting tool called SAP BI (Business Intelligence) was used to compile a number of maintenance performance reports such as PM:CM ratio, man-hours per system etc. At the Wyeth site it took over 3 years to eventually start getting his level of performance data back out of the SAP CMMS system.

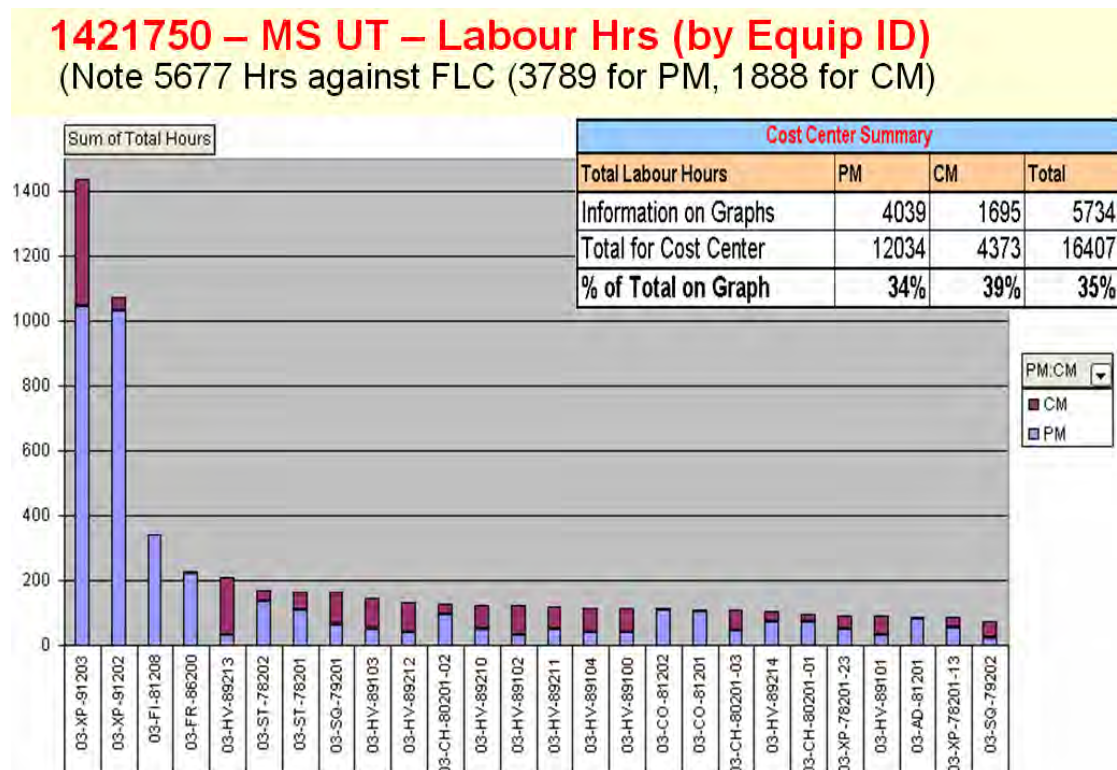


Figure 3.15 PM:CM ratio results that can be obtained from the SAP BI reporting tool

Evaluation of the SAP Computerised Maintenance Management System

The company SAP are software giants in industry; primarily the system is a money tool which tracks the costs of the business. The backbone of their system in Wyeth and most companies is the finance tool which tracks operating costs of the business, stock control etc. SAP is used corporate wide with all the different factories linked together on the one system so data for certain sectors or the entire business can be controlled. The SAP CMMS package is only really an add-on that is used to remain consistent across the business. The overall SAP system was not designed with maintenance in mind and the CMMS part of the system is difficult to use and lacks

any straight forward way of extracting useful maintenance performance data. The SAP BI reporting tool is an extra cost and requires software experts to setup.

There are other CMMS systems available for industry that were specifically designed with maintenance in mind, they are a lot more user friendly and performance reporting is built in. Unfortunately not all of these systems support the regulatory software requirements of the pharmaceutical industry. The software package „Maximo’ which was developed by IBM was specifically designed for asset & maintenance management and from the authors experience is far more suited to the needs of the maintenance department. There are other packages such as „Pragma On Key’ and ‘PEMAC’ CMMS systems that are just as powerful and are used widely in industry. To get the full potential from a CMMS system the choice of software is very important. Engineering & Maintenance Managers need to be careful when CMMS systems are being selected for the first time, they should try not be forced to use the overall business „money’ tools with cumbersome CMMS add-ons like the SAP maintenance system.

3.5 Maintenance Planning

The literature review showed that the successful implementation of a CMMS in the maintenance department relies heavily on the role of the maintenance planner. This chapter will seek to accurately define the role of the maintenance planner in a maintenance excellence environment, identify the skill set best suits the job and outline procedural steps that should be followed in this role on a daily, weekly, monthly and yearly timeframe.

Defining the role of the Maintenance Planner

The planner in conjunction with the CMMS system is one of the most important functions in the maintenance department, the role brings about structure and order of the maintenance program being executed. The planner allocates resources, organises equipment downtime and tracks progress in order to best implement the preventative maintenance program. From the authors experience the role of planner can differ a lot from plant to plant, in 2007 the Wyeth Maintenance Excellence Team (which the

author is a member) worked together to define the actual role of the maintenance planner. The following outlines the requirements for effective maintenance planning:

➤ **Maintenance Planner – Overall Role & Responsibilities**

- Documenting maintenance work activities in the CMMS system to enable trend analysis.
- Apply time standards to PM & CM related work.
- Ensure all maintenance work that requires equipment downtime is prioritised and group to minimise impact to production.
- Review yearly and monthly PM schedules and ensure work load levels match resource availability.
- Issue weekly and monthly maintenance schedules detailing PM and CM work planned.
- Review progress of the planned maintenance program (planned Vs actual) and report out to maintenance supervisors.
- Monitor, track and report out on equipment downtime – planned & unplanned.
- Seek feedback on the current PM content. Work to continuously improve the current maintenance program by ensuring that resource time, work steps, tools and parts are accurately documented on the CMMS system.
- Facilitate post maintenance shutdown meetings to gather feedback and lessons learnt.
- Effectively manage a work backlog system (outstanding items), prioritise and plan the work to be completed alongside the relevant monthly PM program.

➤ **Maintenance Planner – Major Shutdown Planning**

In most plants the majority of intrusive maintenance activities which require equipment downtime are all carried out together during a specific time period in the year. It is common for plants to ‘shutdown’ for 1 – 2 weeks at which time maintenance overhauls, calibrations and projects are carried out. This is one of the most difficult parts of the planning role and requires detailed shutdown execution plans which could involve the entire utilities plant being shutdown for maintenance

activities. Given the potential for things to go wrong (i.e. equipment not back up in time for production and safety concerns) it is advised that the planning for a major shutdown should be a year running activity, the more preparation there is the more likely a shutdown is going to succeed. The Wyeth maintenance excellence team have outlined the activities and timelines before and after a major maintenance shutdown:

4 months prior to shutdown

- Review annual maintenance plan for opportunistic maintenance activities.
- Conduct CMMS query and organise by work type, location and equipment.
- Draft shutdown project plan. Review plan with maintenance teams, supervisors and production.
- Conduct a spare parts requirement review with maintenance teams and stores to identify parts required for shutdown.
- Establish the requirement for outside vendor support and begin communications.

2 months prior to shutdown

- Set up a shutdown meeting schedule dates with the maintenance teams (i.e. a weekly meeting), make adjustments to tasks or new requirements.
- Assign owners to maintenance of each system.
- Follow-up on all spares parts orders and expected delivery timelines, ensure contracts or costs for external vendor support have been finalised.

1 month prior to shutdown

- Continue with weekly shutdown meetings.
- „Lock-down’ the shutdown plan and allow no new work or projects to be submitted.
- Draft a detailed sequence of operations for the shutdown (this will usually be structured per 12 hour shifts).
- Finalise specific dates and requirements with service vendors.
- Book out all spare parts requirements from stores.

- Submit the official shutdown schedule to the maintenance supervisor for execution.

Post shutdown review

- Meet with the maintenance teams for a post shutdown review.
- Review maintenance completion on each system and compile lessons learnt.
- Evaluate reports of the condition of equipment found during maintenance and update the PM program (e.g. if the condition of the equipment found was immaculate there could be an opportunity to decrease the frequency of the task).

The authors opinion is that the previous two sections (roles & responsibilities, shutdown planning) contains all the important areas of maintenance planning. Given that effective planning and scheduling can increase craft utilisation by 10 to 15 percent (figure published by ESS Maintenance consultants 2007) it is important that the planner is given time to concentrate on these core activities. From the authors experience all too often the planner can drift into other various administration functions and the effectiveness of maintenance execution can suffer. It is the responsibility of the maintenance manager to understand fully the function of the planning role and to ensure that the core planning activities are always addressed.

3.6 Summary and Conclusions

This chapter has outlined some of the strict regulatory maintenance requirements for clean utility systems. A practical example showed that some areas of regulation (such as soft parts changeout) are still open to interpretation; this leaves opportunities to improve maintenance content with the correct supporting rationale. Although it is time consuming to implement maintenance change the benefits are clear to be seen.

Given the above difficulties faced to obtain maintenance improvement, during the plant databuild process, at which time the maintenance programs are first created, it

pays to put a lot of thought and consideration when determining the desired maintenance program. The spare parts database build process is a balance between risk and own maintenance experience. This chapter has identified a structured approach in determining the spare parts requirements for the plant.

The CMMS section of the chapter shows how computer technologies are now making their way into the pharmaceutical industry in a big way. Regulatory legislation passed in 2007 has allowed computer records to replace paper records. However the idea of the 'paperless office' in the pharmaceutical industry is still at its infancy stages. Choosing the right CMMS system can have a big impact on being able to obtain useful maintenance performance data. Using maintenance performance data to aid improvement of the maintenance program is an integral part of maintenance excellence. The SAP CMMS system falls short of this requirement unless companies are willing to pay the cost for complicated reporting tool add-ons.

This chapter has outlined clearly the role of the maintenance planner in a maintenance excellence environment. Good craft utilisation can be directly linked to the planning role and the planner must be allowed to concentrate on these core activities.

Overall, this chapter has laid out the critical maintenance processes that need to be implemented in order to bring a green-field factory site to a fully operational facility that is in line with maintenance excellence standards.

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CHAPTER 4 – RELIABILITY IMPROVEMENT

4.1 Introduction

The Industrial Maintenance Roundtable (IMR) defines Reliability Improvement as:

„The extent to which maintenance is attuned to the needs of its customer and in particular the strength of the focus on the reliability of equipment, the identification and elimination of the root cause of failure and the prioritising of improvement tasks according to safety impact or business benefit’

Reliability Improvement as part of a Maintenance Excellence culture is a maintenance department that focuses everything they do in order to obtain outstanding equipment reliability. Higher equipment reliability = higher production rates which = business benefit. This chapter will explore the different tools and strategies that are employed to increase equipment reliability, how they are used and highlight the practical benefits that can be achieved.

Conditional based monitoring (CBM)

Condition based monitoring (CBM) is the future for the maintenance department, more and more time is being spent on detecting failures before they occur by using condition based monitoring technologies. By detecting failures before they occur it allows the maintenance teams to effectively plan their maintenance activities and request equipment downtime from production well in advance of the problem occurring. In this chapter the author will present four of the main types of condition based monitoring and highlight the sort of results an organisation can hope to achieve. CBM uses an array of scientific measurement methods to detect failures; the following CBM techniques will be covered in this chapter:

- Vibration Analysis (accelerometer instruments can be used to detect abnormal or high vibration particularly in bearings).
- Thermal or Infrared Imaging (infra-red imaging to detect abnormal temperatures or hot spots particularly in electrical panels).
- Oil Analysis (sampling of oil which is then analysed can detect the deterioration or breaking down of an internal equipment part).

- Ultrasonic measurement (use of ultrasound technologies to detect leaks or blockages on utility systems).

Criticality and single point of failure analysis

Before spending a huge amount of effort employing expensive analysis and maintenance techniques on equipment the maintenance engineer must first know what the most critical systems are?. This involves working with production to understand and rate the importance of utility systems feeding their processes. When the criticalities of utility systems are ranked then this is the order in which maintenance improvement should be tackled. This chapter will outline a structured approach to carrying out a criticality analysis of utility systems. An extension of criticality analysis is single point of failure analysis, this process identifies „weak’ areas of utility systems that are liable to fail and shut the entire system down. An exercise of robusting of identified weak areas is then carried out in order to improve the overall reliability of the system. This chapter aims to detail a practical approach to completing a criticality and single point of failure analysis on utility systems.

Reliability Centred Maintenance (RCM)

Once the criticality of utility systems has been determined tools such as Reliability Centred Maintenance (RCM) can be employed to design the maintenance program. The maintenance program is designed with the sole aim of keeping the system up and running and working within the desired parameters. RCM is a structured approach to improving equipment reliability and blends failure and risk analysis with preventative and condition based maintenance. The RCM approach ensures that only the maintenance that matters is carried out and all non-value adding activities are removed. RCM is not a new tool the technique has been used in the aircraft industry since the 1960’s, given the success of aircraft reliability obtained by RCM it has now made its way into general industry applications. In 2008 the author led an RCM program on a Low Pressure Hot Water (LPHW) system at Wyeth, Grange castle, the LPHW system is critical to temperature control in manufacturing clean rooms and the program designed an optimal maintenance program for the system. This chapter will detail this RCM process carried out and show how the maintenance program can be designed around equipment reliability.

Root cause analysis and corrective/preventative actions

Continuous reliability improvement is considered to be an integral part of maintenance excellence; it can be achieved by carrying out equipment failure investigations in order to determine the root cause and implementing suitable controls to ensure the equipment failure cannot re-occur. These corrective/preventative actions may involve updating the maintenance program, introducing conditional monitoring or a design improvement change to the process. Unless the maintenance department fully understand why equipment is failing then it is difficult to design the most beneficial maintenance program. The author has carried out utility system failure investigations at Wyeth, Grangecastle for the past 3 years. This chapter will outline the investigation process for equipment failures and how it can drive reliability improvements on utility systems.

4.2 Condition Based Monitoring (CBM)

As discussed in the introduction conditional based monitoring is the future for the maintenance department, more and more companies are taking on board these technologies in order to maximise the reliability of their equipment by detecting failures well in advance. Some failure modes cannot be designed out (I.e. mechanical bearings are here to stay, electrical panels will always be an integral part of any system) but if failures can be detected early then the maintenance team can plan in the work in an organised manner. Unplanned maintenance can cost as much as 3 times that of planned maintenance (figure published by ESS Maintenance consultants 2007) so CBM is of huge benefit, also by detecting a failure early means that the level of damage that can follow an actual failure can also be avoided. An example of this is when a bearing on an air handling unit fan fails it could have disastrous consequences on the internals of the fan which may start breaking up and the shaft can become damaged beyond repair. If this example was to be laid out in terms of cost before and after:

- Case 1 (with CBM) – Potential bearing failure is detected using vibration analysis, replacement cost of bearing ~ €100.
- Case 2 (without CBM) – No vibration analysis program, catastrophic failure of fan bearing causing fan impellers to break and the shaft is

beyond repair, cost of new fan ~ €8,000 + cost of downtime to manufacturing.

It is clear to be seen that condition based maintenance pays for itself many times over and this is why it is becoming so popular. This section will detail 4 of the main CBM techniques used and will also document some practical examples of where failures can be detected/avoided using CBM techniques. At the Wyeth plant, Grangecastle the author manages the sitewide conditional monitoring team.

Vibration Analysis

➤ **Vibration analysis principles**

Vibration can be defined as simply the cyclic or oscillating motion of a machine or machine component from its position of rest. It is normal for all machines to have some level of small vibration, however when this vibration increases or becomes excessive it usually indicates a mechanical fault of some description. Vibration analysis uses accelerometer instruments to detect these vibration movements, the results of these vibration readings can be plotted (magnitude Vs frequency) using a mathematical representation called Fast Fourier Transform (FFT). The FFT plot will highlight the level of vibration and identify which frequencies they are present in. The frequencies present are related to the machine cyclic movement such as RPM and using this data the origin of the fault can be determined.

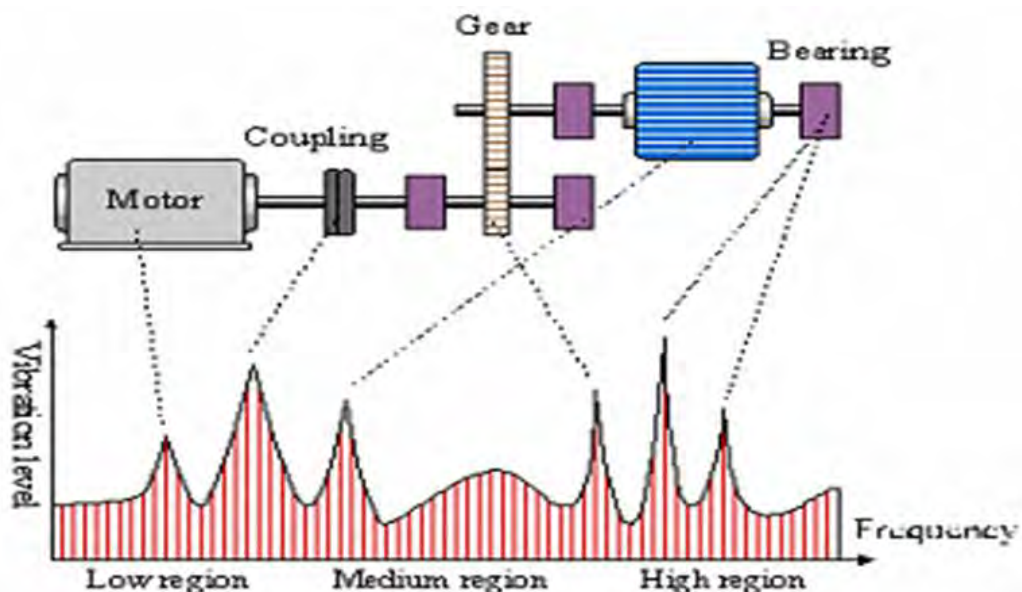


Figure 4.1 Typical vibration analysis FFT plot (magnitude Vs Frequency)

Figure 4.1 above shows a typical vibration plot for a motor drive unit, the different frequencies present relate to the different moving components within the drive unit. The vibration levels or magnitude levels will tell the vibration analyst how severe the vibration is and whether any action is needed. It is common in industry to take a set of baseline readings when the equipment is first installed, the condition of the equipment can then be trended over time and areas of deterioration can be identified. Vibration analysis is quite a complex subject and takes a lot of mechanical expertise and training in order to become proficient. The vibration analysis plots can often contain multiple fault frequencies and in order to determine their origin the analyst needs to have detailed knowledge of the operating characteristics of the equipment (such as no. of fan blades, RPM's, pulley ratios, bearing types etc.). For this reason false diagnosis can sometimes be a problem. With the correct training and mechanical proficiency the following types of problems can be determined using vibration analysis:

- Misalignment of drive systems
- Unbalance of rotary components
- Mechanical looseness
- Bearing deterioration and gear wear
- Belt deflection

➤ **Vibration analysis – practical applications**

At the Wyeth plant, Grange castle the vibration analysis program covers a wide range of equipment and has detected a number of significant faults over the past number of years. Figure 4.2 below shows the array of equipment currently on the vibration analysis program, as new equipment is installed this list grows. Laser alignment (a precise technique using laser beams to accurately align drive units, its benefits are reduced vibration levels and reduced energy consumption) of pumps and fan balancing (balancing is a technique used to evenly distribute weight loads on rotating components and therefore reducing vibration) is also available as a follow-up activity in order to rectify problems detected from the vibration analysis:

System	Program	Frequency
Vibration Analysis	228 Pumps 124 Air Handlers 138 Extract Fans 9 York Chillers 9 Atlas Copco Compressors 8 Cooling Towers On Demand Following Repairs	3 Months
Laser Alignment	Based On Vibration Analysis Reports Following Repairs New Installation On Demand	As Required
Fan Balancing	Based On Vibration Analysis Reports Following Repairs On Demand	As Required

Figure 4.2 Wyeth, Grange castle vibration analysis program

Figure 4.3 below shows a list of actual results obtained from the vibration analysis program in 2007, note that there have been a number of catastrophic failures avoided using this program and the faults identified were able to be responded to by the maintenance teams in a planned manner:

Application / Faults Identified	BENEFIT
VA- 10 AHU Fans identified with Level 3 Faults (Failure eminent)	CATASTROPHIC FAILURES AVOIDED
VA - 40 AHU Fans identified with Level 2 Faults (High Vibration)	REMEDIAL WORKS CARRIED OUT
VA - DS HV 89005 - Seed Lab AHU's Beat vibration causing excessive vibration on Fan.	NEW TYPE BELT FITTED. VIBRATION REDUCED / MTBF EXTENDED
VA - DP Glycol Pumps - Excessive Vibration with rapid bearing deterioration of bearings - MTBF = 3 Mths	EQUIPMENT REDESIGN. VIBRATION REDUCED / MTBF EXTENDED
50 Pump Alignments Carried out	VIBRATION MINIMISED (Energy Savings)

Figure 4.3 Vibration Analysis (VA) – 2007 program results summary

Thermal Imaging

➤ Thermal Imaging principles

Thermal imaging uses infra-red (IR) technology to identify high temperature areas on the surface of equipment. Thermal imaging is used primarily on electrical panels to identify loose contacts or overheating of cables but there are other ranges of applications such as checking for blockages in pipes or carrying out heat surveys in plant rooms. The equipment used is an infra red camera which can range in cost between €10,000 - €40,000 which usually comes with a software package to load,

store and compile results. Use of the infra-red camera requires specific training as setting up of the camera and interpretation of results requires a level of expertise. From the authors experience it is better to have an electrician carrying out thermal imaging surveys as the causes of faults particularly in electrical panels can be diagnosed straight away giving the maintenance team useful information before carrying out repair works. It is important to note that infrared imaging requires a direct exposure to the surface being measured; infra-red cannot penetrate through surfaces such as glass or plastic unless specifically designed IR windows are installed. When setting up the IR camera the emissivity (ε) factor is an important parameter, emissivity is a heat factor which allows for the material type being scanned, its colour and the angle of heat being radiated. A true black body would have an emissivity factor of $\varepsilon = 1$ with other surfaces being less $\varepsilon < 1$. Its value is important because if not set correctly the true temperature reading could be offset; there are ranges of emissivity settings available for common types of material such as PVC cables in electrical panels.

➤ Thermal Imaging – practical applications

Figure 4.4 below shows a thermal scan of a cleanroom HVAC electrical isolator taken in 2007, the top left photo shows a normal exposure and the shot on the right is a thermal image. This particular fault was severe with a maximum temperature of 133.2°C.

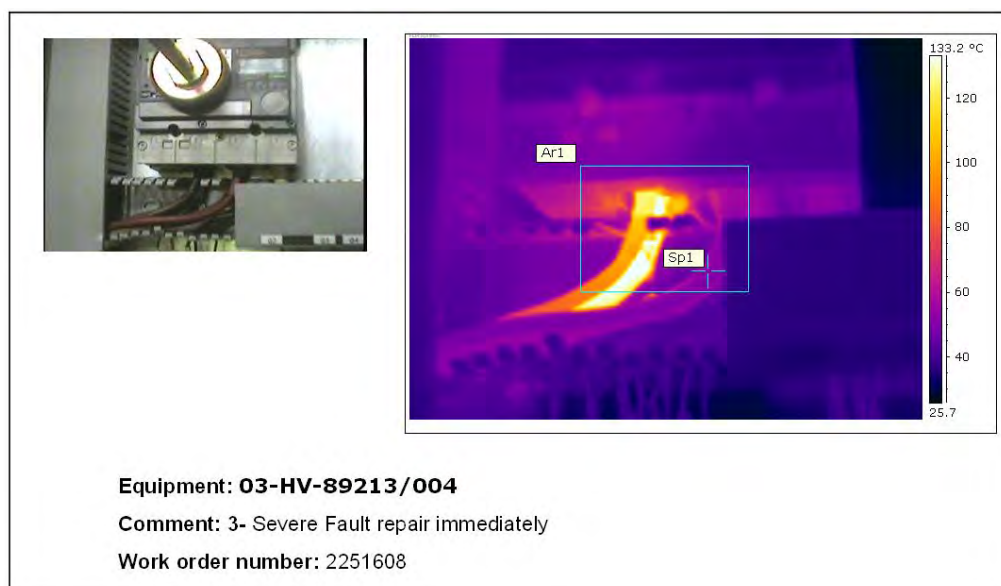


Figure 4.4 Thermal Image of a HVAC electrical isolator

The fault which was found on the incoming cables was due to internal deterioration of the cable and was creating immense heat. A condition like this left over time would eventually cause the equipment to fail and possibly lead to fire. Once the maintenance team are notified this fault can be repaired by replacing the cables and ensuring all connections are secure. The repaired panel is then rescanned to ensure that the fault no longer exists.

As mentioned at the beginning of this section there are other applications that thermal imaging can be used. In 2006 due to concerns of excessive heat in a plant room in Wyeth, Grangeastle it was decided to carry out a thermal scan of the area utilities to identify hot spots which could then be insulated and help reduce overall heat levels in plant room.

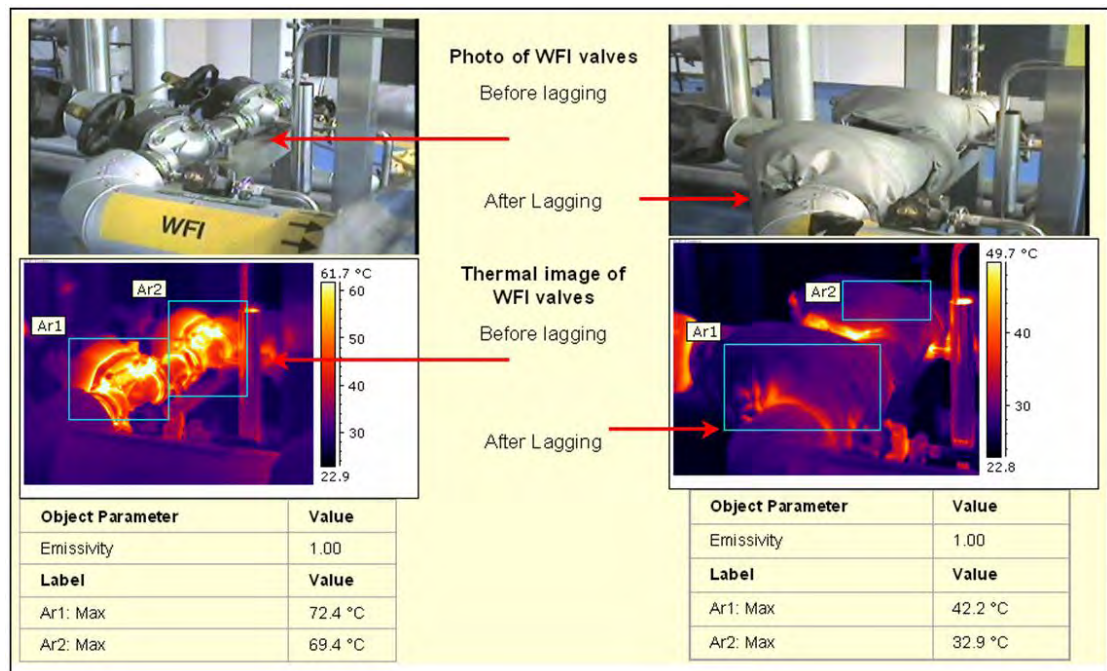


Figure 4.5 Thermal Image survey of utility pipework

Figure 4.5 above shows a thermal scan of a clean water system pipework and valves, temperatures of approximately 70°. Following lagging of the pipework and valves identified the temperature was reduced by around 30°. This survey was carried out for the entire plant room and identified numerous areas where high temperatures were being given off and contributing to the overall high temperatures in the plant room.

At the Wyeth plant, Grange castle the thermal imaging program covers a wide range of equipment and has detected a number of significant faults over the past number of years. Figure 4.6 below shows the array of equipment currently on the thermal imaging program:

System	Program	Frequency
Thermal Imaging	33 MV Transformers/ Associated MV Switchgear 43 Motor Control Centers 205 MCB Panels 316 Frequency Drives 22 UPS Panels 88 Process Panels Fabric/Roof Membrane Inspection On Demand Insulation Inspection	12 Months

Figure 4.6 Wyeth, Grange castle thermal imaging program

Figure 4.7 below shows a list of actual results obtained from the thermal imaging program in 2007, note that there have been a number of equipment failures avoided using this program and the faults identified were able to be responded to by the maintenance teams in a planned manner:

Application / Faults Identified	BENEFIT
TI -Main Cable Faulty connections found on 30 VSD Units	FAILURE OF 30 AHU'S AVOIDED
TI - Poor connections found on 20 MCB panels	LOSS OF ASSOCIATED SERVICES AVOIDED.
TI - DS WFI Still Investigation - TI used to scan fuses - Operating as high as 90oC	ONGOING INVESTIGATION

Figure 4.7 Thermal Imaging (TI) – 2007 program results summary

Oil Analysis

➤ Oil Analysis principles

Oils, greases and other lubricants are commonly used in equipment with moving parts such as gears and bearings. There are specific grades of lubricants that are suited to different applications, if the grade of lubricant used is known then the chemical properties of the lubricant can be tested. Using oil analysis the quality of the lubricant and material constituents can be tested and compared against the original specification. Oil analysis can be used to determine when an oil changeout is required

but can also detect wear of internal components. For example if the gears inside a machine are wearing then fragments of metal are deposited in the oil, when the oil is tested traces of this metal debris shows up and will give the maintenance team prior warning of a failure. The oil samples are generally taken by technicians in-house and then sent to specialist chemical labs for testing after which the test results will be issued.

➤ Oil analysis – practical applications

At the Wyeth plant, Grange castle the oil analysis program covers a wide range of equipment and has detected a number of problems over the past number of years. Figure 4.8 below shows the array of equipment currently on the oil analysis program:

System	Program	Frequency
Oil Analysis	9 Atlas Copco Compressors 9 York Chillers 8 Grasso Refrigeration Compressors 4 WFI Still Compressors 2 Vauccum Pumps	3 Months
Oil Analysis	9 Hydraulic Lifts 1 Main Diesel Oil Tank 4 Diesel Oil Day Tanks	12 Months

Figure 4.8 Wyeth, Grange castle oil analysis program

Results obtained from the oil analysis program over the past number of years have identified frequencies for oil changes, also moisture and metal debris have been found in samples which indicated equipment deterioration. The oil analysis reports are compiled by the condition monitoring team and circulated to the maintenance area owners giving useful information to act on.

Ultrasonic measurement

➤ Ultrasonic measurement principles

Ultrasonic measurement is primarily used for leak detection on steam and air systems, it can also be used to detect closed valves that are passing.

(Bandes, 2003) states that ultrasonic measurement instruments translate high frequency sounds produced by steam or air leaks into the audible range where users hear them through headphones and can view these sounds on a meter or display. The high-frequency ultrasonic components of these sounds are extremely short wave signals that tend to be fairly directional. It is easy to isolate these signals from background plant noises and detect their exact location.



Figure 4.9 Ultrasonic measurement instrument

Courtesy: UE Systems Inc. (uesystems.com)

➤ **Ultrasonic testing of steam traps – principles**

As mentioned at the beginning of this section ultrasonic measurement is primarily used for checking the operating condition of steam traps. Steam traps are used on steam distribution lines to remove unwanted condensate build up. When a steam trap fails, the build up of condensate can dramatically increase in temperature due to the live steam mixing with the condensate. This will result in additional demand on site steam boilers, poor efficiency of heating coils, potential for water hammer in the steam pipework and an overall inefficient steam system. Steam traps are temperature sensitive devices and open and close automatically to allow condensate build up to be removed to drain. Steam traps can fail open (in which case both steam and condensate passes to the drain) and fail closed (which allows an internal build of condensate in the steam line). The fail open steam trap can be detected by the ultrasonic frequencies present from the steam and condensate continuously leaking through the trap. A fail closed trap can be detected by the absence of ultrasonic frequencies at the trap.

Periodic steam trap surveys using ultrasonic measurement to identify faults can have significant cost savings by increasing the efficiency of the steam system.

➤ Ultrasonic testing of steam traps – case study

A sitewide plant ultrasonic inspection program of 803 steam traps was carried out at Wyeth, Grangecastle in 2006. Results from the inspection program identified approximately 15% in a failed state (15% is a high failure rate but the majority of steam traps had been in service since 2002). Steam trap Manufacturers provide steam loss Tables (100% Trap Passing). When the capacity of the steam system (Kg/hr) and the size of the steam trap are known then the failed percent can be factored in to calculate the real steam loss. Figure 4.10 below shows a typical calculation for steam loss in Kg/hr for a 75% failed steam trap:

[Kg/H]		Trap FAIL = 75% Trap Passing = 25%		Real steam loss		[Kg/H]		[€(1000 Kg)]		Calculate the unit €(1000Kg) into [€/Kg]		Parts of the Steam will be reused -> [%]		[Hours / anum]		[€/Year]
13.1	X	75%	➡	9.83		9.83	X	€ 20.00	X	1.E-08	X	60%	X	8760	➡	€ 1,033

Figure 4.10 Steam loss calculation for failed steam traps

The results of the steam trap testing were issued to maintenance area owners and replacement/repairs were made to the failed steam traps. The cost savings were significant with over €65,000 attributed to steam losses due to the failed traps, figure 4.11 shows the breakdown of results:

Loss Calculation:			
STATUSOK / COLDP	Steam Service	STEAM LOSS [KG/H]real	COST OF STEAM LOSS [€/Year]
FAIL		623.1 €	65,639.91
	Link Corridor Plant Steam	207.2 €	21,783.49
	Boiler Room Plant Steam	207.2 €	21,783.49
	MS Plant Steam	58.0 €	6,095.65
	DS Clean Steam	53.5 €	5,758.30
	MS Hum Steam	39.9 €	4,190.08
	MS Clean Steam	24.2 €	2,545.48
	DS Hum Steam	17.4 €	1,827.25
	Pilot Lab Plant Steam	8.8 €	930.05
	DS Plant Steam	6.9 €	726.12
	Warehouse Cleansteam	0.0 €	-
Grand Total		623.1 €	65,639.91

Figure 4.11 Steam trap survey results

Due to the success of this program, ultrasonic measurement at Wyeth, Grangecastle is now part of a fixed condition monitoring program which includes regular leak inspections on compressed air, nitrogen and CO² systems. The steam trap inspection program includes 980 traps tested every 6 months on 3 sitewide plant steam and clean steam systems.

4.3 Criticality and single point of failure analysis

Criticality Analysis of utility systems to production

In a plant which has a large array of utilities equipment, maintenance improvement can not happen on everything at once, the maintenance professionals must first begin to understand which systems really matter. Critical equipment in a manufacturing environment is that which can stop production, production equipment in the pharmaceutical industry may have a number of different utilities serving it, some losses of these utilities may be tolerated others may cause the loss of product batches at a cost of millions of euro. To seek effective maintenance improvement the utilities and production groups must work together in order to map out their processes and understand which systems are the most critical. The author in 2007 in conjunction with the sitewide maintenance excellence team met with the manufacturing suites building production groups to start working on a process that would determine the most critical utilities systems to production. The following details the steps taken and results obtained:

➤ Process Mapping

There are many different variations of the process mapping processes and it is used in many different quality techniques such as six sigma and business process re-engineering. The result of process mapping is to be able to detail or describe individual or groups of processes; its use in determining utility system criticality is no different. The first step of the criticality assessment process is to list out all the plant utilities and map out the production users for each one. This process map is then used as a guide to determining inter-dependencies of the systems. Figure 4.12 below shows the process map obtained for the manufacturing suites building, each utility system is listed and branches out to the end production users. This is a very useful tool and during the process of building this map the utilities and production teams begin to learn how their production equipment interacts with utility systems. Not only are there inter-dependencies between production equipment and utility systems, some utilities actually depend on other utilities and the process map also accounts for this:

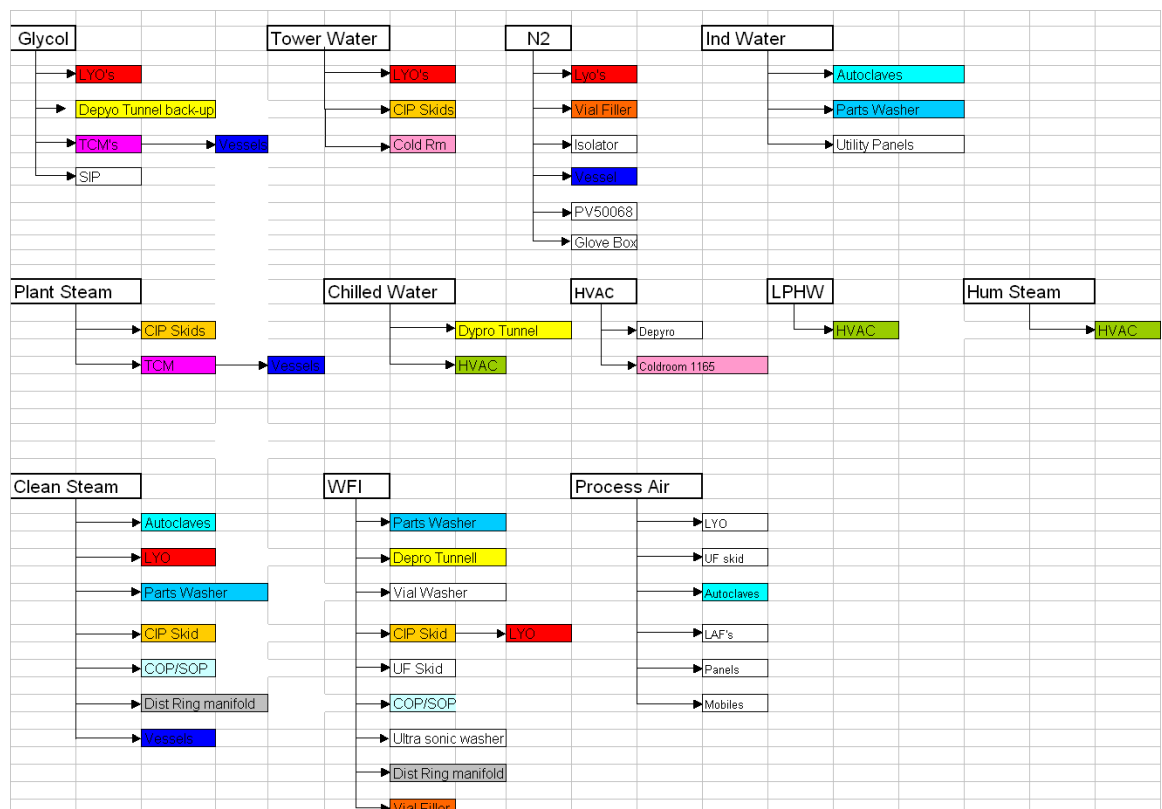


Figure 4.12 Utilities-Production process map

➤ Criticality assessment of utility systems

The next step in the critical assessment process is to compile the effect of operational problems/shutdowns of each utility; a weighting system is used under the following categories (scoring 1-5):

- Quality (will the loss of this system cause compliance problems)
- Safety (is there a potential for injury)
- Maintainability (can the system be maintained, if not then maintenance improvement is not really possible)
- Upgrade (can the system be re-designed, upgraded or robusted to improve reliability)
- Recovery Cost (production/batch costs for loss of utility service)

The above 5 categories include all the important areas that will influence the order of the systems to target reliability and maintenance improvement on. The results are then compiled on a criticality assessment grid, figure 4.13 below shows an extract from the criticality assessment grid completed for the manufacturing suites building:

Building	Description	Quality	Safety	Maintainability	Upgrade	Recovery Cost	TOTAL	Comments
MS	CHILLED GLYCOL DISTRIBUTION CHILLED GLYCOL GENERATION	5	4	5	5	5	92.9%	Can impact up to 5 batches across the 3 suites if system lose occurs. Glycol Dist feeds WFI Processes and also TCM it cools the WFI. In Certain Applications We have 3 Centrifugal Chillers at the moment 2 have problems, Tubes due to continually running on no load.
MS	PLANT STEAM & CONDENSATE SYSTEM	5	4	4	4	5	87.1%	Plant Steam
MS	NITROGEN DISTRIBUTION	5	5	4	1	5	87.1%	Used for batch making, extended loss will result in stopping production and loss of batches.
MS	WFI GENERATION WFI DISTRIBUTION	5	4	4	4	4	85.9%	Impact to Production, Jitter blood of Environmental Control from a Cleaning Point of View
MS	AHS - FIRST S1 - LYO PLANTROOM (89105)	5	4	4	4	4	85.9%	105 Controls the Temperature in room 1199. Instrumentation heats up possible malfunction in WFI System
MS	CLEAN STEAM SYSTEM	5	5	2	4	3	84.7%	Clean Steam is used to SIP Equipment. We have in the past 4 Months switched on a new generator which allows Maintenance to be carried out with ease

Figure 4.13 Utilities criticality assessment results

The results of the assessment found that the utility glycol generation and distribution was the most critical system in the building. The glycol system is a low freezing point liquid that is circulated at approximately 0°C, the glycol liquid is circulated through product vessels in order to maintain its temperature within specified limits. The loss of this utility could result in loss of product costing millions of euro. The criticality

assessment process provided some very useful information on the utility systems that really matter to production.

Single point of failure (SPOF) analysis

Single point of failure (SPOF) analysis is a detailed review of a system and its sub-components to determine which items if they fail will cause the entire system to shutdown. It is a useful process in reliability engineering to identify areas in a utility system which can be further robusted or equipment redundancy added in. Like the criticality assessment process it involves mapping out the utility system to include all main pieces of equipment and investigating the overall impact if one item was to fail.

➤ **Low Pressure Hot Water System – Single point of failure analysis**

In 2008 the author completed a single point of failure analysis on a low pressure hot water (LPHW) system that provides temperature control for cleanroom air-conditioning systems. Some important recommendations came out of this exercise, the single point of failure analysis is generally one of the first activities completed during preparations for reliability centred maintenance program.

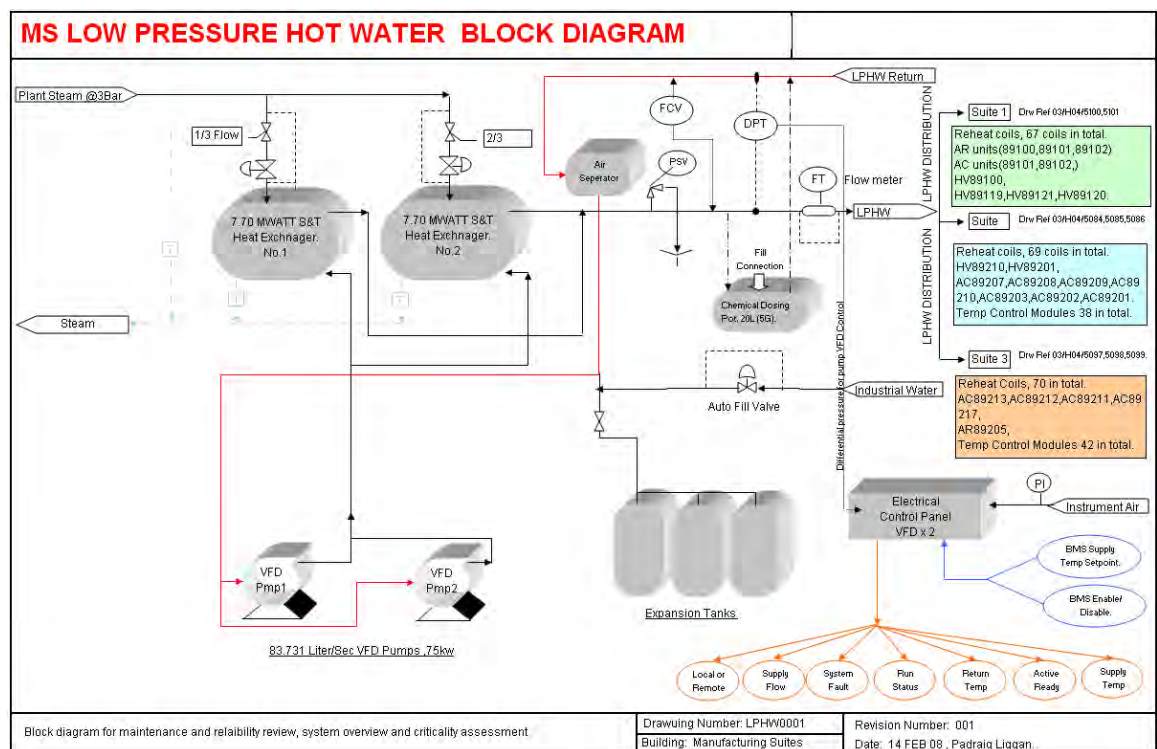


Figure 4.14 LPHW Block diagram

Figure 4.14 above shows the LPHW system block diagram, this is then used to determine the effects of individual pieces of equipment or instrumentation failing. The following documents some of the signal points of failure found and the recommendations that were submitted top the maintenance teams:

Item 1:

The end of line Differential Pressure Transducer in S1 has been identified as a single point of failure and will cause the LPHW system to shutdown. Also this instrument is not currently on any calibration schedule.



Figure 4.15 End of Line Differential Pressure Transducer (single point of failure)

Actions:

- Instrument to be placed on a 12M calibration schedule.
- New DPT instrument to be installed to act as a duty/standby arrangement, the DPT is to be wired back to control panel and programmable logic controller (PLC) code updated to accept either instrument to remain controlling the system.

Item 2:

LPHW PLC code is not currently backed up on RS Mak, also PLC battery is not currently on a PM schedule. This is a single point of failure and following a lengthy power loss (PLC is backed up by UPS) will prevent the LPHW system being restarted.

Actions:

- PLC code to be downloaded and new battery installed asap.

Item 3:

LPHW supply temperature transmitter is a single point of failure and will cause the LPHW system to shutdown. Also this instrument is not currently on any calibration schedule.

Actions:

- Instrument to be placed on a 12M calibration schedule.

In April 2008 the author met with the maintenance teams to review the results above; the actions were assigned to relevant personnel and are now in the process of being implemented. These actions all contribute towards reliability improvement and will help robust the LPHW system and prevent against potential failures of the system.

4.4 Reliability Centred Maintenance (RCM)

RCM is a structured approach to improving equipment reliability and blends failure and Risk Analysis with Preventative and Predictive Maintenance.

The RCM program at Grange Castle uses a process called RAG (Risk Analysis Grid). One of the key objectives of the RAG process is to increase plant availability by designing a maintenance program based on the type of failures that can occur. The RAG process involves gathering a multi-disciplined team to analyse all the failure modes of a system and design an appropriate maintenance program to reduce or eliminate potential failures identified. The following are some of the key benefits of adopting the RCM approach to maintenance:

- Involvement in the RCM process will help everyone build their technical knowledge of utility systems.

- Involvement in the RCM process will aid increased ownership (i.e. technicians will help develop, complete and own the maintenance for their systems).
- Increased plant availability, reduced breakdowns, reduced unplanned maintenance and reduced costs associated with failures.
- Identifying hidden failures, discovering significant and previously unknown failure scenarios.
- Identify areas for potential design Improvement.

The RCM process involves breaking down the utility system into maintainable items, a series of 7 questions are then asked for each line item leading to eventually determining most suitable maintenance strategy to employ. These 7 questions were developed during the original RCM programs used in the aircraft industry in the 1960's, the questions are also published and explained in detail in John Moubrays' book „Reliability Centred Maintenance’:

1. What is the system designed to do?
2. How are we using the system – Operations, capacity vs. design?
3. What would we consider to be a failure?
4. What happens when it fails?
5. In what way does each failure mode matter?
6. What can be done to predict or prevent the failure?
7. What is the appropriate maintenance program to be utilized?

When designing a maintenance program using RCM the following maintenance strategies are all considered in implementing the most effective optimised maintenance program:

- Preventative Maintenance / Fixed Time Maintenance (PM / FTM)
- Condition based monitoring (CBM)
- Corrective Maintenance (CM)
- Run to fail (RTF)
- Design out Maintenance (DOM)

RCM can be quite a time consuming process both in preparations and carrying out the analysis, this is why activities such as criticality analysis is important to enable an understanding of which systems are the most important. With this information at hand resources can then be allocated to complete RCM programs on the most critical systems first.

➤ **RCM Program case study – LPHW System**

In April 2008 the author led an RCM program on the manufacturing suites building LPHW system. The preparation for this program took a number of weeks to complete and included a single point of failure analysis on the system, the actual RCM session which included a team of varied disciplines (electrical, automation, maintenance and mechanical engineering) took just under 2 days to complete. The preparation process involved the following main areas:

- Obtaining all relevant P&ID's (piping and instrumentation drawings) and technical manuals.
- Preparing a detailed block diagram of the system and also identifying single points of failures.
- Walking down the LPHW generation & distribution and compiling a list of maintainable items under the 3 main categories (Mechanical, Electrical, Automation and instrumentation).
- Photographing all main equipment items on the system.

A risk analysis RCM grid was then compiled with a list of the maintainable items, the grid is populated during the RCM sessions and the net result being a newly designed maintenance program based around preventing or eliminating potential system failures. Figure 4.16 below shows an extract from the LPHW risk analysis grid:

Grundfos Distribution Pumps,75Kw 150A	Motor Bearings	GREASE BEARINGS EVERY 3 MONTHS	3	R	0.5
Grundfos Distribution Pumps,75Kw 150A	Mechanical Seal	INSPECT PUMP FOR LEAKS	3	R	0.5
Expansion Vessels	Vessels x 3	CHECK THE EXPANSION VESSELS AND CONNECTING PIPE-WORK FOR ANY LEAKS.	3 *	R	0.25
Expansion Vessels	Vessels x 3	REMOVE THE AIR VALVE CAP AND CHECK THE PRESSURE USING A PRESSURE GAUGE. REFER TO NAMEPLATE ON VESSELS TO ENSURE THE PRESSURE RECORDED MATCHES OR EXCEEDS THE PRE-CHARGE PRESSURE. RE-CHARGE IF LOW.	3 *	R	0.25
Expansion Vessels	Vessels x 3	WHEN REMOVING THE PRESSURE GAUGE, ENSURE THAT THE SMALL AMOUNT OF AIR RELEASED DURING DISCONNECTION DOES NOT INCLUDE ANY WATER. IF THE AIR IS DRY, THE DIAPHRAGM WITHIN THE VESSEL IS INTACT AND FUNCTIONING CORRECTLY. REPLACE THE AIR VALVE CAP WHEN FINISHED.	3 *	R	0.25
Expansion Vessels	Vessels x 3	VISUALLY INSPECT THE OUTSIDE OF THE VESSELS TO ENSURE THEY ARE FREE FROM CORROSION.	3 *	R	0.1

6 Monthly PM – LPHW System

Mechanical					
Grundfos Distribution Pumps,75Kw 150A	Motor Bearings	CARRY OUT VIBRATION ANALYSIS	6	R	0.5

12 Monthly PM – LPHW System

Mechanical					
LPHW Generation:	7.7 MWatt Shell And Tube Heat Exchangers	CLEAN MAIN STEAM & LPHW STRAINERS AT THE SKID	12	S	2
LPHW Generation	Air/Dirt Separator	PURGE DRAIN VALVE	12	R	0.1
LPHW Generation	BSA1 Manual 8" Isolation valves	OPERATE AND CHECK CONDITION OF BSA1 ISOLATION VALVES	12	S	0.75
LPHW Generation	Manual 10" Valve	OPERATE AND CHECK CONDITION OF BSA1 ISOLATION VALVES	12	S	0.75
Electrical					
Distribution Pumps,75Kw 150A	Motor Thermal Block	OPEN MOTOR/TERMINAL BLOCK AND INSPECT FOR SIGNS OF OVERHEATING OR BURNING, INSPECT THERMISTOR WIRING AND TERMINAL CONNECTIONS	12	S	0.5
Distribution Pumps,75Kw 150A	Main Cable Glands	INSPECT MOTOR CABLE GLANDS TO ENSURE ALL CONNECTIONS ARE FIRMLY SEALED	12	S	0.25
Distribution Pumps,75Kw 150A	Local Isolator	INSPECT CONDITION OF ISOATOR	12	R	0.1
Distribution Pumps,75Kw 150A	Variable Frequency Drive, Schneider Altivar 58, Internal Fan	INSPECT AND REPLACE PANEL FILTERS, INSPECT OPERATION OF EXTERNALPANEL FANS	12	R	0.25
Main Control Panel	Main Supply Cable No.1	INFRARED IMAGING OF ENTIRE PANEL	12	R	0.25
Main Control Panel	Main Control panel Frame & Door earthing.	VISUAL INSPECTION ON EARTH CONNECTION INSIDE PANEL DOOR	12	R	0.1
Main Elec Supply	Main Upstream Breaker	TEST FUNCTIONALITY OF MAIN UPSTREAM BREAKERS SUPPLY	12	S	0.5
Main Control Panel	Allen Bradley PLC battery back up.	REPLACE BATTERY	12	R	0.5
Calibrations					
Supply & Return Main distribution lines	Sontay, Differential Pressure transducer	CALIBRATION EVERY 12 M	12	R	2

Supply & Return Main distribution lines	Temperature Supply/Return Probes	CALIBRATION EVERY 12 M	12	R	2
LPHW Generation	Spirax/Sarco Steam Control Valves	24 M SCHEDULED CAL	12	S	1

When completing an RCM program on a clean utility system the risk analysis grid provides more than enough rationale for maintenance change, it is a structured approach that considers the impact to the end user (production) at all times while allowing the creation of an optimized maintenance program.

4.5 Root cause analysis and corrective/preventative actions

Root cause analysis and corrective/preventative actions for utility equipment failures is a continuous improvement process. It involves the maintenance teams or reliability engineers investigating an equipment failure in order to identify exactly what the root cause was and to implement suitable actions in order to ensure it cannot happen again. With a successful investigation program common failures are eliminated and will aid smooth running of plant and equipment. The equipment failure investigation process in the pharmaceutical industry for clean utility systems is a regulatory requirement and demonstrates that the maintenance and engineering teams have a certain level of control over their processes. There are many different methods of determining the root cause of a failure such as „fishbone diagrams’, ‘5 whys’ and „root cause prioritisation matrices’. The author currently owns all investigations carried out on utility systems in the manufacturing suites building, Grangecastle. Over the past 3 years the number of investigations completed is approaching 300, the main criteria that each investigation follows is detailed below:

- Description of the event and immediate actions taken
- Impact assessment of the failure
- Detailed investigation and root cause analysis
- Actual or most probable root cause
- Corrective and preventative actions

➤ Maintenance troubleshooting guides

With a database of utility failures spanning 3 years the author initiated a program of developing troubleshooting guides for main systems, the troubleshooting guide (the same as what you commonly get with a TV or electronic device at home) documents all the common types of faults and identifies actions to try and resolve the problem. This information is very useful for operations teams trying to restart a system following a breakdown, instead of spending hours trying to find the problem the troubleshooting guide points them in the right direction. The troubleshooting guides can also be used as a learning tool for new staff and by presenting them with all known equipment failures and suggested troubleshooting techniques. Figure 4.17 below shows an extract of a troubleshooting guide for a humidification steam system that was created in 2007:




Troubleshooting guide			
Problem	Origin	Possible Cause	Possible Solution
Tank Low level / high level.	<i>Tank level control valve.</i>   Controller parameters settings: Set Pt 55% Control Band 20% Alarm Low 00% Alarm High 80% Alarm delay 05s	Loss of supply air pressure.	Check supply pressure at regulator to be correct @5-6Bar.
		Loss of 4-20mA signal from level controller to valve.	a) Check both % travel indicators on valve and output of controller to be the same. If not re-setup valve as per manual B) Check loop voltage, if no loop voltage present, check all control fuses. C) Manually drive valve using milliamp source (fluke or Beamex meter) to check valve stroke. Reset-up may be required as per valve manual. d) Request a demand cal to be performed by calibration group.
		Mechanical obstruction on stem shaft.	Manually drive valve from actuator and observe movement. Remove/reset up any mechanical obstruction observed.
	<i>RO drop supply valves.</i> 	Plug/Sear arrangement of valve obstructing RO supply flow.	Using a calibrated flow-rig check flow difference between incoming side and outgoing side of valve. Flows taken 15Jun06 = 100% open- 130 l/min If flows are incorrect replace valve and recheck flows are correct.
		Valve gaskets worn/leaking.	Replace damaged gasket.
		Valve air pressure loss, not fully opening.	Check all connections on solenoid block @valve for leaks and around valve diaphragm. replace valve if diaphragm is leaking. Remove plastic head cover and observe movement of valve stem for any mechanical obstructions. Check air supply pressure is correct at main manifold and shut-off valve is open.
		Loss of device net signal to valve.	Check all connections at device net terminations are secured tightly. Swap drop cable with new, making sure same length of cable is used as resistance of cable will alter comms.

Figure 4.17 Troubleshooting guide for humidification steam system

➤ **Clean Utilities investigation case study – WFI brown fibres**

Tools such as fishbone diagrams and prioritisation matrices can be very useful when complex investigations are being carried out. In 2007 the author was the lead investigator for one of the biggest ever utilities investigation carried out in the manufacturing suites building; the investigation was initiated following numerous traces of brown fibres observed in samples taken from the clean water for injection (WFI) system. Given that the WFI system is mixed directly with drug product meant that this problem had the potential to halt production. The brown fibres were sent to a chemical lab in the UK in order to determine the make-up of this material, it was found to be a type of polypropylene. An investigation team was assembled and following documents the steps taken in order to identify the root cause and put in place corrective actions to protect against a re-occurrence:

Step 1 - Fishbone diagram

The first part of this process was to create a definitive description of the problem; following consultation with the group the following statement was created:

Problem statement:

Description failures of Microscopic Brown Fibers only in 16+ samples from 4 sample point locations (of 18 test points) on S1 WFI Loop since end of Apr'07 [Especially DP-WFI-027]

With the problem now accurately defined then the fishbone diagram could be constructed, the fishbone diagram (also known as the Ishikawa diagram) which is a commonly used quality tool was constructed using the following main headings as a possible source of the problem:

- Equipment
- Facilities
- People
- Methods/procedures
- Materials

Using the fishbone diagram possible contributory root causes (however unlikely) are populated.

Step 2 - Cause/effect prioritisation matrix

With a detailed list of all the possible root causes a cause and effect prioritisation matrix is then populated, each line item is then rated using a factor of probability (1-10) and severity (1-10). The highest ranked results are the areas that the team will spend the most time on further investigations, using this process the actual root cause of the problem is commonly among the top ranked items. Figure 4.18 below shows an extract of the cause/effect prioritization matrix:

Root Cause Prioritization Matrix						
Potential Cause	Probability	Severity	P*S	Action	Resp	Due
Manufacturing Flushing, possible WFI Re-flux	5	6	30	2. Contamination from flush path - How is flushing currently been done and is it as per DPPS-0142	MH	07-Jun-07
Material Decay	3	8	24	1. Is there any soft parts in the system that contains Polypropylene	PL/MW	07-Jun-07
Duplex Vent System	2	9	18	1. Filter material sent of for lab analysis to determine match with brown particles found COMMENT: Filter material is not thought to be fiber shedding	DC	17-Jun-07
Wrong Spec of soft parts fitted	2	8	16	1. Is there any soft parts available on the market of similar type that we use that may have been placed into the line by mistake, also is it possible that the wrong spec soft parts came through stores?	PL/MW	07-Jun-07
External object, including intrusive work on system	2	4	8	1. List and Date all System Interventions - Contract Work - Tie-in's - Line Break - Construction - Maintenance (On the loop, Pumps, Hx) - Hx - Calibrations	JB	07-Jun-07
Probability Score: 7-10 Very Likely 4-6 Highly Possible 1-3 Unlikely Severity Score: 7-10 Critical 4-6 Moderate 1-3 Low						

Figure 4.18 Cause/Effect prioritization matrix

As shown above the prioritisation matrix provided the order in which different areas were further investigated. Within the next week the actual root cause was found, the duplex vent system on the WFI storage tank was breaking up due to oxidization from cleaning chemicals being dumped in a plant room drain near-by. The inner layers of the vent filters are constructed with a polypropylene matrix and were shedding into the WFI tank and being distributed to the end users. Before the investigation sessions were carried out, the vent filters were not even considered to be a problem as it was assumed that they did not shed fibers of this type. It is also interesting to note that the actual root cause was within the top 3 ranked items ensuring that the investigation

team did not focus on any of the lower ranked items unless the top ones could be ruled out first.

Step 3 – Future actions for prevention of re-occurrence

With the definite root cause known the following corrective actions were implemented:

- Type of vent filter was changed to a different manufacturer to protect against possible product flaws with the original type.
- Visual inspections of the internals of the vent filter were set up on a 3-monthly frequency.
- The drain in the plant room beside the WFI storage tank was sealed and taken out of use.
- Air breaks were installed on the vent line to prevent against chemical vapours being sucked in through the vents and therefore further protecting the filters.

The result of the investigation process using the fishbone diagram and prioritisation method provided a definite root cause, one which was not immediately apparent. A number of robust corrective actions were implemented to ensure this incident could never re-occur.

4.6 Summary and Conclusions

This chapter has presented in detail the relatively new area of condition based monitoring (CBM) which is making its way into industry in a big way. The benefits of CBM are clear to be seen and it also promotes a proactive approach to maintenance. The authors' opinion is that any factory with utility systems should employ some methods of CBM, the initial investment is negligible because the CBM programs have been shown to pay for themselves many times over through increased plant reliability.

The criticality analysis process is an excellent way to engage both the maintenance and production teams and begin to really understand their own processes. The results of the assessment allows maintenance and reliability engineers to focus reliability improvement projects on the systems that really matter.

Using tools such as single point of failure analysis and RCM aids improvement in equipment reliability. With the introduction of RCM, the most effective maintenance program can be created whilst removing non-value adding maintenance activities.

From the authors' own experience, many companies simply opt to „maintain everything’, this may in-fact achieve good plant performance but the maintenance program could be very inefficient and heavy on resources.

In a maintenance excellence environment, the maintenance teams should always seek improvement in everything they do. Carrying out equipment failure investigations is in line with maintenance best practices and is a proven method of achieving continuous reliability improvement.

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CHAPTER 5 – MAINTENANCE PERFORMANCE MEASUREMENT

5.1 Introduction

One of the most important areas of maintenance excellence is the ability to measure the performance of the maintenance program and to be able to use these measurements to highlight areas which need improvement. This should be a continuous process by identifying areas of improvement and implementing solutions. In a maintenance excellence environment every aspect of the maintenance department should also be audited and benchmarked against what are considered to be best practices. This chapter will explore these areas in detail by using some of the latest standards and guides available to industry.

Maintenance Standardisation

Asset management standards such as PAS-55 „*Publicly Available Specification for Asset Management*’ and reliability engineering communities through collaboration with numerous industry leaders have benchmarked the categories and levels of achievement that are considered „best practices’. One of the key requirements of PAS-55 is to have maintenance key performance measurements (KPI’s) in place that drives improvement. Benchmark figure ranges for an array of important KPI’s are available from a number of sources but very few provide guidance on how to obtain these KPI’s or ensure that they are being measured correctly and are consistent with the rest of industry. This is where the European standards EN13306 „Maintenance Terminology’ and EN 15341 „Maintenance Key Performance Indicators’ complement PAS55 by giving guidance on standardising the classification of maintenance types and maintenance KPI’s. By allowing industry as a whole to standardise its maintenance measurement then results can be more easily compared and benchmarked. This sort of standardisation also becomes useful when comparing the performance of different factories within the same company. This section will look at the implementation of the standard EN13306 „Maintenance Terminology’ and how your maintenance systems can be structured to match this common approach. This exercise is an important prerequisite before starting to measure maintenance KPI’s accurately and consistently.

Maintenance Key Performance Indicators

Maintenance performance data is an important part of maintenance excellence and it allows both the effectiveness and efficiency of the maintenance program to be measured. These results can help identify areas of improvement, the KPI's are 'hard facts' and ignore personal opinion or bias. With an infinite amount of possible KPI's to measure, companies often tend to measure a wide variety of KPI's with the majority not really giving any valuable information. Valuable maintenance KPI's are those which can be directly linked to the performance of the business, this chapter will look at the use of the European standard EN 15341 'Maintenance Key Performance Indicators' to aid in the KPI selection process and how to integrate them into your maintenance systems.

Maintenance Improvement

Producing useful Maintenance KPI's is only the start; interpreting them, acting on them and improving as a result is the aim. This chapter will look at how to interpret the KPI results and to compare similar equipment and develop a structured approach to carrying out a maintenance performance review. The systems to be tackled should be the ones that use up most of your resources, cost money on spares and downtime etc., this chapter details a Pareto style approach to prioritising systems KPI results used for maintenance improvement.

Maintenance Auditing and Benchmarking

Auditing of maintenance is carried out in an attempt to quantify the actual status of the maintenance department in number of important categories and to identify opportunities for improvement. The results of the maintenance audit should then be benchmarked against what are considered to be best practices. The International Maintenance Roundtable (IMR Australian Maintenance Excellence Awards) provide a publicly available maintenance auditing assessment, it provides comprehensive auditing criteria and identifies the targets which from industry research are deemed to be best maintenance practices or maintenance excellence. The results from the audit assessment can then be plotted on the PAS-55 Web chart which displays all the key areas audited and their status related to best practices or world class. In this chapter the auditing and benchmarking process will be laid out in detail and an actual audit

using the IMR assessment will be carried out on utilities maintenance at Wyeth Biopharma. The aim of this process is to identify where exactly are the utilities maintenance team in relation to best practices? and what gaps (if any) of improvement are needed in order to get there?

5.2 Maintenance Standardisation

➤ Maintenance Classification as per EN13306

The European standard EN13306 „Maintenance Terminology’ was published in 2001 and is one of the first attempts to standardise maintenance terminology and classification in industry. The standard should be studied and employed prior to setting up maintenance key performance indicators, there are variations in the way maintenance activities are defined particularly what criteria distinguishes the difference between preventative and corrective maintenance (PM and CM). To explain this author has laid out an example of this:

Example – During an equipment in-operation PM check on air handling unit fan belts the technician noticed that the belts were slightly loose and possibly damaged; it was not an immediate concern so a notification was raised in order to change the belts in the future when a suitable equipment downtime window could be arranged.

Question – Is the follow-up task to change the belts corrective maintenance or preventative?

Answer – Traditionally maintenance people would classify this as corrective maintenance (follow-up) because it could not be done during the PM and the CMMS maintenance system would also default the coding of this work as corrective.

EN13306 would classify this work as „Preventative’ as it clearly shows that the PM checks caught the problem and it was able to be resolved through follow-up work at a later date before the failure occurred.

The PM:CM ratio is a common maintenance KPI used in industry, if companies are classifying all follow-up work from PM as „CM’ then they are not giving themselves recognition for how good their PM program is. A world class PM:CM ratio is considered to be 85:15, without correct classification of activities the PM:CM ratio could look poor but in reality (if the correct classification of PM and CM were

applied) could be very good. Given that the majority of calculated maintenance KPI's are based on PM and CM data then it is important to get this right. If these variations in maintenance terminology are allowed to exist then the maintenance key performance indicators will differ from factory to factory and can be difficult to benchmark.

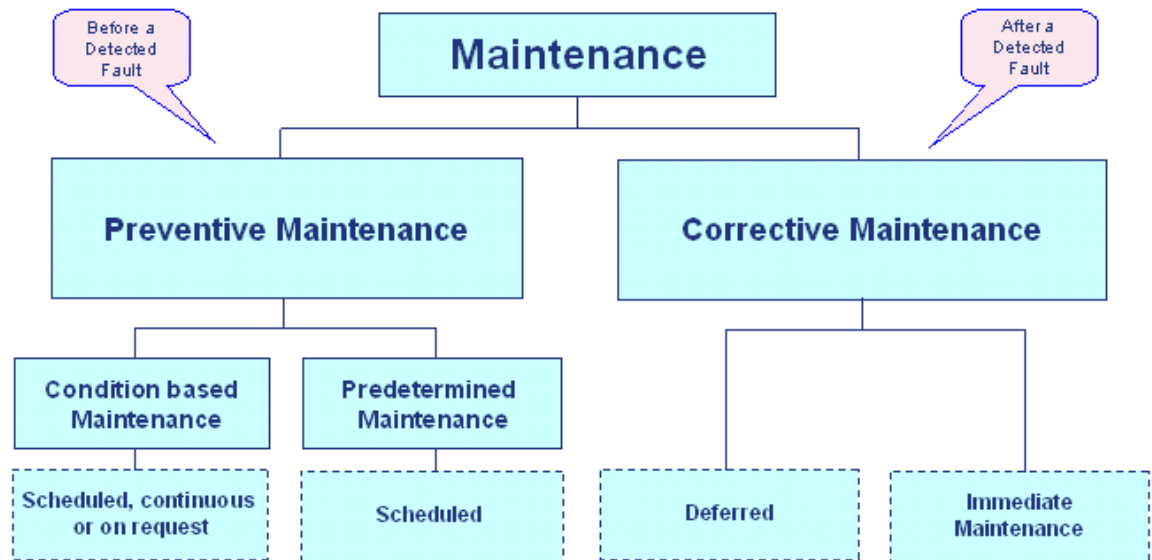


Figure 5.1 EN13306 Maintenance Classification Model

The EN13306 maintenance classification model is shown above in figure 5.1, an important part here to note that Preventative Maintenance is „before the failure’ occurs and corrective is „after the failure’. If we were to use this model to interpret the last example then the PM check on the air handling belts would be classified as „Pre-determine Maintenance’ and the follow-up work to change the belts would be classified as „scheduled’ (note: both activities remain under the overall tree of Preventative Maintenance).

The following lists the exact definitions of the different types of maintenance as per EN13306, it is important to understand these definitions clearly before attempting to restructure the maintenance system to suit. The definitions below all link in to the EN13306 model shown in figure 5.1:

Preventative:

Maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or degradation of the functioning of an item.

Pre-determined:

Preventative maintenance carried out in accordance with established intervals of time or number of units of use but without previous condition investigation.

Scheduled:

Preventative maintenance carried out in accordance with an established time schedule or established number of units of use.

Condition Based:

Preventative maintenance based on performance and/or parameter monitoring and the subsequent actions [NOTE: Performance and parameter monitoring may be scheduled, on request or continuous].

Corrective:

Maintenance carried out after fault recognition and intended to put an item into a state in which it can perform a required function.

Deferred:

Corrective maintenance which is not immediately carried out after a fault detection but is delayed in accordance with given maintenance rules.

Immediate:

Maintenance which is carried out without delay after a fault has been detected to avoid unacceptable consequences.

➤ **Aligning your maintenance systems with EN13306**

After reviewing the EN13306 standard and understanding clearly the way maintenance activities should be classified then the next step is to change your own maintenance system to suit. This activity was completed in 2006 by the sitewide maintenance excellence team (which the author is a member) at Wyeth, Grangecastle in order to get the SAP CMMS system and maintenance procedures aligned with the EN13306 standard.

From reviewing the EN13306 structure it was evident that the maintenance system was already closely in line, the SAP CMMS system classifies maintenance work order types as follows:

- PM12 or PM17 (Preventative Maintenance)
- PM11 (Deferred Maintenance or follow up from PM12/17)
- PM14 (Immediate Maintenance)

The „Maintenance Activity’ coding option in SAP gives the ability to uniquely identify each of the distinct categories in which maintenance work orders fall. The SAP maintenance activity coding system was not being used to its full potential but played a key part in mirroring the SAP maintenance system with the EN13306 model. The following lists of activity codes that are available in SAP:

Maintenance Activity Type			
001	Improvement	007	Rounds
002	Preventative (Predetermined)	008	Shutdowns
003	Predictive	016	Investigation Report
004	Corrective	018	Project Support
005	Calibration	023	Condition Based

Figure 5.2 SAP Maintenance Activity Type Codes

By introducing the maintenance activity coding (Fig. 5.2) above with the PM11/12/14/17 work order classification any maintenance work order in SAP can be uniquely identified in line with EN13306. The EN13306 model was revised to include the SAP maintenance system coding and is shown below in Figure 5.3:

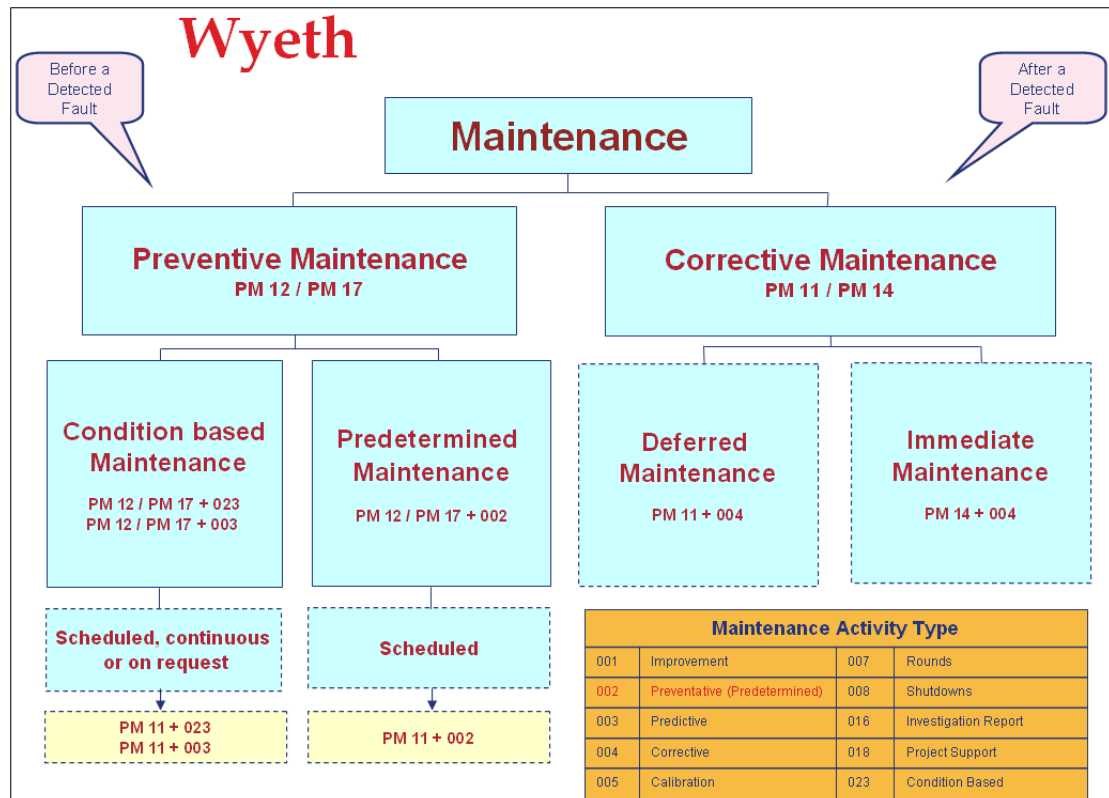


Figure 5.3 EN13306 / SAP CMMS model

The SAP CMMS system and local maintenance procedures were updated to reflect the new coding system and align with EN13306. This was the first major step completed prior to implementing the reporting of accurate maintenance KPI data.

5.3 Maintenance Key Performance Indicators

➤ Maintenance Key Performance Indicators as per EN13306

The European standard EN15341 „Maintenance Key performance Indicators’ was first published in 2007, it aim is to:

„Support management in achieving maintenance excellence and to utilise technical assets in a competitive manner’

The standard includes 70 possible KPI’s under the following categories:

- Economical Indicators
- Technical Indicators
- Organisational Indicators

Most of these indicators can be used at different levels depending on whether they are being used to measure the performance of the entire plant, individual systems or individual system components (equipment). The standard offers a number of important areas to consider when attempting to select the most appropriate KPI's for your business, the standard also recommends to test the results over a defined period before actually moving towards automatic reporting.

➤ Selecting the EN15341 Maintenance KPI's

MS Utilities KPI pilot program overview

In 2007 the author using the newly published EN15341 standard conducted a KPI pilot program on clean room HVAC systems for 17 identified KPI's from the standard. The 17 KPI's were selected by the sitewide maintenance excellence team out of a possible 70 and were considered to be potentially useful and were applicable to our operating context. In following the recommendations of the standard these 17 KPI's needed to be fully tested and evaluated prior to finalising them.

The pilot program was conducted on a portion (Suite 1) of the Manufacturing Suites building Utilities HVAC Systems (5 Systems) that serve critical production cleanrooms, system list below in figure 5.4:

HVAC Suite 1 (Equipment Tags)	Functional Location	System Description
HV-89100	1103-513	AHS - S1 FINAL FILL/ASP. STAGING (89100)
HV-89106		
HV-89116		
HV-89101	1103-514	AHS - S1 CONJUGATION ROOMS (89101)
HV-89111		
HV-89118		
FA89101-01		
FA89101-02		
FA89101-03		
FA89101-05		
FA89101-06	1103-524	AHS - S1 BUFFER PREP & WEIGH (89102)
HV-89102		
HV-89117		
FA-89102-01		
FA-89102-02		
FA-89102-03	1103-516	AHS - S1 CORRIDORS / GOWNING (89103)
HV-89103		
FA-89103-01	1103-517	AHS - S1 ACTIV./ LYO/ WASH&PREP (89104)
HV-89104		
HV-89108		
HV-89109		
HV-89110		
HV-89112		
HV-89113		
FA-89104-03		
FA-89104-04		
FA-89104-05		

Figure 5.4 Suite 1 Validated HVAC Systems List

The maintenance history, spares usage and downtime details for the 5 systems was to be collected from a number of sources and compiled, this would provide the base data for calculation of the 17 KPI's. Post analysis of the KPI results would be required in order to determine the most meaningful KPI's to implement for use by engineering departments across the site.

Project Key objectives:

The key objectives required from the MS Utilities Pilot were laid prior to commencing work:

1. Can we measure the 17 maintenance excellence KPI's as per EN15341

With the information currently available to us on site, is it possible to calculate the 17 KPI's.

2. Is all of the data obtainable, i.e. what are the current gaps (SAP, Automation systems etc.)

How much of the required data is readily available from the current automated systems such as SAP and the manufacturing control system (MCS).

3. Highlight reliability issues at equipment level

Can the maintenance excellence KPI's highlight reliability problems at equipment level even when the overall system/service continuity is good.

4. How useful are the KPI's

Each KPI set of results is to be reviewed and ranked, all duplication and non-meaningful KPI's to be excluded from the implementation stage.

5. Summarise & report the issues and agree the possible solutions (i.e. SAP reporting, procedure revisions etc.)

Detail how each KPI was calculated and where the base data was obtained, identify modifications to the SAP maintenance/MCS system that will enable reporting of the base data easier. The above should directly link into a User Requirement Specification (URS) for implementing the KPI's.

Obtaining the base data

From reviewing the calculations required for the 17 KPI's the common base data required was determined and included an array of data under the following headings:

- Maintenance history hours (CBM, PM, CM and breakdowns)
- Spares cost information
- Actual cost of the equipment
- Total maintenance man-hours available
- Equipment downtime (CBM, PM, CM and breakdowns)
- Equipment availability data (operating time Vs required uptime)

The tool used to collate all the information together was Microsoft Excel, in the future the selected KPI's out of the pilot would be generated automatically from the relevant system. The time period used was the maintenance history for 2006 as this was the closest full year of data available. Initially two separate reports were required to run from the SAP CMMS system, at this stage a number of data gaps were identified and the data had to be obtained from local planning information:

Report No. 1 (Maintenance History)

A report was generated from SAP for 5 HVAC systems 2006, the information included:

- Work Order number
- Functional Location No. & description
- Equipment ID & description
- PM Work Order type (PM11/12/14/17)

Report No. 2 (Maintenance Spares History)

A report was generated from SAP for 5 HVAC systems 2006, the information included:

- Work Order Number
- Functional Location No. & description
- Equipment ID & description
- PM Work Order type (PM11/12/14/17)
- Spares cost assigned

With the above report information an additional number of manual columns were added and the activity codes detailed earlier were added for each line item, in the future if these codes were correctly assigned this would not be required.

This enabled correct filtering of the work orders as per the Maintenance Excellence structure EN13306:

Order	Order Type	TechIdentNo	Description	Maintenance Activity Code	Type 1	Type 2	Spares Correct Cost €
1852770	PM12	03-HV-89106	1MON PM FOR AIR HANDLING UNIT	023	Prev Maint	CBM	#N/A
1941650	PM12	03-HV-89106	6MON PM FOR AIR HANDLING UNIT	002	Prev Maint	Predetermined Maint	30
1910602	PM11	03-HV-89104	FOLLOW-UP TO VIBRATION ANALYSIS HV-89104	023	Prev Maint	CBM	30
1985002	PM11	03-HU-89104-01	FOLLOW-UP TO 6MON PM HUMIDIFIER PIPEWORK	004	Prev Maint	Predetermined Maint	#N/A
1895392	PM11	03-HU-89101-01	REPAIR STEAM LEAK ON HUM STEAM STATION	004	Corrective Maint	Deferred	#N/A
1878438	PM14	03-HV-89101	UNPLANNED SHUTDOWN OF HV-89101	004	Corrective Maint	Immediate	#N/A

Figure 5.5 Maintenance Excellence KPI – SAP CMMS Report

The above Figure 5.5 shows an extract from the HVAC 2006 report of how each maintenance activity in the SAP report was classified.

It is important here to note that follow up planned work orders to CBM and pre-determined should remain in the same category (preventative maintenance) even though traditionally these activities were considered as ‘CM’.

Examples from Figure 5.5:

Order 1910602 (PM11) is „Follow up to vibration analysis’ is a follow up from PM condition based maintenance and remains in this classification (Prev Maint, CBM).

Order 1852770 (PM12) is a 1 monthly PM however is classified as „Prev Maint’ and condition based maintenance „CBM’. All of the 1 Mon PM’s were classed as condition based (i.e. check belts, take readings, inspect etc.)

Order 191650 (PM12) is a 6 monthly PM and is classified as „Prev Maint’ and „Pre-determined’ as there a definite set of pre-determined physical tasks such as „Replace belts, replace filters, grease bearings etc.’

Order 1895392 (PM11) „Repair leak on Hum steam’ is ‘Corrective Maint’ and ‘deferred’ as it was a planned task which was deferred to be completed at some point in the future.

Order 1878438 (PM14) „Unplanned shutdown of HV-89101’ is ‘Corrective Maint’ and ‘immediate’ as it was an unplanned event that was responded to immediately.

The addition of the column ‘Maintenance activity type code’ allowed the unique identification for each classification of maintenance activity. The codes used:

- 002 Preventive (pre-determined)
- 004 Corrective
- 023 Condition based

Please note that these codes were entered into the report manually as SAP did not utilise these codes fully at the time. In the future these codes when used in conjunction with the PM11/12/14/17 codes will allow a unique classification of any maintenance type of work order, and this will be easily extracted into report format.

Cost of Spares

Cost of spares was automatically generated from SAP and costs were placed against each work order number.

Maintenance Man-hours

Maintenance Man-hours was automatically generated from sap and placed against each work order.

Equipment Asset Cost

This is the original cost or ‘Sticker Price’ of the individual equipment and was obtained from the original site purchase order index. Currently most of this information is available from SAP.

Downtime hours, number of failures etc.

The ability to extract downtime hours from SAP was available, however from reviewing the data this important information had not always been captured correctly. For the purpose of the pilot program in MS Utilities, a separate source of this information was obtained. Over the past few years MS Utilities Operations have been recording down time on all critical equipment and classified each as „Planned’ corrective, „unplanned’, „planned PM’ etc. as shown in Figure 5.6 below, the information is for 2006 Suite 1 HVAC and was easily transferred into the pilot program:

DP Utilities Availability Report										
Week 32		20-Aug	21-Aug	22-Aug	23-Aug	24-Aug	25-Aug	26-Aug		
	% Available 24/7	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	COMMENT	
Direct Utilities										
									22Aug07 - Partial shutdown of WFI Suite 1 to repair a leak on Heat Exchanger 03-EX-50148. Work Order Number 2237495.	
WFI Suite 1	100.0			2						
WFI Suite 2	100.0									
WFI Suite 3	100.0									
RMDU	100.0									
Clean Steam	100.0									
Process Air	100.0									
HVAC Grade A/B Suite 1	100.0									
HVAC Grade A/B Suite 2	100.0									
HVAC Grade C Suite 1	100.0									
HVAC Grade C Suite 2	100.0									
HVAC Grade D Suite 1	100.0									
									21Aug07 - Planned Shutdown of HV-89211 to replace Fusible Links and re-tension & re-align belts following the previous shutdown of the unit. Duration of shutdown 1 hour 52 minutes (06:00 - 07:52). Work Order Number 2233680.	
HVAC Grade D Suite 2	100.0		1.86							
									22Aug07 - Planned Shutdown of HV-89250 to re-tension / re-align belts & Calibrate Multiplexers. 23Aug07 - Planned Shutdown of HV-89250 to investigate problems re-starting the unit following the previous shutdown. Work Order Number 2237729.	
SAT LAB	100.0			12		2				
Chilled Glycol	100.0									
Industrial Water	100.0									
Nitrogen	100.0									
Fire System	100.0									
Coldroom 1165	100.0									
Indirect Utilities										
Humidification Steam	100.0									
RO	100.0									
Others	100.0									
Note: Entries indicate number of hours system was unavailable/outside normal operating parameters										
Availability to Manufacturing										
Required by Manufacturing & Available										
Planned Downtime - agreed with Manufacturing. Planned PM work										
Planned Downtime - agreed with Manufacturing. Corrective work										
Unplanned Downtime - But no Manufacturing availability impact										
Unplanned Downtime - Required by Manufacturing, but not Available										
Unplanned Downtime - But out of our Jurisdiction										

Figure 5.6 Maintenance Excellence KPI – MS Utilities Availability Report

With all the information and SAP reports obtained above, the base data for the maintenance excellence KPI’s could be calculated, the following Figure 5.7 shows an extract of the calculated base data:

Base Information Required				
	Functional Location	1103-513	1103-513	1103-513
WO Numbers	Equipment Tag	HV-89100	HV-89106	HV-89116
# Condition Base Maintenance Wos		23	14	14
# of Preventive Maintenance (PM12/PM17)		2	2	2
# of Planned PM Wos (PM11)	# Predetermined Wos	0	0	0
# of Deferred CMs (PM11)		12	1	1
# of Immediated CMs (PM14)	Total # CM Wos	2	0	0
	Total # of Maintenance Wos			
WO Hours				
HRS Condition Base Maintenance Wos		46.24	18	17.25
HRS of Preventive Maintenance (PM12/PM17)		16	16	16
HRS of Planned PM Wos (PM11)	HRS Predetermined Wos	0	0	0
HRS Rounds & Readings				
# of Deferred CMs (PM11)		111.6	0.5	3
# of Immediated CMs (PM14)	Total HRS CM Wos	11	0	0
Spares (cost) Information				
Spares for Condition Base Maintenance Wos		57.76	0	0
Spares of Preventive Maintenance (PM12/PM17)		476.6	30	30
Spares of Planned PM Wos (PM11)	Spares cost Predetermined Wos	0	0	0
Spares of Deferred CMs (PM11)		8452.22	0	0.01
Spares of Immediated CMs (PM14)	Total Spares cost CM Wos	500	0	0
Asset Cost		74,995	11,110	11,472
Total maintenance man hours available				
Downtime				
Intrusive CBM work		32.50	16.50	16.50
Intrusive - PM (PM12/17)		55.50	47.50	47.50
Intrusive - Predetermined (PM11)	PM work causing downtime			
Intrusive - (deferred) PM11		1.00	1.00	1.00
Intrusive (immediate) work (PM14)	Total downtime relating to failures	4.30	0.00	0.00
Required Time		8671.00	8695.00	8695.00
Achieved uptime (during required time)		8666.70	8695.00	8695.00
Total Operating time		8671	8695	8695
# of Failures		2	0	0
Total Time to restore failures		4.30	0.00	0.00

Figure 5.7 Maintenance Excellence KPI Base Data

The KPI calculation formulas taken from the EN15341 standard were entered into excel and the base data was used to calculate the results. The 17 KPI results were presented in bar chart format as shown in the extract Figure 5.8 below and were reviewed by the maintenance excellence team:

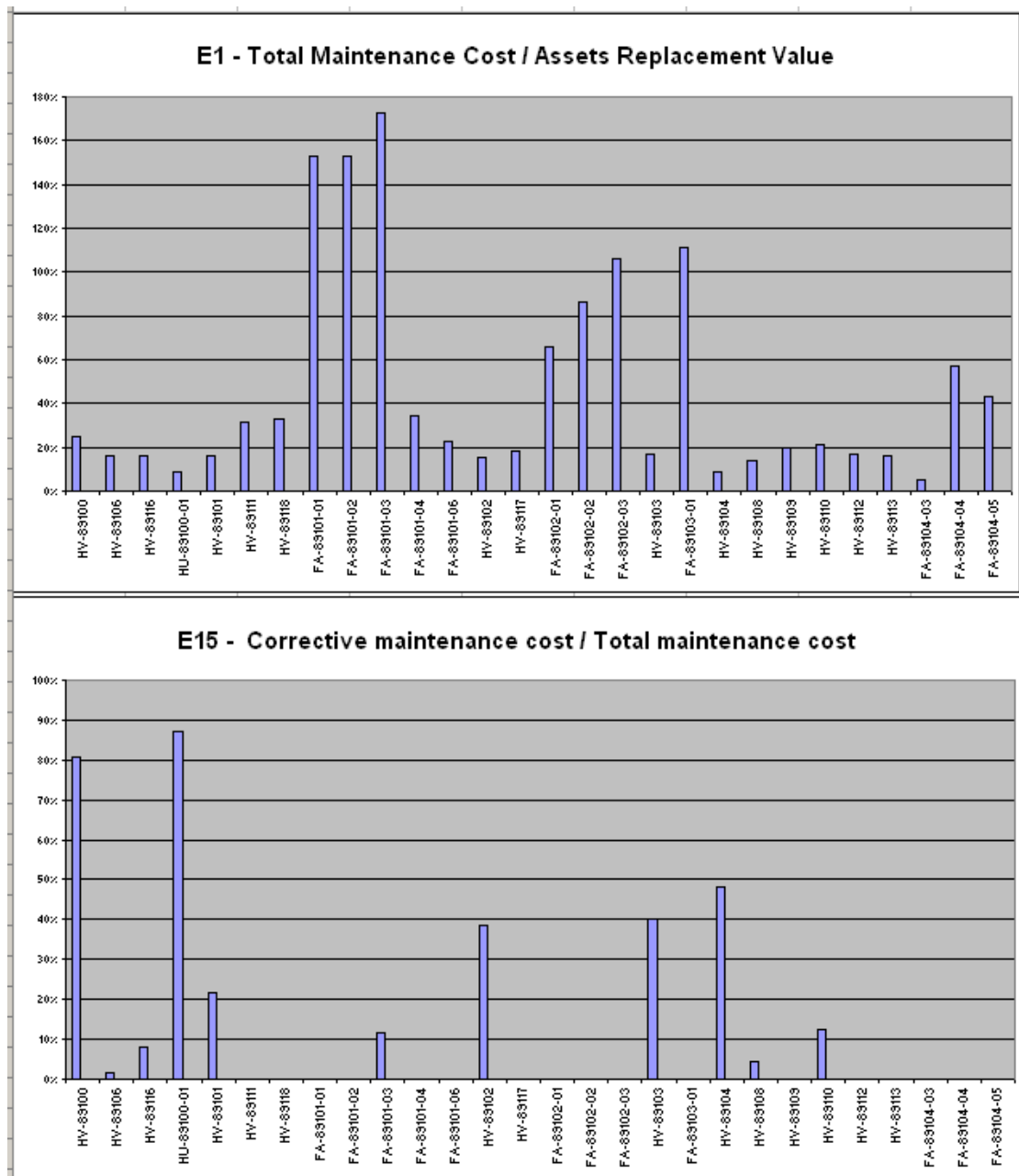


Figure 5.8 Extract of the calculated Maintenance Excellence KPI's

Following the review of the 17 KPI results the list was narrowed down to 6 maintenance KPI's that were deemed suitable for possible use in sustaining operations. All of the 6 maintenance KPI's had shown to give very useful data on the performance of the maintenance department:

1. Maintenance Work Order Quantity per equipment ID (CM, PM, including ratio)

2. Maintenance Work Order Man-hours per equipment ID (CM, PM, including ratio)
3. Maintenance Spares Cost per equipment ID (CM, PM, including ratio)
4. Equipment Availability % per equipment
5. Mean Time Between Failure per equipment ID
6. Mean Time to Repair per Equipment ID

Recommendations following the KPI pilot program

The following details the actual recommendations made by the author. They include possible solutions as a way forward to realistically implement frequent measurement of these Maintenance KPI's across process and utilities systems.

Compatibility of SAP with Maintenance Excellence KPI's

Three important areas (data gaps) were highlighted during the pilot program; solving these areas would allow the running of the KPI reports solely from the SAP MMS system.

1. Downtime information at equipment level is not being logged in the SAP system accurately enough. The KPI pilot program relied heavily on an offline downtime tracker and data was entered in manually. The revision of the Maintenance work order templates to ensure downtime information (at equipment level) is recorded; a revision of the procedure MNTC0012 and awareness rolled out with Planners and Supervisors is a possible solution.

Alternatively (for the interim) an adoption of the availability tracker (detailed in section 2) in order to start initial KPI programs in each area.

2. The introduction of Maintenance Activity Codes (for all work order types) will allow unique identification of maintenance work categories as per the maintenance excellence structure BS EN 13306:2001.

This could also be incorporated into an MNTC0012 revision for using these codes when CM work orders are being raised.

The PM existing plans in SAP would need to be updated to include the pre-dominant work activity codes that apply.

3. The use of approved satellite spares areas has a big impact on accurately using SAP to calculate the cost of maintenance materials used. The separate storage areas are not necessarily being logged correctly (in SAP) for each individual work order as they are used. This problem arises during major maintenance shutdown activities where bulk Spares are ordered through the stores and not assigned individually to the relevant work task.

With accurate information and all data gaps closed in the SAP system, an application such as „Crystal Reports’ or „SAP BI’ could be used to run the maintenance excellence KPI’s results automatically.

Implementation of Maintenance Excellence KPI’s

1. SHORT TERM – In the short term with the information provided in the pilot report and maintenance excellence KPI spreadsheet setup, it would be quite straight forward to implement KPI measurements on select systems in each area. This function could be facilitated by the area maintenance planners.
2. LONG TERM – In the long term the revision of SAP procedures and configuration of coding systems available (as detailed above), reports could be generated automatically. It would be ideal to work towards sourcing the data from the SAP system only; other options will prove time consuming and expensive.

Maintenance Excellence KPI’s pilot project conclusion

The pilot project on MS Utilities has shown that the implementation of Maintenance Excellence KPI’s as per EN15341 is definitely possible and achievable with the current systems on site.

Analysis of the final selected 6 KPI’s showed meaningful results, which can highlight reliability issues and maintenance effectiveness at an equipment level.

Implementing automatic reporting of the Maintenance Excellence KPI's

The results of the KPI pilot program were used to progress to automatic reporting via the SAP CMMS system. The following maintenance system and procedural changes were made prior to this:

- SAP Maintenance Work Order coding system was implemented in order to align with the European standards
- Equipment downtime options were expanded in SAP and related maintenance documentation provided fields for logging this information
- SAP BI (business intelligence tool) was utilised to facilitate the automatic reporting of the KPI's

The final 6 maintenance KPI's were submitted to the SAP group to setup the system to run these KPI reports automatically. The program was successful and a KPI report was generated for each area on the site for 2007, Figure 5.9 shows an extract from this report:

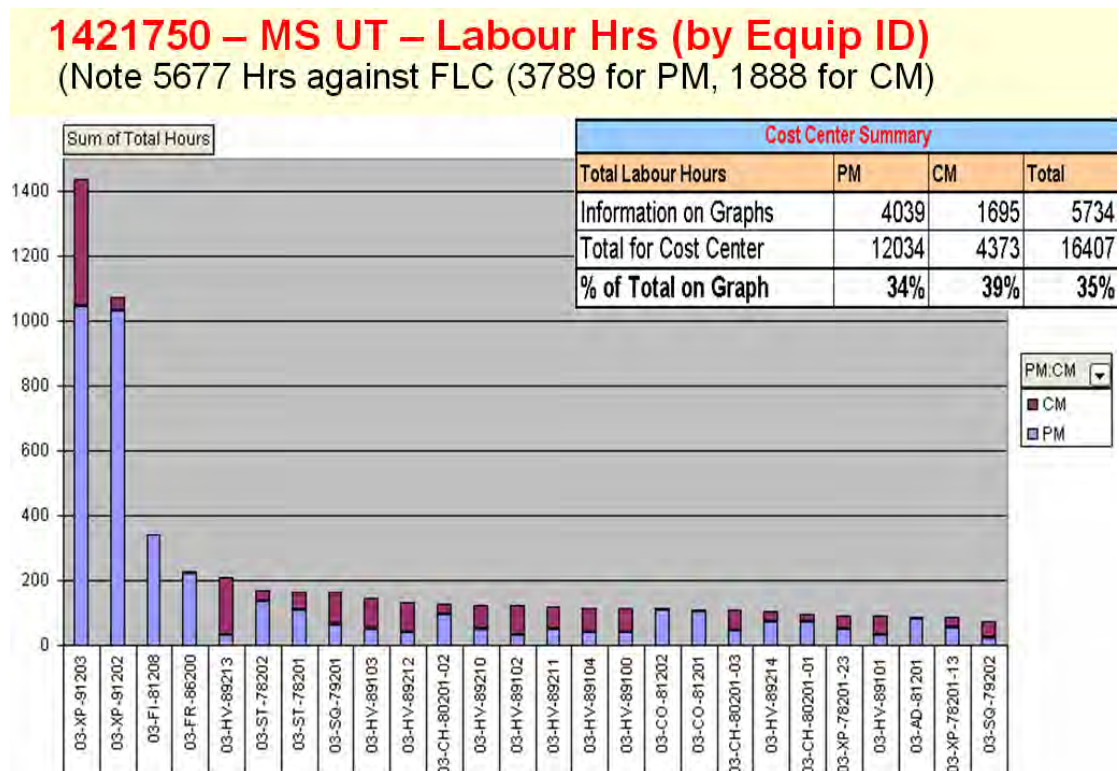


Figure 5.9 Sample of maintenance KPI results from the SAP system

In the future it is planned to run these reports per area every month and submitted to area management in order to drive maintenance improvement.

5.4 Maintenance Improvement

➤ Using Pareto style analysis for the Maintenance KPI results

The Pareto principle more commonly known as the 80:20 rule is a rule of thumb that states that 80% of the effect comes from 20% of the causes. The Pareto analysis principle can easily be applied to the maintenance KPI results, i.e. 80% of the problems stem from 20% of the equipment. With KPI results spanning every piece of equipment in the plant some performance issues are negligible compared to others. By using the KPI results to address the top 20% ranked equipment we know that we are tackling around 80% of the problems to the maintenance department. As improvements and changes are made the next set of KPI results should also change showing some other pieces of equipment making its way into the category, this is a continuous improvement process. The 2007 KPI results for the manufacturing building utilities equipment were reviewed and opportunities for improvement were identified. By using the KPI results the following example areas of improvement were identified using the KPI charts in Figure 5.10 below:

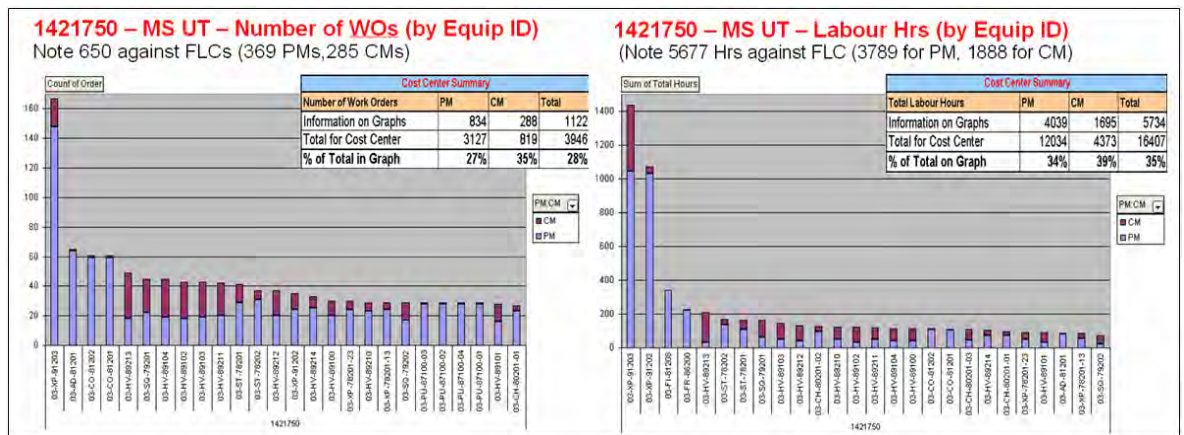


Figure 5.10 KPI results – No. of Work Orders and Labour Man-hours

- **Example 1:** In the Maintenance Work Order quantity chart, areas that were associated with a lot of paper work were investigated; given that the administration costs alone for each work order is ~ €36 it is a worthwhile exercise to try and reduce this. It was found that one the highest work order count was for air compressors (03-AD-81201 and 03-CO-81201/2). However the labour hours PM:CM ratio was found to be around 95:5 which in excess of best practices (85:15). It was found

that reason for this was because weekly PM work orders were completed on the equipment, it was determined that only 3 monthly checks were required as the equipment was very reliable.

- **Example 2:** From the equipment labour hours KPI chart there are a number of HVAC air-handling units that have a very poor PM:CM ratio, particularly 03-HV-89213 which has a PM:CM ratio of 15:85 which is significantly below best practices (85:15). This would indicate that the equipment has been attributed to a lot of problems and failures and that the PM program is not adequate. The result will drive a review of the PM program and potential equipment design improvements.

The maintenance KPI results provide the analyst with a snapshot of performance data that directs further investigation and eventual improvement when problem areas found are addressed. A similar exercise was carried out for equipment availability, spares usage, Mean Time Between Failure (MTBF) and Mean Time to Repair (MTTR).

➤ **Comparing the KPI results and benchmarking the data**

Benchmarking the KPI results

In the previous section there are a number of references to KPI data that are considered to be best practices (i.e. PM:CM ratio of 85:15). When reviewing the KPI data the analyst must have a clear understanding of what the desired target results are, or in other words at what level do the KPI results need to be at to be considered best practices. MaintenanceBenchmarking.com which is an online resource for reliability engineers have published industry best practices benchmarking data for a wide range of maintenance excellence KPI's, this benchmarking data is widely used and the results were sourced from industry, members experience and reliability/maintenance literature. The following benchmarking data was extracted and this data should be used as a maintenance excellence target for the KPI results:

Best Practices Maintenance Benchmarks	
Category	Benchmark
Planned Maintenance:	
Preventative Maintenance/Total Maintenance (PM:CM ratio)	> 85%
Planned & Scheduled Maintenance as a % of hours worked	~85-95%
Unplanned Down Time	~0%
Reactive Maintenance	< 15%
Run to Fail (Emergency + Non-Emergency)	< 10%
Yearly Spares Inventory Turns:	
Turns Ratio of Spare Parts	> 2-3
Yearly Safety Performance:	
OSHA Recordable Injuries per 200,000 labor hours	< 2
Housekeeping	~96%
Monthly Maintenance Strategies:	
Preventive Maintenance: Total Hours PM/Total Maintenance Hours Available	~20%
Predictive Maintenance: Total Hours PdM/Total Maintenance Hours Available	~50%
Planned Reactive Maintenance: Total Hours PRM/Total Maintenance Hours Available	~20%
Reactive Emergency: Total REM/Total Maintenance Hours Available	~2%
Reactive Non-Emergency: Total RNEM/Total Maintenance Hours Available	~8%
Plant Availability:	
Available Time/ Maximum Available Time	> 97%

Figure 5.11 Maintenance Excellence KPI benchmarks

Courtesy: maintenancebenchmarking.com

Comparing the KPI results

When analysing the KPI results it is often useful to look at results from different areas for similar pieces of equipment, if there is a significant difference then the best of the two areas can be reviewed to see what is different (i.e. design, preventative maintenance programs, operating context etc.). By approaching the KPI analysis in this way different areas can learn of each other and work to improve together. The KPI results produced enabled cross building comparison of similar equipment and are contributing towards synergy of maintenance programs across the site.

5.5 Maintenance Auditing and Benchmarking

Maintenance Excellence Auditing Overview

As mentioned in the introduction auditing of maintenance is carried out in an attempt to quantify the actual status of the maintenance department in number of important categories and to identify opportunities for improvement. The International

Maintenance Roundtable (IMR Australian Maintenance Excellence Awards) provide a publicly available auditing tool which covers all the important areas of the maintenance department. The results are then plotted on the PAS-55 Web chart, example of web chart shown in Figure 5.12 below:

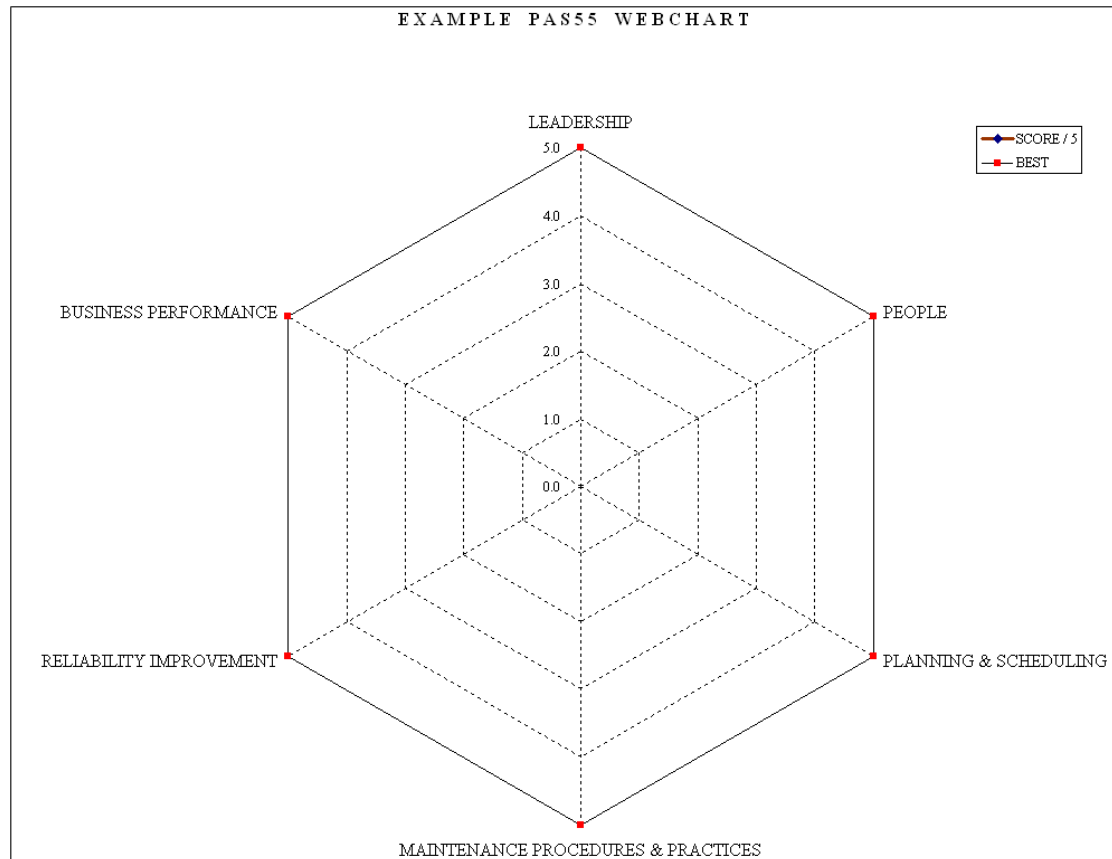


Figure 5.12 Example audit results using PASS-55 Web Chart

As can be seen in the web chart above in Figure 5.12 the results for each category are plotted 0 to 5, 5 being the best possible score, results in the region of 4.5 to 5 are considered to be in line with maintenance best practices or maintenance excellence. The IMR audit assessment is completed under the following maintenance excellence categories:

- **Leadership** (weighting 16% of total)
- **People** (weighting 20% of total)
- **Planning & Scheduling** (weighting 13% of total)
- **Maintenance Procedures & Practices** (weighting 18% of total)
- **Reliability Improvement** (weighting 20% of total)
- **Business Performance** (weighting 13% of total)

The overall % score of the weighted results should be 90% or above is considered to be within the best practices category overall.

The audit assessment contains a series of questions to be answered and scored under the above categories. Each category is weighted in terms of importance to the overall maintenance function, the scoring guidelines for each question is as follows:

- 1 = No system in place
- 2 = System planning beginning
- 3 = System planning complete
- 4 = System implemented
- 5 = System implemented and mature

The results of the auditing process will identify areas that are performing well and also areas that require improvement, following review of the audit results an action plan register should be setup to address the areas that need improvement.

Conducting the Audit

In May'08 the author conducted a maintenance excellence audit on the manufacturing building utilities maintenance department, the following documents the process and results obtained.

➤ **Audit categories, questions and results**

See **Appendix 1** – Maintenance Excellence Audit on MS Utilities

Individual category results:

The individual category results from the audit are as follows (Fig 5.13):

RESULTS SUMMARY TABLE				
		SCORE %	SCORE / 5	BEST
LEADERSHIP	1	92.00%	4.6	5
PEOPLE	2	100.00%	5.0	5
PLANNING & SCHEDULING	3	84.44%	4.2	5
MAINTENANCE PROCEDURES & PRACTICES	4	94.00%	4.7	5
RELIABILITY IMPROVEMENT	5	84.00%	4.2	5
BUSINESS PERFORMANCE	6	88.00%	4.4	5

Figure 5.13 Results Summary Table Chart

The individual category results shows that 3 of the 6 areas are in-line with maintenance best practices (4.5 or above), the category „People’ scored a maximum of 5. All other areas are greater than 4 meaning that the best practices systems have been implemented but may not be matured yet. The above results table was then plotted on the PAS-55 Web plot shown in Figure 5.14 below:

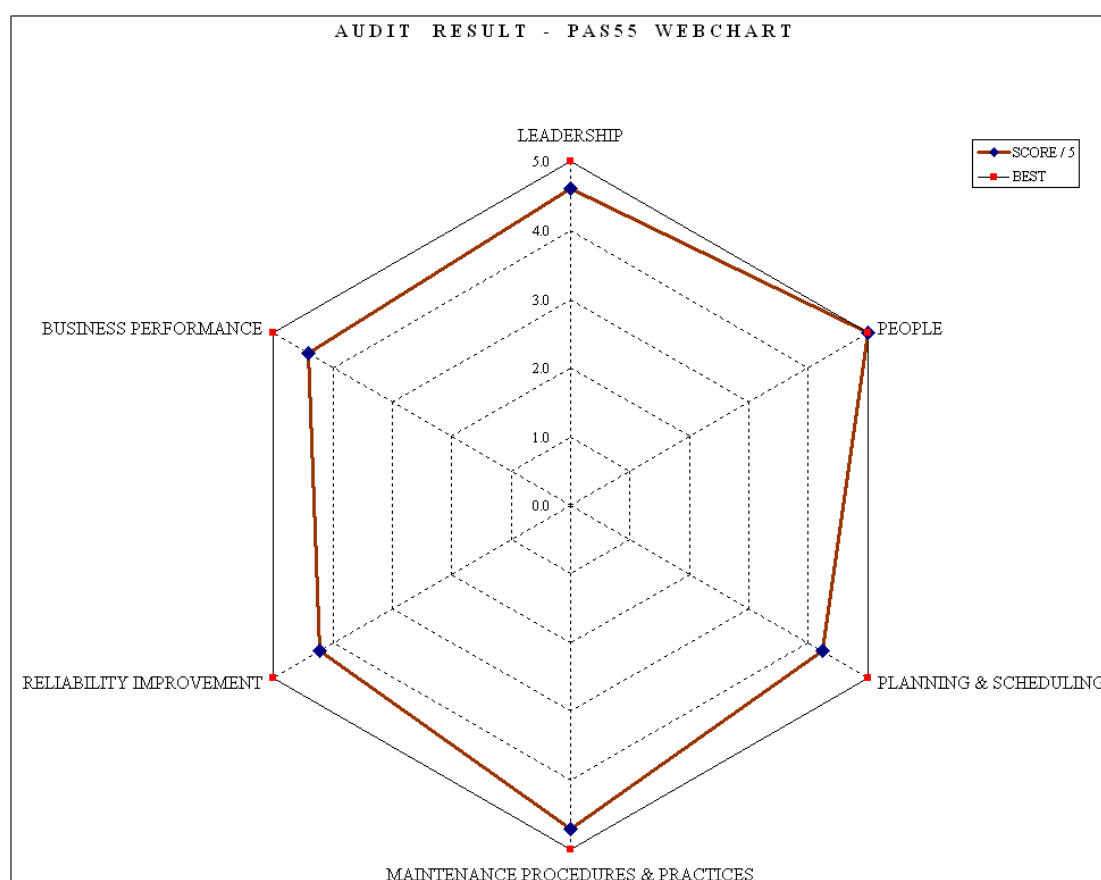


Figure 5.14 MS Utility Audit Results 2008 - PASS-55 Web Chart

Overall audit result (weighted):

The IMR auditing process has weighted all the relevant maintenance categories as some are more critical to the maintenance function than others. The overall weighted results are detailed in Figure 5.15 below:

<u>OVERALL WEIGHTED RESULTS</u>		
		WEIGHTED % SCORE
LEADERSHIP	1	14.72%
PEOPLE	2	20.00%
PLANNING & SCHEDULING	3	10.98%
MAINTENANCE PROCEDURES & PRACTICES	4	16.92%
RELIABILITY IMPROVEMENT	5	16.80%
BUSINESS PERFORMANCE	6	11.44%
	TOTAL =	90.86%

Figure 5.15 MS Utilities – Overall weighted results

The overall % score of the weighted results is 90.86% which is just within the best maintenance practices region (90% or above is considered to be within the best practices). This result also shows that there is still room for improvement, nearly 10%.

Potential improvements identified from the audit process:

The audit process is a worthless exercise if the areas of improvement identified are not acted on. Some results of the audit achieved 4 or above and just require the same momentum to be maintained in order to become an integral part of the maintenance function and mature. Other areas identified require some work:

Planning & scheduling:

- Continue with building in maintenance awareness with manufacturing groups, agreed maintenance downtime schedules needs to be endorsed by manufacturing and adhered to.
- The process of preparing materials, parts and support needs to be clearly defined, also the responsibility of this function needs to be clearly defined

- Manufacturing reporting system has been setup, needs to be further expanded to highlight agreed equipment downtime for maintenance not being adhered to (i.e. downtime windows delayed or cancelled at short notice).

Reliability Improvement

- Long term maintenance and operational strategy is needed to consider the operating lifetime of equipment.

The audit carried out was a worthwhile activity and demonstrated the actual status of the utilities maintenance department, it showed that the majority of maintenance practices and new initiatives were worthwhile and need to be continued. Areas of improvements were also identified, some of which were not immediately apparent.

5.6 Summary and Conclusions

In order to move towards a consistent industry, where performance measurements are coherent, maintenance standardization is important. The EN13306 „Maintenance Terminology’ standard is important as it provides guidance on correct maintenance classification. The standard in the future will help the benchmarking process across industry. This chapter has highlighted that aligning this standard with your maintenance systems is an important pre-requisite to implementing accurate maintenance key performance indicators.

It is difficult to manage something that is not measured, this chapter has laid out a practical process for evaluating and selecting maintenance excellence KPI’s that suit the business needs. The KPI results analysis using the Pareto style approach has been shown to be very useful in identifying important areas of improvement. The KPI results should be regularly updated and reviewed in order to continuously improve.

Maintenance auditing and benchmarking allows the maintenance function to identify where they are in relation to best practices. As mentioned in this chapter it is

important that areas of improvement identified as a result of the audit need to be acted on to gain full benefit from the process. For the audit carried out on MS Utilities there were many areas that were found to be in-line with best practices. The overall result although within the maintenance excellence region still showed nearly 10% potential improvements.

REFERENCES

International Standards

PAS 55-1 (Apr 2004) „*Publicly Available Specification for Asset Management*’

BS EN 13306:2001 (Mar 2001) „*Maintenance Terminology*’

BS EN 15341:2007 (Apr 2007) „*Maintenance Key performance Indicators*’

Internet References:

Industrial Maintenance Roundtable (Australian Maintenance Excellence Awards) -
<http://www.sirfrt.com.au>

Best Practices Maintenance Benchmarking -
<http://www.maintenancebenchmarking.com>

CHAPTER 6 – THESIS SUMMARY AND CONCLUSIONS

6.1 Introduction

This thesis has been structured around the 5 main areas of maintenance excellence; it has documented all the important functions of the maintenance department that contributes towards maintenance excellence. Demonstrating maintenance excellence is a big achievement however demonstrating it on pharmaceutical clean utility systems with strict regulatory controls is a major challenge. This thesis has explored the regulatory aspects of the business in-dept and presented a number of practical approaches to building in a world-class maintenance program whilst still ensuring the utmost of safety and quality to the patient.

The projects aim was to research and document what is required and how best to implement a world class maintenance excellence program. The overall aim for this project is to serve as a practical guide for implementing best maintenance practices in a heavily regulated industry such as pharmaceutical production.

During the project this project key areas were benchmarked against industry best practices. These benchmarks were researched from established best practices data available from well established reliability organisations.

This chapter will highlight the important results, findings, cost savings and conclusions from this thesis and to also make recommendations on possible future applications and areas of further research.

6.2 Key areas of research and findings

The evolution of the maintenance department

As shown in the literature review the area of maintenance has dramatically changed over the past 50 years, the maintenance strategy has changed from „fix it when it's broke' to a strategy aimed at preventing the failures that matter and increasing equipment reliability. In today's maintenance environment „prevention' is truly better than „cure' and this thesis has shown the economical benefits of this to the business. The relatively new area of condition based monitoring (CBM) is making its way into industry in a big way, the author envisages that the future of maintenance will involve the use of more and more condition based monitoring techniques in order to make maintenance decisions.

Reliability centred maintenance which has been prevalent in the aircraft industry since the 1960's has now found many uses in designing the maintenance programs for utility systems. With the majority of factories now running 24/7 production schedules the focus is to have systems with high reliability, achieve maximum up-time and the ability to carry out maintenance with little or no interruption to the end user and at minimal cost.

The emergence of Computerised Maintenance Management Systems (CMMS) and effective planning has enabled the maintenance department to generate and schedule the preventative maintenance program with ease and effectively allocate maintenance resources. With a large array of CMMS systems available on the market careful consideration should be taken in order to choose one that suits the needs of the maintenance department. The role of the maintenance planner should be clearly defined and dedicated to the core planning function, if planning breaks down then so too does the maintenance team.

Industry are now working together in order to standardise maintenance concepts and to create a common approach to performance measurement, companies can now measure their status against best practice and clearly identify the gaps needed to get there. With the introduction of a number of European maintenance standards and PAS-55 „Publicly Available Specification for Asset Management' the maintenance community now have clear guidance on best practices, prior to this there were no real standards available that specifically addressed maintenance.

To stay in line with a true maintenance excellence culture, maintenance need to „involved from the start'. The maintenance function are starting to get early consideration at the equipment design stage, commissioning and eventual handover; this thesis has shown the significant savings and operational benefits that can be obtained by implementing this relatively simple concept.

Maintenance has now become a subject and profession in its own right and companies are starting to realise the benefits of best maintenance practices to the overall business.

Maintenance links with quality management

Current maintenance techniques are closely aligned with quality management with areas such as continuous improvement, process improvement; reliability centred

maintenance, performance measurement and defined management strategies being employed. In Chapter 4 which details the „WFI brown fibres’ investigation the maintenance teams turned to the quality tool root cause analysis using the „cause and effect’ method which has been around since the Japanese quality revolution in the 1960’s, its use was critical in identifying the actual root cause. This thesis has shown that Maintenance excellence could not exist or be successful without implementing some of the widely known quality techniques.

Maintenance in a regulatory environment

When striving towards maintenance excellence people must not forget that maintenance is regulatory requirement for pharmaceutical clean utility systems feeding manufacturing areas. This must always be kept in mind, an improvement to the maintenance program that might make sense based on cost and plant efficiency may not always be compliant and in some case may bring about a hidden risk to the qualified processes and product. This thesis has set out the requirements of the maintenance programs on clean utilities systems in the pharmaceutical industry and outlined some of the strict regulatory maintenance requirements for clean utility systems. A practical example from Chapter 3 showed that some areas of regulation (such as soft parts changeout) are still open to interpretation; this leaves opportunities to improve maintenance content with the correct supporting rationale. Although it is time consuming to implement maintenance change the benefits are clear to be seen.

Maintenance Outsourcing

Research during this thesis found that 30 percent of World Class manufacturing organisations will out-source the maintenance organisation, particularly in the area of utility systems. The outsourcing of maintenance is a relatively new trend with as little as 5 percent outsourcing in the early 1990’s. The area of maintenance outsourcing has been identified as a major part of modern industry. The main reason for manufacturing companies to outsource maintenance is cost reduction and to enable them to concentrate on core activities which is making product. However this is only the baseline of possibilities, so much more can be achieved by approaching outsourcing correctly such as high degree of ownership by the outsourcing partner, continuous improvement and a Win-Win culture which promotes open/honest communication.

The future for outsourcing is moving towards full ownership of utility systems through long-term fixed contracts which have shown clear benefits for both parties involved.

6.3 Cost Savings Overview

This Thesis presented a number of key savings made through implementation of maintenance best practices. Some are difficult to quantify especially when it relates to impact to production, depending on the production stage at the time, costs incurred could range from negligible to millions of Euro. This section will layout the economical benefits of implementing maintenance best practices; in terms of actual quantifiable savings.

Quantifiable cost savings

All of the cost savings highlighted in this section were through implementation of maintenance best practices; the author has led and managed the teams involved in the implementation of the associated projects:

- **Operations and Maintenance Synergy**

This synergy project commenced in September 2007 and is targeted for completion in June 2008. The second phase of this project which will commence in June 2008 is to target the synergy of maintenance content and to remove equipment single points of failure and increase equipment reliability. The projects first phase focused on two manufacturing buildings with similar utility systems and operating procedures, the objective of the project was to merge all the operational procedures and to allow the maintenance operations teams to merge as one utilities team supporting the operation and maintenance of both buildings. The following identifies an overview the key cost saving areas made:

- Total savings for Engineering Work Instructions and Standard Operating Procedures synergisation = **€135k / year**
- Full integration of shift teams for MS & DS allowing reduction of 4 shift staff through natural employee turnover = **€570K / Year**

Total estimated yearly savings = **€705,000**

- **Embedding the maintenance function in the Suite 3 project**

Suite 3 is new syringe fill manufacturing building which was constructed at the Wyeth site in 2006/7. The author led a team of engineers who were embedded in the project in order to influence the design, installation and commissioning of the new utility systems from a maintenance perspective. The following cost savings were made:

- Suite 3 Maintenance spares project, estimated savings ~ **€200K**
- Suite 3 Access platforms for maintenance: Approx annual saving on scaffolding required per year for operations = **€59,985 / Year**

Total estimated savings = **€259,985**

- **Soft parts change out improvement project**

This project involved revising the maintenance strategy for soft part on high purity water and clean steam systems in the manufacturing suites building. The change required collecting robust data to move out the frequency of full soft parts change out and only targeting frequent maintenance on areas of the system that were likely to degrade over short time periods.

Total estimated yearly savings = **€87,500**

- **Ultrasonic testing of steam traps**

A site wide ultrasonic steam trap inspection carried out in 2006 identified major savings in terms of steam and energy losses:

Total estimated savings = **€65,639**

- **Total cost savings made**

The total quantifiable savings made through implementing maintenance best practices projects:

=

€1.12 million

6.4 Results Summary

This Thesis covered all the key functions of the maintenance department that need to be implemented in order to contribute towards maintenance excellence. In the Chapter 6 „Maintenance Performance Measurement’ the MS Utilities maintenance department was audited. The results of the maintenance audit were then benchmarked against what are considered to be maintenance best practices. The audit assessment was completed under the following maintenance excellence categories:

- **Leadership** (weighting 16% of total)
- **People** (weighting 20% of total)
- **Planning & Scheduling** (weighting 13% of total)
- **Maintenance Procedures & Practices** (weighting 18% of total)
- **Reliability Improvement** (weighting 20% of total)
- **Business Performance** (weighting 13% of total)

Individual category results:

The individual category results from the audit are as follows (Fig 6.1):

RESULTS SUMMARY TABLE				
		SCORE %	SCORE / 5	BEST
LEADERSHIP	1	92.00%	4.6	5
PEOPLE	2	100.00%	5.0	5
PLANNING & SCHEDULING	3	84.44%	4.2	5
MAINTENANCE PROCEDURES & PRACTICES	4	94.00%	4.7	5
RELIABILITY IMPROVEMENT	5	84.00%	4.2	5
BUSINESS PERFORMANCE	6	88.00%	4.4	5

Figure 6.1 Results Summary Table Chart

The individual category results shows that 3 of the 6 areas are in-line with maintenance best practices (4.5 or above), the category „People’ scored a maximum of 5. All other areas are greater than 4 meaning that the best practices systems have been implemented but may not be matured yet. The above results table was then plotted on the PAS-55 Web plot shown in Figure 6.2 below:

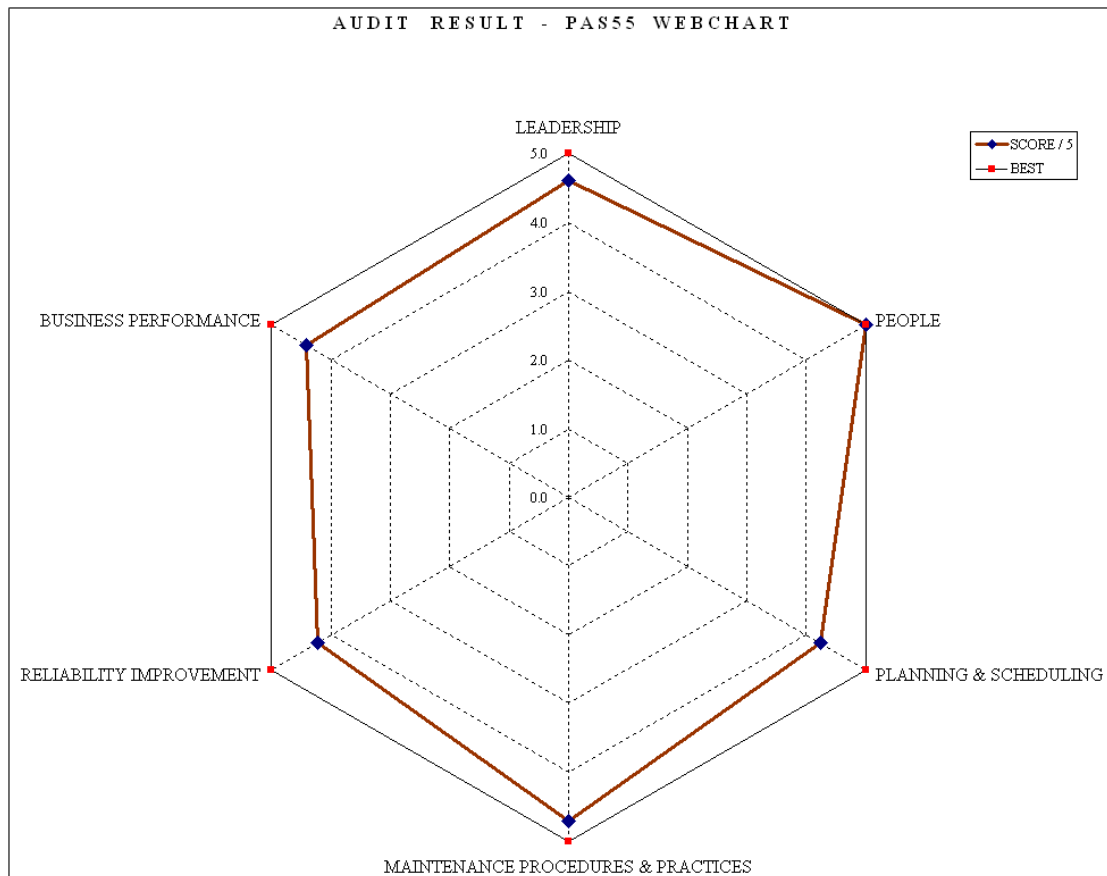


Figure 6.2 MS Utility Audit Results 2008 - PASS-55 Web Chart

Overall audit result (weighted):

The auditing process has weighted all the relevant maintenance categories as some are more critical to the maintenance function than others. The overall weighted results are detailed in Figure 6.3 below:

<u>OVERALL WEIGHTED RESULTS</u>		
		WEIGHTED % SCORE
LEADERSHIP	1	14.72%
PEOPLE	2	20.00%
PLANNING & SCHEDULING	3	10.98%
MAINTENANCE PROCEDURES & PRACTICES	4	16.92%
RELIABILITY IMPROVEMENT	5	16.80%
BUSINESS PERFORMANCE	6	11.44%
	TOTAL =	90.86%

Figure 6.3 MS Utilities – Overall weighted results

The overall % score of the weighted results is 90.86% which is just within the best maintenance practices region (90% or above is considered to be within the best practices). This result also shows that there is still room for improvement, nearly 10%. The areas identified for improvement were as follows:

Planning & scheduling:

- Continue with building in maintenance awareness with manufacturing groups, agreed maintenance downtime schedules needs to be endorsed by manufacturing and adhered to.
- The process of preparing materials, parts and support needs to be clearly defined, also the responsibility of this function needs to be clearly defined
- Manufacturing reporting system has been setup, needs to be further expanded to highlight agreed equipment downtime for maintenance not being adhered to (i.e. downtime windows delayed or cancelled at short notice).

Reliability Improvement

- Long term maintenance and operational strategy is needed to consider the operating lifetime of equipment.

The above areas identified for improvement were communicated to the maintenance management teams at Wyeth and are currently being addressed.

6.5 Future Thesis Applications and Recommendations

Future Thesis Applications and Recommendations

This thesis aimed to serve as practical A-Z guide to implementing maintenance excellence; the author believes that this has been achieved. The thesis may have commercial applications in the future for industry by being able to reference all the main areas of maintenance excellence and to work towards implementing best maintenance practices. The method of maintenance excellence auditing has been clearly laid out and allows any industry to be audited in order to identify its status in relation to best practices. The results and recommendations of the audit carried out on

MS Utilities have identified areas that are going well and need to be continued and also the areas where potential improvements can be made.

When a company truly believes that they have reached the maintenance excellence milestone they should seek other companies who are also achieving maintenance excellence. The two companies should then form a partnership to work together by benchmarking each other, there will always be something to learn of each other and both can work to improve together.

Future areas of research

In the larger picture of the organisation, maintenance excellence is only a small part. In order to compete as a world-class organisation then every part of the business needs to adopt best practices. As an extension of this thesis future research could be carried out on every function of a pharmaceutical company organisation to identify the best working practices in order to achieve world-class status. Unlike the high-tech sector such as computers & electronics, the pharmaceutical business has been the slowest to revolutionise the efficiency of their business, this is mostly due to high profit margins along with little or no competition due to drug patent laws. However, in the past decade or more, with an increasing amount of company's now manufacturing generic versions of drugs, competition is fierce. The industry has been forced to start looking at building efficiency into their business at all levels. With so many different functions within a pharmaceutical company such as marketing, finance, HR, development and operations this research area is considerable. The regulatory aspects to consider during research would also be significant. There are pharmaceutical companies out there who have been proactive, seek radical change and have improved as a result. The use of tools like business process re-engineering (BPR) could also be used to look at the organisational processes to try re-shaping the way things are done.

6.6 Thesis Conclusions

This thesis has shown that Maintenance excellence has a direct influence on business performance and top management should consider the quest towards maintenance

excellence a worthwhile exercise. Maintenance excellence needs to be supported by top management in order for it to succeed.

From the results of the maintenance excellence audit carried out on MS Utilities there were many areas that were found to be in-line with best practices, these need to be continued. The overall result although within the maintenance excellence region still showed nearly 10% potential improvements which need to be addressed.

Overall, this thesis has laid out the critical maintenance processes that need to be implemented in order to bring a green-field factory site to a fully operational facility that is in line with maintenance excellence standards. This thesis has the ability to serve as an A-Z guide for implementing maintenance best practices; it can be used for any industry but most importantly it accounts for a highly regulated industry such as the pharmaceutical sector.

MS Utilities Maintenance Excellence Audit

1. LEADERSHIP (16% of total)

The intent of this Category is to cover the role of leadership in the development of the maintaining function within the organisation at a corporate and enterprise level.

Questions	Score (1-5)	Comments
a. Planned maintenance is part of our written business philosophy, mission or aim.	5	Business corporate and site engineering policies and procedure define preventative maintenance programs as part of our operating philosophy
b. We have written goals, objectives and measures that document continued improvement of the maintenance function's contribution to the business.	4	Sitewide Maintenance Excellence team have publish the sitewide mainteance strategy, improvement plans and goals in line with the business 5 year model. This process however is not yet mature
c. There is a leadership network that provides guidance and direction for continual functional improvement of the maintenance function.	4	The sitewide maintenance excellence team have fulfilled this function, issuing of monthly maintenance KPI reports is starting to drive improvement. This process however is still not mature
d. Reports measuring planned maintenance performance, i.e., key parameters VS goal are periodically issued.	5	Planned maintenance completion Vs Target are issued weekly and monthly, success of maintenance program is also related to equipment availability
e. Company reference documents, such as "Maintenance Procedures" and "Engineering Standards" are routinely adhered to.	5	Maintenance and Engineering procedures & standards are in place and are strictly adhered to

Category Total	23
Category, % Max. Score	92.00%
Category Total, Weighted	14.72%

2. PEOPLE (20% of total)

The intent of this category is cover the extent to which the organisation provides people at all levels in the enterprise with the appropriate skills, and engenders the commitment required to achieve the maintenance goals and objectives.

Questions	Score (1-5)	Comments
a. A long-range strategic plan for maintenance is in place that defines what the maintenance job will look like, what skills will be necessary and how these skills will be acquired.	5	Each maintenance technician has a defined training curricula identifying all the requirements for his/her role (mech, elec, auto), the completion progress is regulary monitored. The curricula content is also reguarly reviewed against current requirements
b. A job analysis that defines required skills has been conducted and is updated periodically.	5	Each maintenance technician have clearly defined job descriptions, this is communicated to the staff and this is reviewed periodically
c. Resource persons available to answer questions during the training process and available to assist in developing troubleshooting skills with skills demonstrations.	5	Equipment, maintenance and troubleshooting training is carried out by identified system experts
d. A formal program to refresh the skills of trades people and to introduce new skills is in place.	5	All maintenance technicians have opportunities to refresh and expand skills, equipment specific vendor training plans are exectuted each year, the maintenance technicinas have a direct input into this
e. A formal cross-training plan is in place to develop versatility in the workforce.	5	All equipment training is carried out through cross training from other staff identified as being experienced and competant
f. A means of measuring results, such as task-certification programs and detailed training records to track the effectiveness of the program are in place.	5	All equipment training requires on-the-job competency assessments to ensure that the staff are proficient
g. A means to train maintenance supervisory personnel in maintenance best practices and systems.	5	Maintenance supervisors have a number of maintenance & management skills training available to them which is targeted for completion each year

Category Total	35
Category, % Max. Score	100.00%
Category Total, Weighted	20.00%

3. PLANNING AND SCHEDULING (13% of total)

The intent of this category is to cover how the enterprise develops, implements, controls, measures and improves its planning and scheduling of its maintenance work to achieve the corporate objectives.

Questions	Score (1-5)	Comments
a. Production, maintenance and technical strongly support the concept of planned and scheduled maintenance and, as partners, are committed to its success.	3	Good understanding and focus on preventative maintenance within the department, however the manufacturing teams do not always embrace the maintenance concept and obtaining downtime for maintenance can be difficult. Communication programs have been setup to build maintenance awareness in with the production teams. This process is in the early stages, a 2 year shutdown plan is being developed and in review with the manufacturing groups.
b. A team dedicated to the planning, scheduling and coordinating of routine maintenance work is in place.	5	Dedicated maintenance planning team
c. Preventive and predictive maintenance work is an integral part of this P&S effort.	5	Maintenance planner plans and schedules all maintenance activities, reviews maintenance content and seeks feedback. Preventative and predictive maintenance programs are in place
d. Routinely, the right materials and resources are brought together at the right place and the right time to work on properly prepared equipment.	3	Preparation of spares, tools and support are completed in a timely mannor most of the time. The clear responsibility of this function is not yet clear and is currently a mix of maintenance technicians, supervisors and planner. Best practices indicate that this should be the role of the planner/scheduler.
e. Repairs are promptly made when indicated by trend analysis.	5	Equipment performance is monitred 24/7 and frequent inspection programs are in place, follow-up is recored and tracked to completion
f. Inspection records are in place and are carried out at deifned intervals	5	Full Preventative Maintenance program is in place, documented and loaded on to CMMS
g. Systems are in place which ensure action is taken when inspections and repairs do not occur as scheduled.	3	MCRS (Management Control and reporting system) has been rolled out by Wyeth to improve communication between all groups, planned against scheduled work is tracked, downtime not obtained when agreed with production is beginning to be tracked
h. Systems are in place to track all maintenance activities and equipment downtime	5	CMMS tracks all maintenance activities, equipment downtime is tracked and reported out on
i. Records for inspections and repairs meet requirements of local codes and corporate standards (pressure vessels, boilers, expansion joints, etc).	4	Statutory register has been setup and regularity safety inspections are carried out at defined intervals. This process is not yet mature.

Category Total	38
Category, % Max. Score	84.44%
Category Total, Weighted	10.98%

4. MAINTENANCE PROCESSES AND PRACTICES (18% of total)

The intent of this category is to cover how the enterprise establishes, implements, monitors, analyses and improves its preventive, predictive and reactive maintenance systems to meet the goals of the organisation.

Questions	Score (1-5)	Comments
a. A formal, periodic equipment inspection system is in place that is consistent with manufacturers' specifications and in compliance with government regulations.	5	Full preventative maintenance program in place in line with vendor recommendations, in-house experience and statutory requirements
b. Predictive maintenance inspection routes have been established and inspections are made on schedule.	5	Full predictive maintenance program (vibration, oil, ultra-sonic, thermal imaging) are in place
c. Inspections are always carried out exactly as specified and at the specified inspection frequency.	4	Maintenance task list detail step by step instruction, this is signed by the maint tech and reviewed by the supervisor. Due to production constraints some maintenance tasks may need to be deferred
d. Discrepancies are always corrected before the process/equipment is returned to operation.	4	Where production window time constraints are not a factor all faults are generally rectified within the downtime window
e. A lubrication program is in place to ensure equipment is lubricated routinely and adequately with the proper lubricant.	5	Preventative maintenance program defines greasing schedules for equipment, oil analysis program in place to determine changeout frequencies, critical air handling units feeding production have automatic greasers installed which help prolong bearing life
f. Critical equipment (based on impact on safety, production, quality, environment, cost etc) have been identified and listed for the purpose of applying predictive maintenance techniques.	5	All critical equipment are subject to a number of predictive monitoring techniques
g. Alert and danger limits for parameters have been established and published.	5	Plant rounds and reading specify required operational limits, predictive maintenance program has clearly defined action and alert limits which are communicated to each maintenance department
h. Records are formalised and trend analysis is routinely used to monitor equipment condition.	4	Periodic reviews of maintenance history is carried out, this process has been further revised to incorporate equipment performance measurements. This system is not yet mature.
i. A system is in place to ensure that inspections occur.	5	Maintenance completion progress is tracked (planned Vs Scheduled), all activities are documented by the maintenance technicians and approved by the maintenance supervisor
j. Equipment specifications are maintained and are easily retrieved when needed.	5	Statutory register has been setup and regularity safety inspections are carried out at defined intervals. This process is not yet mature.

Category Total	47
Category, % Max. Score	94.00%
Category Total, Weighted	16.92%

5. RELIABILITY IMPROVEMENT (20% of total)

The intent of this category is to cover how the enterprise establishes and maintains a focus on the needs of the business in particular on the reliability improvement process using problem solving techniques, increasing uptime, improving yields and process reliability and assuring quality.

Questions	Score (1-5)	Comments
a. Records are maintained and periodically audited to ensure preventive maintenance is performed on each piece of equipment as intended.	4	Periodic reviews of maintenance history is carried out, this process has been further revised to incorporate equipment performance measurements. This system is not yet mature.
b. A long-range program is in place that enhances equipment reliability through: Initial design to enhance maintainability through life cycle cost analyses and proper operation of equipment during its normal life span.	3	Maintenance teams are now embedded in all new utility installation to ensure desing for operation and maintenance. Grangecastle is a relatively new plant and there are no clear steps in place that considers the life time constraints of the equipment or life cylce costs
c. A formal system exists to attack equipment problems that includes: Identification and qualification of the problem and definition of the underlying root cause, long-term corrective actions and effective tracking of corrective action to ensure success.	5	Full investigation (TIR) process is in place that identifies equipment failure roots causes and corrective/preventative actions. All corrective actions are tracked to closure.
d. Measures that emphasise uptime are identified, collected, tracked and reported throughout the organisation.	5	Equipment availability is tracked, monitored and communicated
e. Equipment performance and maintenance history are stored and used to trend reliability, repair frequencies, failure modes, mean time to failure, etc.	4	Maintenance excellence KPI program in place to measure performance of equipment under the listed areas. Process is not yet mature.

Category Total	21
Category, % Max. Score	84.00%
Category Total, Weighted	16.80%

6. BUSINESS PERFORMANCE (13% of total)

The intent of this category is to cover how the enterprise establishes and maintains a focus on the needs of the business in particular on the reliability improvement process using problem solving techniques, increasing uptime, improving yields and proces

Questions	Score (1-5)	Comments
a. Goals have been set and performance is measured and reported throughout the organisation; corrective action is aimed at continued improvement.	4	SLA agreement with the utility service provider is in place, performance metrics are measured and published each month and quarter. Corrective action to improve are put in palce at a local level. Maintenance KPI reports are issued allowing area management to identify potential improvements. This system is not yet mature.
b. Performance reports exist that show progress toward a long-range strategic plan for maintenance.	4	SLA agreement with the utility service provider is in place, performance metrics are measured and published each month and quarter. Corrective action to improve are put in palce at a local level. Maintenance KPI reports are issued allowing area management to identify potential improvements. Long term targets and benchmarks have not yet been published. This system is not yet mature.
c. Where maintenance of a facility impacts quality, it is identified, measured and reported: e.g., out of tolerance or variable tolerance product associated with machine breakdown or out of tolerance equipment.	5	All equipment failures and maintenance that impacts quality is reported and investigated fully.
d. Where maintenance of a facility impacts the amount of product produced, it is identified, measured and reported, i.e., rate reduction or scrap associated with machine breakdown or out of tolerance equipment.	5	All equipment failures and maintenance that impacts quality is reported and investigated fully. Clean utility systems are desinged to operate within specified parameter, deviations are investigated and impact to production and product is also assessed.
e. Where maintenance of a facility impacts bottom line cost, it is identified, measured and reported, i.e., cost reductions through improved maintenance procedures/programs.	4	Maintenance costs are tracked and budgeted, ,aintenance programs are targeted for improvmeent along with equipment reliability improvement programs. This process is not yet mature.

Category Total	22
Category, % Max. Score	88.00%
Category Total, Weighted	11.44%

RESULTS SUMMARY TABLE

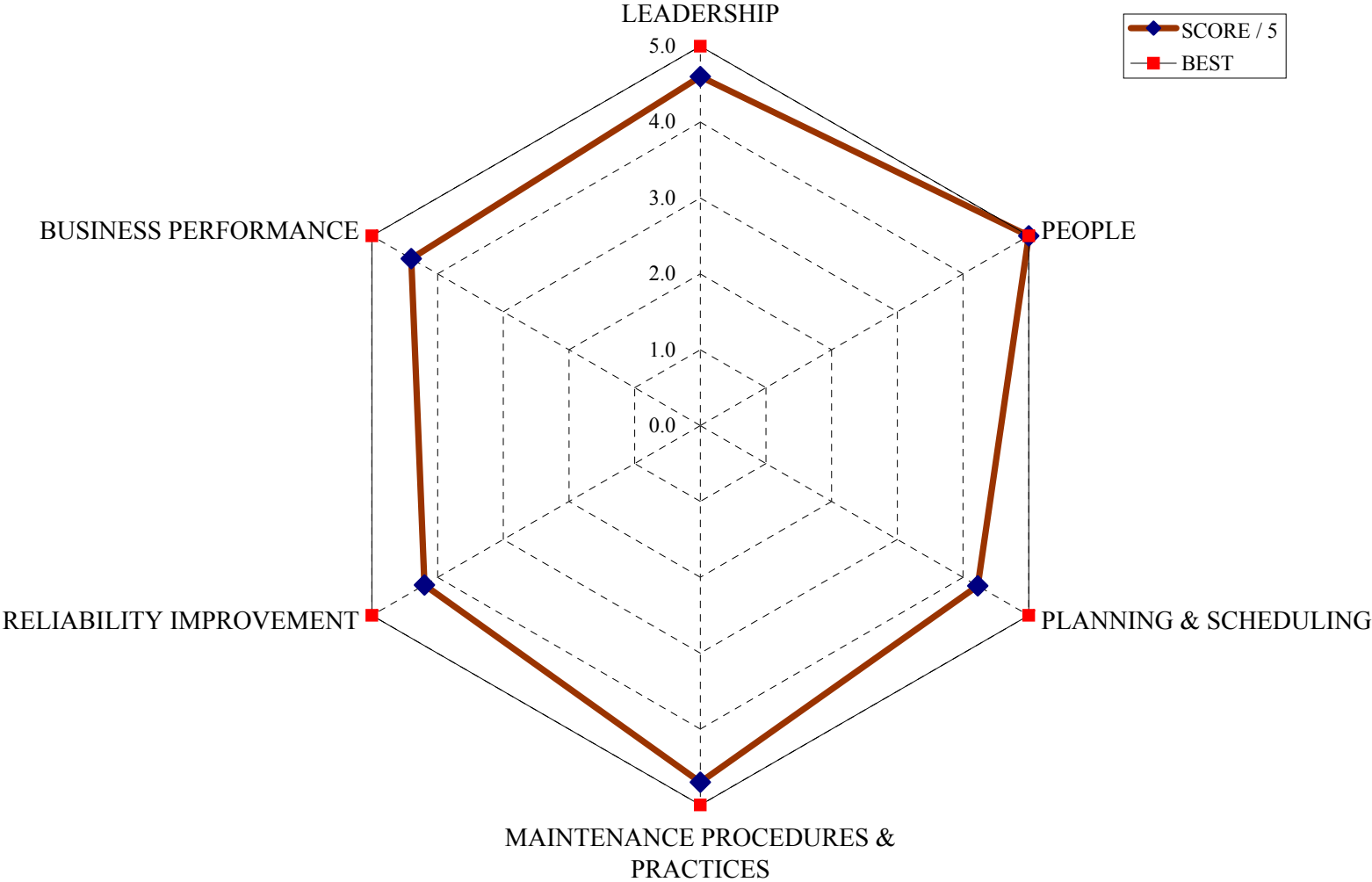
		SCORE %	SCORE / 5	BEST
LEADERSHIP	1	92.00%	4.6	5
PEOPLE	2	100.00%	5.0	5
PLANNING & SCHEDULING	3	84.44%	4.2	5
MAINTENANCE PROCEDURES & PRACTICES	4	94.00%	4.7	5
RELIABILITY IMPROVEMENT	5	84.00%	4.2	5
BUSINESS PERFORMANCE	6	88.00%	4.4	5

OVERALL WEIGHTED RESULTS

		WEIGHTED % SCORE
LEADERSHIP	1	14.72%
PEOPLE	2	20.00%
PLANNING & SCHEDULING	3	10.98%
MAINTENANCE PROCEDURES & PRACTICES	4	16.92%
RELIABILITY IMPROVEMENT	5	16.80%
BUSINESS PERFORMANCE	6	11.44%

TOTAL = 90.86%

AUDIT RESULT - PAS55 WEBCHART



Building Maintenance Outsourcing Excellence (Wyeth:Dalkia – Industry Case Study)

By
Padraig Liggan

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Abstract— In order to enable the manufacturing company to focus more on their core business, which is making product, it can be very beneficial to outsource the maintenance department to an outside company. This structure has become very popular in industry. Today, using an industry case study this paper will explore the benefits of implementing this type of outsourcing and how from the authors own experience this can be successfully achieved.

I. Introduction

According to Jones (1999), it is found that 30 percent of World Class manufacturing organisations will out-source the maintenance organisation, particularly in the area of utility systems. The outsourcing of maintenance is a relatively new trend with as little as 5 percent outsourcing in the early 1990's.

The main reasons for outsourcing are to allow the manufacturing company to concentrate on its core activities, which is making product. Contracting out the maintenance function can reduce costs by eliminating direct company headcount; management can enforce change quickly, drive continuous improvement and improve service levels. This is possible because the company is the 'customer' and they want the most for their money, for the maintenance contractor the customer is valuable and in many cases they will go to any lengths to ensure customer satisfaction.

By setting out clear expectations and outsourcing to an experienced contracting company, great results can be achieved. Outsourcing should not be mistaken with relinquishing of overall responsibilities, legal aspects such as regulatory compliance for Drug Manufacturing must be closely monitored and the manufacturing company must provide safe systems of work. The manufacturing company should employ people to monitor performance of the outsourced contract and to develop service level agreements.

All the major manufacturing companies in Ireland such as Intel, Wyeth, Hewlett Packard and others have all adopted maintenance outsourcing as part of their business strategy. This has paved the way for a new emerging business sector in Ireland which is industrial services; outsourcing services such as facilities, maintenance and security can all be readily provided. Competition in these

areas is fierce which of course drives the standard of service up and the cost down. This is allowing Irish companies to build up expertise in these areas by being able to support large multinational companies who wish to set up in Ireland. This ability of the service companies can help make Ireland attractive to the potential company wishing to setup here.

II. Wyeth and Dalkia: Building Outsourcing Excellence

In 2001 it was announced that pharmaceutical giant Wyeth was to invest €1.8 billion in a state of the art Biopharma plant at Grangeacastle, West Dublin. Later that year the construction of one of the world largest biopharmaceutical plant began at Grangeacastle.

In 2002 maintenance outsourcing began by employing the maintenance expertise of FP2 Ltd (now Dalkia Ireland Ltd) in order to operate plant utilities and to setup maintenance programs for the site. Although we don't see plants of this size being constructed often, perhaps only once every decade, this is the best time to form an alliance partnership with the maintenance outsourcing company, working together from the start.

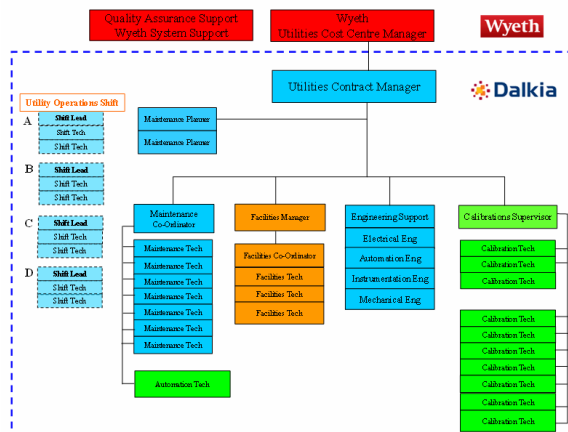


Figure 1 The Wyeth Biopharma Campus at Grangeacastle

Dalkia Ireland Ltd are part of the International company Veolia Ltd which employ over 14,000 people world wide through a large portfolio of businesses operating in the service sector. Dalkia in Ireland employ 600 people and provide maintenance outsourcing, utilities and energy solutions for industry. One quarter of Dalkia's employees in Ireland are based at Wyeth, Grangeacastle and support

Since 2002 to present Wyeth and Dalkia have evolved to form one of the best examples of outsourcing excellence in Ireland Today. From the authors experience there are a number of key areas that have contributed to this success:

Dalkia have a high degree of ownership when it comes to operating and maintaining utility systems. In each manufacturing area the contract is overseen by one Wyeth cost centre owners who monitors contract performance and contract spend. This structure is beneficial to Wyeth and they don't need to get involved in the day to day running of the Utility Systems. Through the cost centre owner Wyeth management have a good visibility of the performance of the contract and the areas that may need to be addressed. Performance is measured through areas such as availability, planned work V's actual, safety and regulatory requirements. For clean utility systems (which are qualified systems and feed manufacturing areas directly) high level compliance is ensured through Wyeth subject matter experts and the Quality Assurance group in each area. Wyeth has overall responsibility for the safety of their products and this structure needs to exist. The following chart details the type of organisational structure that has been set up for the outsourcing of utility systems in manufacturing areas:



One of the key advantages of this structure is that the outsourced company can be measured directly against the equipment/system uptime that is being provided; this is because they own every activity within the maintenance organisation. In some outsourcing situations only certain tasks are contracted, [also known in industry as ‘body shopping’]; in this scenario it can be difficult for the company to achieve full accountability from the contractor for systems performance. Where the

The service level agreement sets out clear expectations and tasks to be performed by the outsourcing partner. The manufacturing company's measurement of the contract is important; company's can't manage what they don't measure so this is where key performance indicators (KPI's) have a part to play. The KPI's are structured in terms of plant availability, scheduled work completion, safety and compliance with specific targets. In the Wyeth-Dalkia contract, penalty clauses are employed for performance targets that are not met, this approach creates a mutual gain 'win-win' (i.e. both share the risks and rewards) environment in which all parties see the benefit of high performance.

IV. Dalkia & Wyeth: An ‘Alliance Partner’ not ‘Contractor’

The term 'contractor' is very rarely used when referring to Dalkia, rather an 'alliance Partner' with Wyeth. In many plants the outsourced company are often referred to as 'those maintenance people' and this stigma creates an 'us versus them' relationship which can inhibit improvement, hinders trust and can have a negative effect on overall plant performance.

At present Dalkia and Wyeth are in the process of negotiating a 10 year long term contract in which Dalkia will purchase the utility services at the plant and take

over full ownership. The utility services are then sold back to Wyeth at a unit cost. This sort of contract arrangement is set to become the future for outsourcing of utilities.

Again this is a 'Win-Win' situation for both parties, on one hand Wyeth the manufacturing company receives an immediate influx of capital and then allows them to set long term fixed budget costs for each year in return for the supply of utility services. For Dalkia the outsourced company, an operational profit is made over the term of the contract, and investment can be made for the long term development of its people without the fear of losing them through loss of short term contracts.

With a long term fixed price contract, it is within Dalkia's own initiative as the outsourced company to continuously improve in order to gain a higher profit margin on high availability utilities being sold back to the client.

VI. Design, Finance, Operate and Maintain

During the construction of a new plant another popular option is completely outsource the plant core utilities. In this scenario the contract company will design the central utilities plant which will include steam, electricity, AIR, water etc. and finance the construction and eventually operate and maintain the plant. With this arrangement the client company can concentrate on getting its manufacturing facilities up and running and be supplied with plant utilities which can be purchased at unit cost.

This package often includes a combined heat and power plant (CHP) which is the simultaneous generation of usable heat and power (electricity) in a single process.

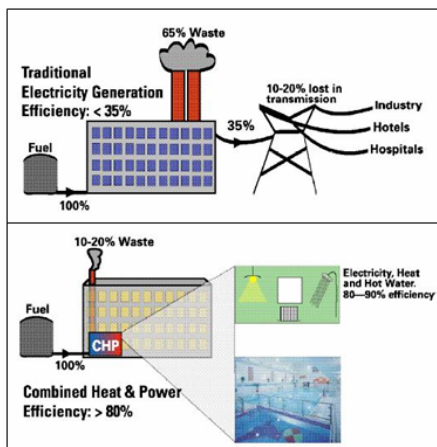


Figure 3 CHP Vs Traditional Power Generation

Courtesy: f4energy.ie

As shown in Figure 3 above the CHP plant is over twice as efficient as a traditional power plant. The CHP plants are built on the factory premises, electricity is sold back to both the factory and the national grid, heat generated by the plant is then re-used in the factory. In 2009 Dalkia Ireland Ltd will be constructing a CHP plant at the Wyeth

plant, the project has been designed, financed and will be operated & maintained by Dalkia.

VIII. Summary and Conclusions

Following research and from the authors own experience the area of maintenance outsourcing has been identified as a major part of modern industry. As discussed earlier the main reason for manufacturing companies to outsource maintenance is cost reduction and to enable them to concentrate on core activities which is making product. However this is only the baseline of possibilities, so much more can be achieved by approaching outsourcing correctly such as high degree of ownership by the outsourcing partner, continuous improvement and a Win-Win culture which promotes open/honest communication.

The future for outsourcing is moving towards full ownership of utility systems through long-term fixed contracts which have shown clear benefits for both parties involved.

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