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Abstract

Nowadays, more than ever, we find business models able to face the substantial changes the Life Sciences sector is experiencing. It's necessary reaching excellence not only in production terms, but also in processing terms, especially in Operations area.

Nonetheless, it's important to dampen the "wastes" and to improve the availability of equipments. This means that, not only it is not possible to consider maintenance as a normal "center of cost" anymore, but also that it needs to become a center of profit; RCM and "continuous improvement" ("Kaizen practices") are practical answers to these needs.

Also in pharmaceutical industry, which was considered to be "the elite" until recently, there is the making up of performance improving methodologies, so that maintenance is intended to be strategic inside business organization, in full synergy with the Quality Assurance.

Through a case study, it will be exposed the implementation of an RCM project applied to the whole pharmaceutical plant specialized in Plasma-derived products. The whole procedure will be analyzed; it started with a complete revising of the Work Order Flow of the maintenance activities and led to a new statistical management of KPI, such as the MTTR and MTTF, a radical revision of SOP and a methodic and systematic employment of the Kaizen approach, and introduced the FMECA analysis into their Risk Assessment approach.

Keywords: RCM – Failure Analysis – MTTR.

1 Introduction

The present demands of market, such as Globalization and harder competition, contributed to develop new management approaches and methods in manufacturing organizations, in order to improve constantly their effectiveness, increasing the product quality and dampening the production and management related costs. Therefore, also maintenance is involved in these visions, as its mission is to guarantee reliability and availability of items/machines, complying with process standards and with the minimum waste of resources, both in terms of cost and workforce.

The best approach, which combine all of these factors, is RCM (Reliability Centered Maintenance). The aim of this presentation is to prove the reachable benefits following the application of this technique, exposing a case study related to the implementation of RCM in a pharmaceutical factory of an Italian organization, world leader in production of plasma-derived products.

2 Manuscript preparation

If well enforced, RCM is a methodology that can contribute to achieve the organization's targets in terms of cost reduction and increment of reliability and availability of all the assets.

Everything is based on the knowing of all the operating costs of the asset by LCC (Life Cycle Cost); this is possible only applying the Reliability Theory: through a straight analysis, precisely following the RCM, not only does it lead to the evaluation of the best Maintenance Policies to implement during the asset's "Useful Life" and of the relative costs, but also to the evaluation of the Failure Cost, as it doesn't exist a 100%-reliable system/component. It depends on what is decided during the design phase, before the definitive construction of the system. All because of the market's contingencies.

This choice is very important for the further selection of the right mix of Maintenance Policies to secure a satisfactory level of reliability and to avoid high operating costs.

Definitively, RCM contributes to make the organization an excellent organization, raising the role of Maintenance from a mere "center of cost" to a "center of profit", contributing not only to reach the predetermined organization's targets but also highlighting the criticalities of the asset, which is customized from time to time on the customer's needs.

The main operative instrument supporting the RCM methodology is the FMECA (Failure Mode, Effects and Criticality Analysis), which is based on the hypothesis that effective and efficient maintenance programs can be developed through a disciplined process of analysis and decision logic, assessed on the consequences the failures could produce and the concerning criticalities (induced damages).

In S. Antimo factory (Naples) there's an ongoing revision of the Maintenance Service organization process flow following the RCM method.

For a better understanding of this method, Kedrion is taking advantage of the consulting support of ABC Srl, leader in Italy in the application of RCM.

The structure and the relative scheduling of the project derive from a preliminary assessment, during which the as-is WOF, the modes of summarization of every action details, the interesting KPIs and the management and storage of spare parts have been analyzed. Following this analysis, it has been made possible to schedule an improvement program.

Everything is based on UNI Standards, in particular:

- UNI EN 13306:2003 – Maintenance – Terminology
- UNI EN 13460:2009 – Maintenance – Documentation for Maintenance
- UNI EN 15341:2007 – Maintenance – Key Performance Indicators

For other guide lines and texts, refer to References at the end of this document.

Further is has been made a report in which there is the comparison between the Status Quo situation and the reference benchmarks.

The definition of the phases and the goals to achieve have been made referring to the scheme of Figure 1, which ABC Srl follows and recognize as its own method for structuring any action of Maintenance Services improvement.

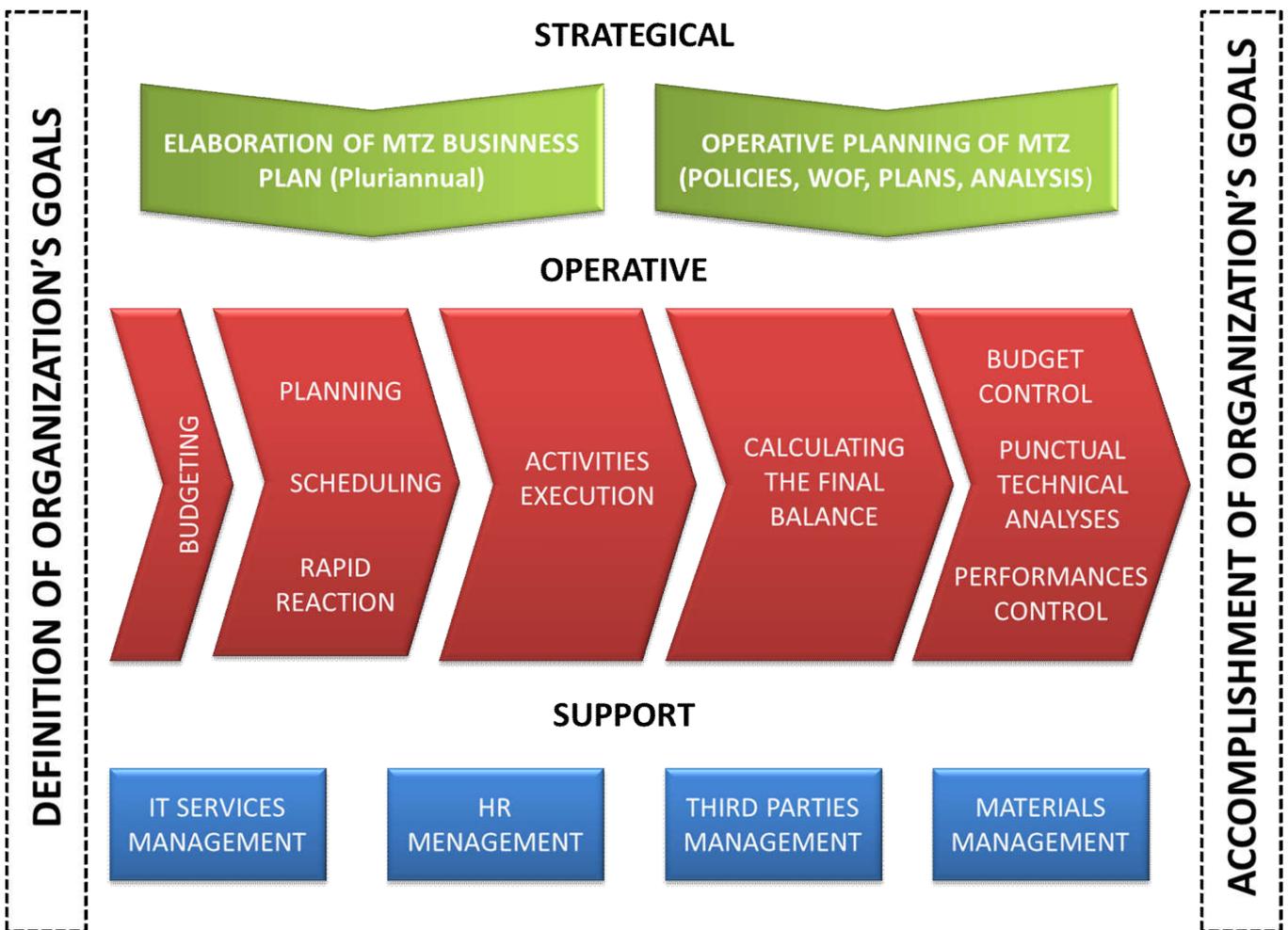


Figure 1: The definition of the phases and the goals to achieve.

Either way, it was considered appropriate to apply the policy of little steps so, both in the definition of KPIs and in their use, as in the establishment of the new WOF and its relative procedures, it was decided to simplify any task, focusing only on some references and finding the way to make their executive calculation procedures explicit, in order to avoid the usual stiffness to changes of the maintenance operators and to have an easy comparison also in the Production area and in the subsequent data analysis.

Eventually, it has been tried to apply a sort of Lean-RCM, following the spirit of Lean Manufacturing, in which we draw fully from the theory of Continuous Improvement and the Visual Management Approach.

This Project started in September 2012 and it will last two years. It has been developed through a predetermined specific schedule, composed of 4 sub-projects called:

- Score Board
- RCM
- Spare Parts
- WOF

The project scheme is reported in Figure 2.

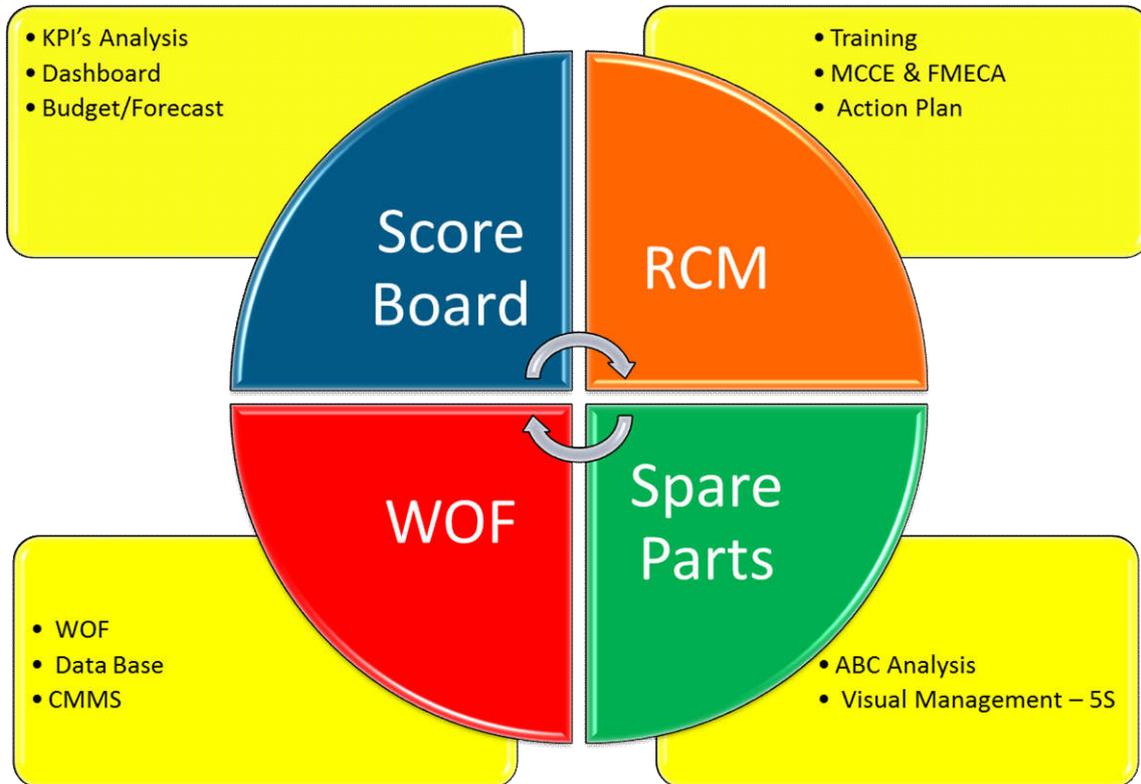


Figure 2: Scheme of ABC Project in Kedrion

Given that it's expected a massive data treatment, as we are convinced that "if we cannot measure, we cannot improve", it's forecast the installation of a new CMMS in a side project, to facilitate a correct and standardized data gathering (summarization of Maintenance Orders, Spare Parts Management, Preventive Activities Scheduling, etc.) and an easier analysis of them. To the purpose, Infor's EAM Software was chosen.

Let's focus on the 4 sub-project in more detail.

Score Board

The main aspect, that should not be underestimated, it's to let the reference KPIs easy to read for the Organization's Management. Therefore it's inescapable fact to define a dashboard, of public domain, in which there'll be reported the target goals and the actual results in the respective reference periods.

Obviously, besides the graphical aspect, it's important to define and to well explain (as a Procedure) which KPIs will be used to describe the effectiveness and operative status of Maintenance Service.

Following the above-mentioned model, the KPIs have been divided in two main groups:

- Strategical
- Operational

These indexes will be associated to the so-called "Systems", which are real Systems and specific Equipments for Kedrion. In this way, the factory registry have been reviewed and it has been performed a Criticality Analysis, following the MCCE (Multi Criterion Classification Equipment [2]) and setting up a cross-functional Team, composed of members from Production, Maintenance and Quality Assurance Services, it has made possible to define, clearly and easily, a classification of the Critical Systems. In this way it have been highlighted which Systems are the most critical and which need an higher attention, in an unambiguous and shared method.

Therefore, the Strategical KPI's to be continuously monitored are:

- Maintenance Costs vs. RAV (Replacement Asset Value);

- Maintenance Costs, due to failure and preventive actions; these costs are calculated as cumulative, as a single action of Internal Maintenance Service, External Maintenance Service (outsourcing) and as materials used.
- The Maintenance category; there are three different categories: “MP” (Preventive Maintenance), “MC” (Corrective Maintenance), “MM” (Proactive Maintenance).

For the “Operative” area, it have been chosen the calculation and the analysis of MTTF (Mean Time To Failure), MTTR (Mean Time To Restoration) and A (Availability), given by the ratio expressed in equation (1).

$$A(t) = \text{MTTF} / (\text{MTTF} + \text{MTTR}) \quad (1)$$

The Availability is a very powerful index: It can be evaluated easily through the calculation of only two values (MTTR and MTTF) and it gives important informations about Maintenance effectiveness on every Critical System and about the effectiveness of every action has been made on them, both Corrective and Preventive.

The MTTF is able to define the failure frequencies, therefore also the Reliability of single Systems, and, through the analysis of the historical trend linked with MTTR, it’s possible to understand which action was decisive, so the most effective. While MTTR can be used to monitor the Operative Efficiency in terms of lead time to intervention or as the organizational ability of planning and scheduling if it’s referred only to Preventive Maintenance actions. So there are two specific MTTRs: one for Corrective Maintenance (MTTRc) and one for Preventive Maintenance (MTTRp).

It’s important to clarify, in this beginning phase of the project, that the MTTRc is evaluated as the downtime period of the System, so as a period of unavailability. Moreover, it have been structured some “OdM” (Order of Maintenance) in order to monitor the difference of time between the instant in which the action is called, considered as the failure’s “acclamation”, and the instant in which the Maintenance Operator’s intervention begins or in which he takes care of the reparation.

As a complement of them, it have been chosen other indexes in order to monitor the Spare Part Warehouse Management.

In that case, it have been considered:

- Level of Service, defined as the ratio between the total number of withdrawals and the successful outcomes, that is to consider the withdrawals in which the spare part was immediately available, compared with the total number of requests to the warehouse;
- Inventory Turnover Ratio (IdR), defined as the number of times in which a specific spare part or kit have been withdrawn in one year, compared with the mean inventory.
- The economic value of the long-term assets in the spare part warehouse.

RCM

As written above, RCM leads to identify the most critical parts of the System, using Reliability Techniques, for what concerns safety and efficiency of the same system, which can be also customized from time to time, therefore it can focus the attention on these parts during the creation of the Maintenance Policy and the Maintenance Efforts.

This task allows to avoid other traditional operations which can be considered of secondary importance for the economy of the system and that could be eliminated or minimized. As a result, this task can also decrease the management cost of the system, for what concerns both Maintenance (which become cost-effective and able to guarantee the expected level of performance) and Production (with a decreased management cost and an higher production effectiveness).

The starting point of system’s reliability analysis is the use of FMECA (Failure Mode, Effects and Criticality Analysis).

This technique is in use only from a few years (in a more or less systematic way), but the approach to this problems must be follow the practical sense, basing on the experience of the maintenance operators and on the availability of reliable data; through the determination of the failure rate of any single component it’s possible to forecast its behavior, reliability and average life.

Before starting to perform any FMECA, it’s better to determine which system will be the object of the Analysis. Basically it’s necessary to define an criticality-ordinated chart of the systems, in order to make coherent decisions everytime it’s needed.

FMECA analysis is already well-known, therefore it’s not useful to go into more details in this context; anyway, in Figure 3 there is reported a basic scheme about its conduction.



Figure 3: Conduction of a FMECA Analysis

In Kedrion, the evaluation of the RPN (Risk Priority Number) has been done following the equation (2).

$$RPN = P * S * D * M \quad (2)$$

The terms of the formula have the following meanings:

- P is the periodicity, that is the annual frequency of the failures;
- S is the severity, that is the consequences' severity related to the failure mode;
- D is the detectability, that is the time required to detect the type of failure;
- M is the maintainability, that is the technical time required to restore system's function.

Following what's reported on MIL-STD 1629 [1], only P and S indexes are in use for the evaluation of RPN; the use of the D and S indexes has been introduced by Eng. Antonio Altobelli for a better characterization of every single failure mode [29].

Eventually, the gained RPN values will generate a Pareto Chart, useful to define an objective ranking, compiled using shared multifunctional visions, through which it's possible to focus the efforts without the "dispersion" of attention on the whole system. In effect, as seen before, every component will suffer of failure, but only some failures are critical. Therefore, it's important to evaluate the weight of the risk and then comparing it with the own available resources (workforce, time, money).

The threshold allow to start the work only on the highest and most critical scores then, when their situation is improving, it's possible to examine other failure modes with a lower (non-null) score, which need to be flattened not losing sight of the cost effectiveness. Going too far in the search for perfection will result in an huge expense in resources, in the Maintenance Typology and in the number of inspection.

So, once every functional group has been characterized for what concerns the failures related to it, and every criticality has been evaluated, there starts the implementation phase of the "Action Plans", for whom is possible to implement improvements in order to flatten the criticalities.

The point of view of the improvement have to be finalized to reduce the criticalities (the Risk), and this can be made only in two ways:

- 1) reducing the Probability of the event (for example, substituting a component with another component more reliable);
- 2) reducing the Damage (that means one or all the parameters $S*D*M$), reducing the severity of the seriousness of the effect (for example using auxiliary systems, specializing the personnel, using spare parts, etc).

The number of the projects is not equal to the number of critical failure modes, because some failure modes are often repeated in the same project, reducing the number of project to carry on.

Anyway, the activities can be also some trivial actions determined following a FMECA so, even with a small amount of time and resources, they can result in the resolution or in a flattening of the criticalities.

Obviously, it's not always possible to resolve every criticality with fast and cheap actions, but FMECA helps the Maintenance Engineer in the definition of improvement projects, that can be presented to the Organization's Management with a study of their feasibility (exposing the duration and the cost for the accomplishment and the relative return of Investment).

Another important output of FMECA is the definition of the best Maintenance Policy.

Maintenance Engineering provides for investigations into the technical-executive, operative or executive control implementations from the point of view of design and management, in order to guarantee the availability of the systems, the economy of their direction, their safety and the best use of environment resources; so, as seen before, not only is it important to define an improvement Action Plan, but also to define the best Maintenance Policies.

As a result of the maintenance option adopted, there is a different operating cost and a different LCC.

So FMECA is crucial to the definition of the entity of every failure mode, in order to adopt the best maintenance activity for it.

In particular, the work in Kedrion began with the execution of a full FMECA on the Freezy Drier Equipment important to mention, as a methodological approach, that the choice to start with the analysis of this implant follows the resulting criticality chart of the MCCE analysis [2].

The MCCE (Multicriterion Classification of Critical Equipment), which was one of the results of a study about Manufacturing Industry made in the Spanish University of Murcia, evaluates the systems in the organization following a criticality index.

In the field of maintenance there are different reasons why it's important to classify systems; in particular:

- to give a guideline for choosing which equipment have to be restored firstly;
- set priority levels for the application of advanced methodologies of maintenance management (for example FMECA and RCM);
- to identify systems and subsystems which have to be the focus of advanced Maintenance Policies, like Predictive and On Condition Preventive Maintenance;
- to determine the exact spare parts stock amount and their convenient Reorder Point in the warehouse;
- to identify possible needs of other resources.

Typically, the concept of "importance of a system" is associated to different aspects, such as: failure frequency, the consequences on the safety and the environment, the quality of the product, productivity, availability, maintenance costs, all the aspect concerning the organization in which things are done (pharmaceutical, chemical, metal workers, petrochemical, etc). In more detail, it's possible to use the following criteria, all of which is associated to a different coefficient used to test the incidence on the overall evaluation:

- potential risk for the operators of the factory;
- effect on the quality of the products;
- effect of the failure on the costumer;
- effect on the effectiveness of the workforce;
- availability of replacement machines;
- operating capacity of the equipment;
- detectability of the failure;
- MTTR and MTTF indexes;
- intervention cost.

To apply the MCCE methodology it's important to define the operating context and to choose the interfunctional team responsible of the performing of the analysis and the following evaluations. Thereafter the individuation of the criteria for the analysis will start; they will be divided in different levels and each criteria will be associated to a weight, which represent how much it will affect the overall result, as shown in the Figure 4 scheme.

	rischio potenziale per gli operatori dell'impianto	effetto del guasto sul servizio di produzione (macchinari)/fornitura [utilities]		possibilità di rilevare il guasto	tempo necessario per ripristinare il servizio di produzione/utility	qualità dei prodotti lavorati	esistenza di macchinari o impianti alternativi /di riserva	regime funzionale equipment/impianto
Livelli di criticità	4- molto alto	4- la fornitura si arresta completamente per tutte le utenze	4- la linea si ferma completamente	4- assoluta certezza di non rilevabilità	4- più di 3 giorni	4- tutti i prodotti lavorati durante il guasto devono essere scartati	4- non esistono macchinari o impianti di riserva	4- Continuo (100%)
	3- alto	3- la fornitura si arresta per una parte delle utenze	3- la linea si ferma dopo un breve periodo di tempo in seguito al guasto/	3- bassa certezza di rilevabilità	3- tra 1 e 3 giorni	3- molti dei prodotti lavorati durante o dopo il guasto devono essere scartati	3- è possibile utilizzare equipment/impianti di riserva per un breve periodo di tempo in seguito al guasto	3- quasi continuo (75%)
	2- normale	2- la fornitura continua ma con prestazioni ridotte per tutte le utenze	2- la linea non si ferma ma si ha una riduzione immediata della sua efficienza/CP	2- possibilità di rilevamento	2- tra 5 e 24 ore	2- alcuni prodotti lavorati durante o dopo il guasto devono essere scartati	2- esiste un equipment/impianto di riserva ma di capacità o caratteristiche non identiche o inferiori	2- non continuo (50%)
	1- basso	1- la fornitura continua ma con prestazioni ridotte per una parte delle	1- la linea non si ferma ma si ha una riduzione graduale della sua	1- possibilità di rilevamento in tempi brevi	1- tra 1 e 5 ore	1- il guasto ha effetti trascurabili sulla qualità dei prodotti lavorati	1- esiste un equipment/impianto simile in riserva	1- non continuo (25%)
	0- molto basso	0- non si ha alcun effetto sul servizio di fornitura	0- non si ha alcun effetto sulla produzione della	0- certezza di rilevare il guasto	0- meno di un'ora	0- il guasto non ha effetti sulla qualità dei prodotti lavorati	0- esiste un equipment/impianto ridondante disponibile	0- occasionale
PESI	4,00	4,00	2,00	1,00	2,00	3,00	3,00	2,00

Figure 4: Weighing of criteria for the analysis

Once the multicriterion matrix has been determined, there will start the evaluation of every system about the previously determined criteria, determining a criticality index that can be represented by the equation in Figure 5

$$I_c = 100 * \frac{\sum_{i=1}^n (d_i * w_i)}{d * \sum_{i=1}^n w_i}$$

Figure 5: Equation for determining a criticality index

where:

- n = number of criteria;
- d = number of criticality levels of the criteria (in Kedrion there were 7 levels);
- d_i = criticality level of the equipment about the i-th criterion C_i (0÷4);
- w_i = weight of the i-th criterion C_i.

The systems are listed on a decreasing scale, so it's now possible to divide them in classes to allow the attribution of each of them to a Maintenance Strategy most suitable to its criticality level, as shown in the Figure 6 scheme.

CLASSIFICAZIONE					
	A- IC >50				
	B- 35 < IC < 50				
	C- 20 < IC < 35				
	D- 10 < IC < 20				
	E- IC < 10				
STRATEGIA	A	B	C	D	E
Analisi di Affidabilità					
Reliability Centered Maintenance	X	X			
FMECA	X	X			
RBD	X				
.....					
Attività di Manutenzione					
Analisi Economica	X				
TPM	X				
Manutenzione su condizione al 10%		X			
Manutenzione Programmata al 30%			X		
Formazione sull'equipment	X	X	X	X	
Gestione delle parti di ricambio	X	X	X	X	
.....					
Attività di miglioramento continuo					
Misura delle prestazioni	X	X	X		
Lean Manufacturing	X	X			
Six Sigma	X	X			

Figure 6: Scheme of systems classification

As the analysis process it's structured, the MCCE allows to choose objectively and rapidly which systems will be the focus of the following RCM study. Indeed one of the peculiarities of MCCE is its operating speed, as it is a totally qualitative analysis; furthermore its simplicity make it suitable to be applied to different functions of the organization, without the need of preparatory theoretical in-depth analysis. This allows to have a shared output, proceed of a collegial study. It's important to notice that, on the average, it's possible to analyze up to 300 different items per day (where the word "item" is used to represent classes of functionally-similar systems located in the same working area).

WOF

Apart from defining, in a clear and shared way, which critical systems are in the factory, it's of main importance to review the work activity flow both for what concerns Corrective Maintenance and Preventive Maintenance, in order to have at our disposal the largest number of informations for statistical studies.

In the specific Kedrion's case, the general SOP for Maintenance Management was rewritten, introducing a new management flow and formalizing a new set of reports. In this way it's now possible to record the different methodologies of Maintenance Policy in a more punctual way, to hold in check the spare parts and the workforce. Moreover, it's now possible to quantify the MTTR for every single activity.

As written above, the purpose of all these changes is to have a better failure record in one year, in order to facilitate the study of improvement activities, both for what concerns the availability of the factory and the effectiveness and efficiency of Maintenance.

SPARE PARTS

The Spare Parts Warehouse have to be considered as a work equipment: without it, the Maintenance Operator cannot do his job. Moreover, it's fundamental that the spare part will be available when it'll be needed, trying to reduce the lead time. For this reason, it's important to have a certain amount of materials available in the factory, without exaggerating or it will increase the cost of immobilized capital.

Here is why, with that aims, it has been conducted a so-called "ABC cross-analysis". This methodological approach, ideated by ABC Srl, has made possible to define a improvement program which is suitable for reducing to minimum the immobilization and to enhance the Level of Service of the warehouse itself.

The "ABC cross-analysis" is a methodology of statistical analysis suitable for finding the most valuable actions with the aim of improving the management of the warehouse of spare parts. It consider the partitioning of the assets in three categories, to point out critical articles for attention.

As a reference, two indexes, evaluated on an annual-basis, have been taken:

- TR (Turnover Ratio) it represent the times in which the spare part inventories are completely renewed in a determined temporal interval (one year in the example); it's calculated using equation (3):

$$TR = QM / AI \quad (3)$$

where:

- QM = Quantity of Materials, that is the number of spare parts taken from warehouse in one year
- AI = Average Inventory amount, that is the sum of all the inventories at the end of the months of one year divided by 12.

- Im (Imobilisation): it represent the total economic value of the stock in the warehouse; it's calculated using equation (4):

$$Im = TI * uv \quad (4)$$

where:

AI = Annual Inventory, that is the inventory at the end of the year;
 uv = unit value.

These index values were evaluated for every spare part. Then the values was sorted in descending order and it allowed to determine:

- incidence in percentage of every TR on the total amount of TR;
- incidence in percentage of every Im on the total amount of Im.

Eventually, the values of the two indexes has been divided in three (ABC) classes using the Pareto Analysis and this led to define a 3x3 matrix as shown in Figure (7). Every element of the matrix is related to different improving actions and projects.

		IMMOBILIZZO		
		A	B	C
IdR	A	1	2	3
	B	4	5	6
	C	7	8	9

Figure 7: Matrix of TR and Im indexes

Therefore, following this cross-analysis it was easy to spot and identify the critical gaps.

Not only do this approach determines benefits for Maintenance Service, but also it helps the Purchasing Department in stipulating better deals and the Production Service for what concerns the reduction of Lead Time and the increasing of the Reliability of single components.

Conclusions

RCM methodology encloses all the benefits of a concrete and optimized production structure, both if it's referred to a physical production of a tangible good or to providing intangible services. The slogan of this methodology could be: "The innovation which is based on the previous". The experience of individuals is not diminished in any way nor demonized (just think about the conduction of a FMECA Analysis). The methodology, which is added in synergy to their experience, becomes the concrete guidance for operations. The standardized approach, combined with the experience of the individuals, makes the process efficient by definition, overcoming all the difficulties typical of the normal "playing by ear". The strategies have been given, just follow them to quickly reach the goal.

The advantages of RCM approach are many. Here there is a short list of them:

- Sharing information: the experience of an individual become heritage of all, freeing the company from the specific experience of the individuals for real → increase in competitiveness.
- Greater focus on implementation: the efforts are no longer scattered in many different projects, the majority of whom is often useless and wasteful. The proposed projects are always the best (the most urgent and with the higher value of cost-benefit ratio) → savings.
- Better rationalization of projects: the overall vision allows automatically to give priority to the operations which can solve the majority of problems. The communication which derive from the RCM approach is an intangible but concrete value of the method → budgets are distributed following different aspects, that lead to a minor impact on work.
- Complete "adaptability" to organization needs, that means high capability to merge the efforts of the organization in one specific direction → success.

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