REPLACEMENT OF PROPOSE SCHEDULE MAKING TOWARDS CRITICAL COMPONENT IN WATER ENGINE FOR INJECTION LOOP PUMP AT ONCOLOGY PLANT PT. SANBE FARMA CIMAREME

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ABSTRAK

PT. Sanbe Farma is a company engaged in pharmacy or medicine, the company has development, production and sale of high-quality drugs, the products produced by the company, these include the drug sterile and non-sterile.

Failure mode, effects, and criticality analysis (FMECA) is a design technique to systematically identify and investigate potential weaknesses of the system (product or process). The model of prevention with the criteria of cost minimization is to replace components that have reached the age to minimize replacement costs, in order to get an optimal maintenance intervals to perform preventive maintenance.

WFI Loop Pump machine is often impaired unpredictable, it is of course very hurt because the output of the machine is a raw material for the production and resulting in ongoing production must stop. Therefore FMECA method is used, calculate the cost of treatment and determine the optimal time interval for replacement of critical components.

The results of the analysis that Mechanical Seals and Bearings are critical components of the engine WFI Loop Pump, then the calculation of the component replacement intervals with the results of 377 hours or 15.7 days to turn these two components.

Key Word: FMECA, Maintenance Costs, Time Interval Replacement

I. Introduction

A. Background

Along with the rapid pace of development and growth of the pharmaceutical industry in the country, requires producers to compete closely in order to meet the needs of consumers as well as a great benefit for the company.

PT. Sanbe Farma is a company engaged in the field of pharmacy or medicine, the company has development, production and sale of high-quality drugs, the products produced by the company, these include the drug sterile and non-sterile. PT. Sanbe Farma also is the only manufacturer that produces its own pharmaceutical anticancer drugs in Indonesia, before other companies importing from foreign companies such as China, India or Europe.

Engine with performance and productivity is good, certainly can operate normally as expected in a production process. Of course, to meet all the necessary good care of the machine, given that each machine has a different resistance against a disturbance or damage to components.

In connection with these problems, the Water For Injection engine that serves Loop Pump as a pump to send WFI to production is not uncommon disorder that is not predictable, it is certainly affect the activity of production should continue to run. Therefore this study will examine how to determine which components are considered the most critical, calculate the cost of care and make the optimal treatment schedule with a small fee for the machine WFI Loop Pump.

The formulation of the problem in this research are:

1. How to determine the critical components on the machine WFI Loop Pump?
2. How much it costs to critical components in the engine WFI Loop Pump?
3. How to create a schedule for replacement of critical components in the engine WFI Loop Pump?

The purpose of this research are:

1. Determine the critical components that exist on the machine WFI Loop Pump.
2. Calculate the cost of care for critical components on the machine WFI Loop Pump.
3. Determining the schedule for replacement of critical components in the engine WFI Loop Pump.

Limitation of problem in this research are:

1. Determination of critical components on the machine only WFI Loop Pump.
2. Costs are calculated only on the treatment of critical components.
3. Creation of a replacement schedule only on engine components WFI Loop Pump deemed most critical.

II. Studiy of Literature

A. Maintenance

Care is the activity of maintenance, repair, cleaning, adjustment and inspection of the treated object. This concept originated from the desire of man to gain the comfort and safety of its object, so as to meet

human needs, to function properly and can survive in the desired time period.

B. *Failure Mode, Effect and Criticality analysis* (*FMECA*)

(*FMECA*) is a design technique to systematically identify and investigate potential weaknesses of the system (product or process). FMECA followed up in a timely manner provide very useful input into the development of cost effective preventative maintenance program and are concerned with the control plan focused. In terms of the commercial spectrum, particularly the automotive industry, uses the metric is called the Risk Priority Number or RPN which can be expressed as follows:

RPN = (severity) x (occurance) x (determinace)

C. Cost Of Maintenance Based To The Time Of Interval Maintenance

Through the calculation of the cost of it can be seen the amount of costs incurred for treatment. Optimal treatment time between preventive replacement activities, can be found by selecting the time interval that has the lowest cost. If the optimal time interval obtained, then the minimum maintenance costs can be known.

D. Preventive Maintenance With Cost Minimization Criterion.

In order to solve the problems of optimal preventive care in one case, the model is developed that represents the real state of the problem. Policies in the replacement show preventive replacement of components that have reached the age of t plus the reimbursement of damage if it is important.

III. Results and Discussion

A. Machine Description

This stage aims to choose the machine that is frequently impaired and then describe the usefulness of these machines.

Selected machine is a machine WFI Loop Pump, which serves to drain pyrogen-free water prepared from purified water depirogenasi process using water for injection generator into the water tank and play with looping system to keep the water sterile. The water is the water used for the manufacture of drugs and raw materials as well as water for sanitation machines for sterile process.

B. System functions work Of WFI Loop Pump Machine

This stage aims to define the workings of the machine as a whole and how each component.

WFI Loop Pump is a pump that has a major element in the form of the motor with angle rotating impeller at high speed. This machine has eight main components and their respective functions, the components include:

1. Ash
   Ash or shaft serves to continue the torque of the drive for the pump operating., This component also serves as the holder of the impeller and other moving parts.
2. Mechanical Seal
   Mechanical Seal is a means of blocking the liquid or gas in a roating equipment attached with Ash.
3. Bearing
   Bearing serves to rivet and the weight of the shaft that can rotate, either a radial load and axial load. Bearing also allows the shaft to be able to spin smoothly and remain in place, thus minimizing friction.
4. Impeller
   Impeller serves to convert mechanical energy from energy manjadi pump speed on the fluid being pumped continuously (continuous). Given this process, the suction channels will work optimally and continuously so that there is no vacancy fluid within the pump housing.
5. Dinamo
   Dinamo is a device that converts mechanical energy (motion) into electrical energy.
6. Motor
   The motor is a device that converts electrical energy into mekank energy (motion) that functions to drive the rotation on the pump.
7. Gasket
   Gasket is one type of seal used on a small slit at the silent component that serves to prevent leakage to the surface of the flat engine loopholes and too dry.
8. Oring
   Oring is shaped rubber lingakaran which serves for retaining fluids, keeping the leak, keep dirt and other material into the system, limiting fluid that is not mixed in the gap between Ash and Mechanical Seal.

C. **Determination of WFI Loop Pump Engine Components Which Considered Critical**

In determining the engine components WFI Loop Pump The most critical component is taken out of the comparison are often damaged. Determination of the most critical components can also be viewed using a diagram that shows the frequency of damage at most of the other components.

Table 1. Data Frequency Component Damage

No	Component	Price	Frequency Of Damage	Presentage	Cumulative
1	Dinamo	Rp. 750.000	2	5.71	5.71
2	Motor	Rp. 600.000	2	5.71	11.43
3	*Gasket*	Rp. 200.000	2	5.71	17.14
4	*Oring*	Rp. 50.000	2	5.71	22.86
5	*Impeller*	Rp. 130,000	6	17.14	40.00
6	*Ash*	Rp. 350,000	7	20.00	60.00
7	*Mechanical Seal*	Rp. 1.300.000	7	20.00	80.00
8	*Bearing*	Rp. 130.000	7	20.00	100.00
Total			35	100.00	

Here are the critical components determining the Pareto diagram:

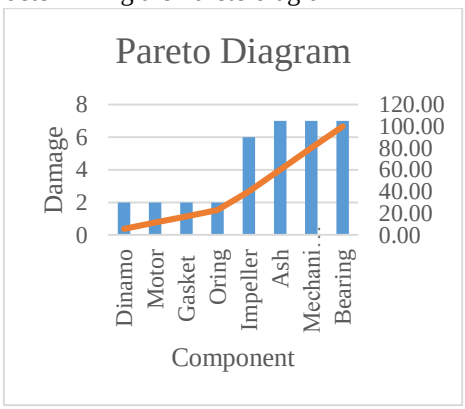


Image 1. Pareto Diagram Determination of Critical Components on WFI Engine Loop Pump

Judging from the chart above and compare how many components are susceptible to interference, that there are two components are often damaged as well as turnover. The second component is a Mechanical Seals and Bearings.

D. Description Of Type Damage Critical Components

1. Mechanical Seal
   Causes damage to the Mechanical Seal is the effect of pressure Ash components, thus making components Mechanical Seal into fast breaks.
2. Bearing
   Bearing damage to the components occurs due to pressure on the blow very strong nonstop Bearing thus making this component be quickly broken and loose.

E. Determining Cause and Effect Of Critical Components.

In identifying the causes and consequences of damage to critical components used Fishbone Diagram. By using fishbone diagram we can determine the cause or factors affecting seiap damage of critical components.

- Here is a fishbone diagram components Mechanical Seal

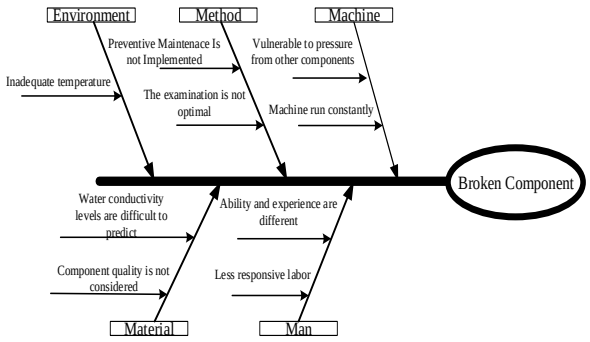


Image 2. Fishbone Diagram Of Mechanical Seal Component

- Here is a fishbone diagram Bearing components

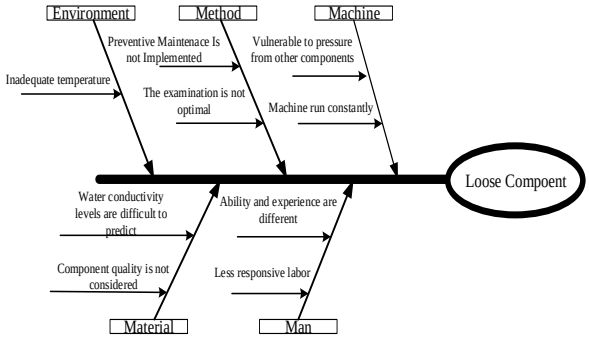


Image 3. Fishbone Diagram Of Bearing Components

F. Determining the Effects Of Damage Critical Components Engineering WIFI Loop Pump

Before determining the effects of damage to the components of a system, we must know the damage of the components. Because of the damage that occurs of course will make the performance of a machine be decreased or even totally dead. Here is the effect of the destruction of these critical components:

Table 2. Effect Damage Of Critical Components

Name Of Component	Damage Effect
Mechanical Seal	The pump can not rotate because the holder Ash rupture thus making the machine could not function.
Bearing	Round pump became stuck and cause a noisy sound.

G. Assessing Damage Type ugliness, Assessing Frequency Event Type Failure Detection and Assessing Probability.

Next is judging ugliness Type of Damage, Assessing Damage Frequency, danMenilai detection probability of each critical component. Those values seen by the list of values and categories listed in the assessment table. After getting these values, we then determine the value of the RPN by multiplying these values for each critical component.

Tabel 3. *Risk Priority Number* For The Each Component

Priority	Name Of Component	Severity	Occurance	Determinan	*RPN*
1	*Mechanical Seal*	10	9	2	180
2	*Bearing*	8	9	1	72

The results are then presented in a table FMECA, which includes the overall results obtained during the processing of the data. In addition to these results, in this table is also shown responses and alternative control measures were carried out

On These critical components.

From these results, we can be sure that the critical component that the first priority is a Mechanical Seal because these components have the effect of ugliness value and high damage frequency.

H. Counting the Cost of Maintenance

The next step is menhitung maintenance costs, such as calculating Cp, the cost of lost profits, as well as calculate the price Cf. The following is the calculation of the cost of care for components Mechanical Seal:

Pricing Cp:
• Subscription Fee = Rp. 1,300,000
• Cost of Care Technician x = Number TK TK Cost per Hour x Time Replacement Prevention = 7 The x Rp. ‘6,750 x 3:38 Jam = Rp. 159 705
• Cost Loss Gain = Profit x Time Hourly Production Replacement = Rp. 250. 000. 000 x 3:38 Jam = Rp. 845 million
• Cp = Subscription Fee + Cost + Cost of Care Technician
Losing Profits = Rp. 1,300,000 + Rp. 159.705 + Rp. 845 000 000 = Rp. 846 459 705
Pricing Cf:
• Subscription Fee = Rp. 1,300,000
• Cost of Care Technician x = Number TK TK Cost per Hour x Time = 7 People Damage Replacement x Rp. 6,750 x 4 hours = Rp. 189 000
• Cost Loss Gain = Profit x Time Hourly Production Replacement = Rp. 250. 000. 000 x 4 hours = Rp. 1,000,000,000
• Cf = Subscription Fee + Cost + Cost of Care Technician Lost Profits = Rp. 1,300,000 + Rp. 189 000 + Rp. 1,000,000,000 = Rp. 1001489

I. Calculation Using Weibull Distribution

This distribution is a distribution that is most often used to analyze the data damage, because the distribution weibull can meet some periods of the damage, namely the initial period (early failure), the normal period and the period of wear (wear out).

The period depends on the value of shape parameter distribution function weibull. Weibull distribution have decreased the rate of damage to β <1, the rate constant damage to β = 1 and the rate of destruction rose to β> 1.

Tabel 4. Perhitungan Distribusi *Weibull* Komponen *Mechanical Seal*

No	Time Between Damage	RANKING	R(Ti)-1	Xi	Yi	Xi.Yi	Xi2
1	472	368	1.1228	-2.1556	6.1570	-13.2721	4.6467
2	496	432	1.3617	-1.1753	6.2066	-7.2944	1.3813
3	520	472	1.7297	-0.6015	6.2538	-3.7620	0.3619
4	368	496	2.3704	-0.1473	5.9081	-0.8702	0.0217
5	504	504	3.7647	0.2819	6.2226	1.7543	0.0795
6	432	520	9.1429	0.7943	6.0684	4.8204	0.6310
Amount				**-3.003**	**36.816**	**-18.624**	**7.122**
B	0.1461	*α*	497.300				
A	6.209	*β*	6.846				

J. Menentukan Fungsi dan Laju Kerusakan

Langkah selanjutnya adalah menentukan laju kerusakan apakah naik atau turun yang mana parameternya adalah α = alfa dan β = beta dilihat dari hasil perhitungan sebelumnya.

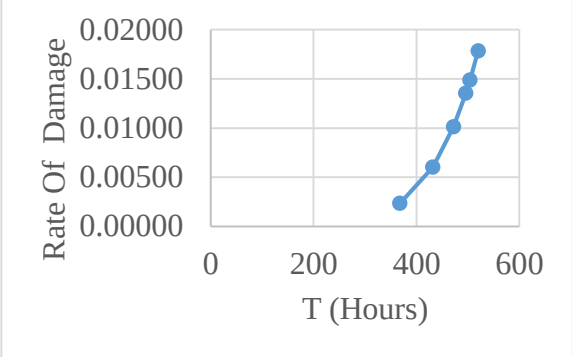


Image 4. Damage rate curve Mechanical Seal

K. Calculating C(tp) Age Substitution

The last step is to perform preventive replacement, replacement of components that have reached the age of t plus the reimbursement of damage if it is important. The purpose of this criterion is to optimize the preventive replacement of components in facilities that have reached the age to minimize replacement costs, in order to get an optimal maintenance intervals to perform preventive maintenance.

Here is a table of the calculation of the time interval component replacement Mechanical Seal along with optimal component replacement costs:

Table 5. Calculation C (top) Component Model Mechanical Seal Replacement Interval

t	R(t)	Cp.R(t)	Cf(1-R(t))	(t+Tp).R(t)	t.f(t)dt	tf(1-R(t))	C(tp)
374	0.86746779	734276533.568	112183171.432	326.602	9×10^{-23}	0.3976	2588567.953
375	0.86519545	732353086.953	114106618.047	326.611	3×10^{-23}	0.4044	2588437.538
376	0.86289350	730404578.000	116055127.000	326.605	9×10^{-23}	0.4113	2588431.105
377	0.86056175	728430843.853	118028861.147	326.583	3×10^{-23}	0.4183	2588549.928
378	0.85820001	726431724.396	120027980.604	326.545	9×10^{-24}	0.4254	2588795.315
379	0.85580809	724407062.367	122052642.633	326.491	2×10^{-24}	0.4326	2589168.608
380	0.85338581	722356703.473	124103001.527	326.420	8×10^{-25}	0.4398	2589671.182
381	0.85093300	720280496.507	126179208.493	326.333	2×10^{-25}	0.4472	2590304.449
382	0.84844948	718178293.471	128281411.529	326.229	6×10^{-26}	0.4547	2591069.856
383	0.84593507	716049949.693	130409755.307	326.108	1×10^{-26}	0.4622	2591968.887

Table 6. Conclusion Results Calculation Of Critical Component Replacement Interval WFI Loop Pump Engineering

Name Of Component	Name Of Machine	Optimal Replacement Time (Hours)	Optimal Replacement Cost (Rp/hours)
Mechanical Seal	*WFI Loop Pump*	377	2588549.928
Bearing	*WFI Loop Pump*	377	3300019.643

After that, the obtained results of calculations C (tp) Mechanical Seal component replacement age is 377 hours / 15.7 days and the cost of replacement is Rp. 2.588.549. As for the components Bearing optimal replacement time is 377 hours / 15.7 days and the cost of replacement is Rp. 3.300.019.

IV. Conclusion

1. Critical component selected is a Mechanical seals and bearings, from the calculation of RPN, Mechanical Seal components are at first priority, it should be of particular concern considering the price of this component is the most expensive of the other components. While the Bearing components that are in the second priority, action component replacements should be done when it sounds noisy.
2. Based on the calculation of the costs incurred for the treatment of critical components Mechanical Seals and Bearings showed a very large number, not to mention the cost of lost profits. The cost of losing gains occurred when the machine was broken when the production process is under way, of course it is very detrimental to the company. Here are the costs incurred for critical components Mechanical Seals and Bearings:

The replacement cost of prevention (Cp) Mechanical Seal:
• Subscription Fee = Rp. 1,300,000

• Cost of Care Technician = Rp. 159 705

• Cost Loss Gain = Rp. 845 million

• Cp = Rp. 846 459 705
The replacement cost of care (Cf) Mechanical Seal:
• Subscription Fee = Rp. 1,300,000

• Cost of Care Technician = Rp. 189 000

• Cost Loss Gain = Rp. 1,000,000,000

• Cf = Rp. 1.001489 billion

The replacement cost of prevention (Cp) Bearing:
• Subscription Fee = Rp. 130.000

• Cost of Care Technician = Rp. 201 285

• Cost Loss Gain = Rp. 1.065 billion

• Cp = Rp. 1065331285

The replacement cost of care (Cf) Bearing:
• Subscription Fee = Rp. 130.000

• Cost of Care Technician = Rp. 165 375

• Cost Loss Gain = Rp. 875 million

• Cf = Rp. 875 295 375

3. Creation of a critical component replacement schedule is done by calculating the cost of critical treatment components selected, and then calculates the value of the parameter $\alpha = \beta$ = alpha and beta distributions for weibull with the value α = 497 300 and β = 6,846 for Mechanical Seal and α and β = 503 579 = 6.2631 for Bearing components. Then with parameters alpha and beta that has been obtained is determined the rate of damage in the curve of the rate of destruction. At this time the calculation of the rate hike and the distribution of damage shows weibull. After that then calculate C (tp) age turn to optimize preventive replacement of components in facilities that have reached the age to minimize replacement costs, in order to get an optimal maintenance intervals to perform preventive maintenance by using the criteria of cost minimization. After that, the obtained results of calculations C (tp) Mechanical Seal component replacement age is 377 hours / 15.7 days and the cost of replacement is Rp. 2.588.549. As for the components Bearing optimal replacement time is 377 hours / 15.7 days and the cost of replacement is Rp. 3.300.019.

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