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Component Replacement Interval Policy based on Downtime Minimization using Age Repaclement Method: A Case Study of Autoclave-035 Machine

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Abstract
PT XYZ is a pharmaceutical company located in West Bandung Regency. The company is engaged in the pharmaceutical sector and manufactures several products. One of the sub-units in this company is the Biological Product division which produces vaccines and sterilizes pharmaceutical equipment. In production activities in this sub-unit requires a steam engine to sterilize livestock machinery, the machine is called an Autoclave. The Autoclave-035 machine uses steam to sterilize so that viruses, bacteria, fungi, and other organisms can die. The Autoclave-035 machine often damage and malfunctions from 2019 to 2021 with 41 times of damage, causing engine downtime because it had not considered the service life of the engine components.. Therefore, it is necessary to analyze and design using the Age Replacement method to obtain the optimal component replacement time interval policy for Autoclave-35 machine. The results of this analysis are the Risk Priority Number values of the two most critical components, namely Drain Chamber and Door Seal. Then based on the Age Replacement model, the optimal service life of the Drain Chamber component is 16 years and the Door Seal is 18,2 years

Keywords: *Downtime Machine, Failure Mode and Effect Analysis, Maintenance, Age Replacement*

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INTRODUCTION

The pharmaceutical industry is one of the industries that has always been in high demand for its production. More and more Indonesian people are aware of the importance of health and medicines (Ministry of Industry, 2021). In producing drugs, the pharmaceutical industry requires a machine as a tool to produce drugs. Machinery is one part of the manufacturing industry that is needed in maintaining productivity in the drug production process. Therefore, machine maintenance and repair are very important to maintain productivity. Every industry wants stable productivity and the products produced are of good quality and according to the standards set by the company. The production process is an activity in the form of cooperation between workers, machines, materials, and funds to increase the usefulness of a production. Process of production can be said to be streamlined if the production process does not experience obstacles in producing an item. By maintaining the ability of the machine so that it can always be used productively and production activities continue, it is necessary to maintain the machine (Lestari et al, 2020).

Maintenance is an activity that is directed at the goal of ensuring the functional continuity of a production system so that the system can be expected to produce the desired output. Amrullah concluded that maintenance is a combination of various activities carried out to maintain production facilities including machines and other production equipment or to repair them to an expected condition (Amrullah, 2019). Good maintenance is maintenance carried out to prevent damage during the production process or ongoing company operations. A well-planned maintenance system is needed to help display manufacturing activity on all machines or equipment second-hand (Nugraha et al, 2021).

Preventive maintenance is maintenance and care activities carried out to prevent unexpected damages and find conditions or circumstances that can cause production facilities to be damaged when used in the production process. Breakdown or corrective maintenance is a maintenance activity that is carried out after the occurrence of a malfunction or abnormality in the facility or equipment so that it cannot function properly and correctly. Breakdown maintenance activities carried out are often referred to as repair or repair activities. Martins et al concluded that machine replacement maintenance has a outstanding effect on the smooth manufaturing process and there is a relationship between improving the quality of machine maintenance on the smooth production process (Martins et al, 2020).

Maintenance management in an industry has an important role in extending the life of the machine and can prevent damage caused by operator error or system failure on the machine. With the maintenance management can prevent the occurrence of damage that can cause some losses in the production process such as the resulting product is by with the standards and quality that should be, not achieving production targets, until the production process stops. These losses can be prevented if the company implements a proper maintenance management system on the production machines it uses (Arsyad & Sultan, 2018).

PT. XYZ is a pharmaceutical company engaged in livestock pharmaceuticals and produces several products located in West Bandung Regency. The main products produced are medicines, vitamins, and livestock vaccines, besides that they also produce livestock equipment to support their main products. This research was conducted at the Biological Product which produces vaccines and sterilizes pharmaceutical equipment. Production activities in this sub-unit require a steam engine to sterilize livestock equipment, the machine is called the Autoclave machine. Autoclave is a steam machine used to sterilize laboratory equipment and personal protective equipment. This steam machine uses steam to sterilize so that viruses, bacteria, fungi, and other organisms can die. Three Autoclave machines often experience downtime and malfunctions from 2019 to 2021. Figure 1. shows a picture of the Autoclave machine at PT. XYZ.

Figure 1. Autoclave Machine

Sterilization is a process of managing equipment or materials that aims to destroy all forms of micro-organisms through physical and chemical processes using a sterilizing machine. The sterilization process occurs by exposing thermal energy in the form of heat, chemicals in the form of liquid/gas, or radiation to an object within a certain time. Autoclave machine has several stages of the process to achieve maximum sterilization. Figure 2. shows the steps for carrying out the sterilization process on the Autoclave-035 machine.

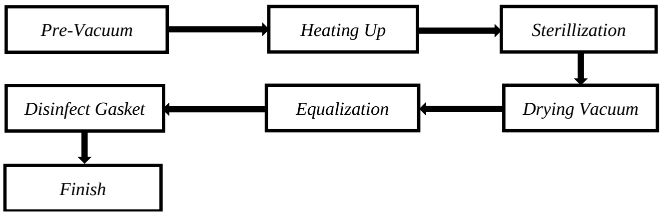

Figure 2. Stages of the Sterilization Process on the Autoclave Machine

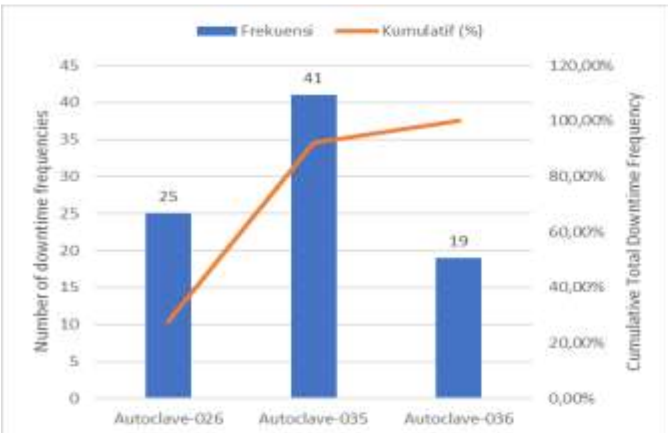

Figure 3. Total Downtime Frequency of Autoclave Machine

Figure 3. shows the frequency of downtime from the three Autoclave machines, from the data it can be seen that the Autoclave-035 engine experienced the most downtime based on historical damage data as much as 41 times. The downtime disrupted the sterilization process for pharmaceutical equipment and made other Autoclave machines have to work hard to meet the existing sterilization targets. This shows that it is important to maintain and repair the Autoclave-035 machine to reduce downtime, so that the effectiveness and productivity of the Autoclave machine can be increased and stabilized, and there are no more machines that experience interference when the sterilization process is running. So far, the maintenance carried out is still not effective because the maintenance carried out has not taken into account the age of use of the engine components.

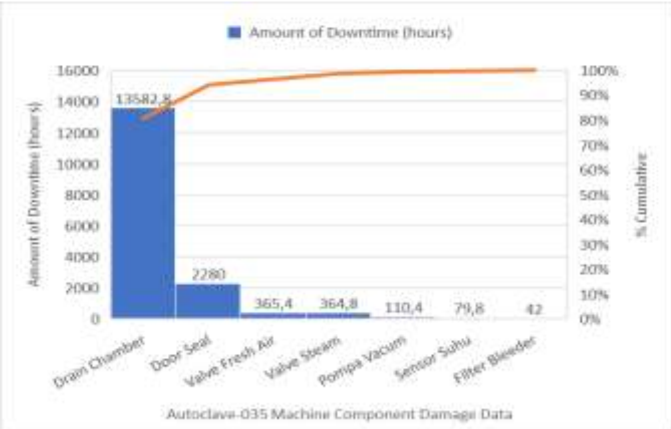

Figure 4. Total Downtime of Autoclave-035 Machine Component

Figure 4. Shows data on damage to the Autoclave-035 machine component and the amount of downtime. This shows that preventive maintenance is the right way to reduce losses from damage caused by the Autoclave machine. Therefore, the purpose of this study is to make a policy proposal for the maintenance time interval for the most critical components of the Autoclave-035 machine, namely the Drain Chamber and Door Seal components and the most optimal component replacement time interval policy for the two most critical components. In making the policy, the researcher uses the Age Replacement method to determine the most optimal component replacement time interval.

METHODS

Maintenance is a very important factor to maintain the ability and reliability of an equipment or machine which has the aim of ensuring a production system can take place functionally (Sariyusda, 2018). Such maintenance can be effective if there is a maintenance time interval to carry out these activities. The steps for determining the most optimal maintenance time interval and component replacement interval are shown in Figure 5.

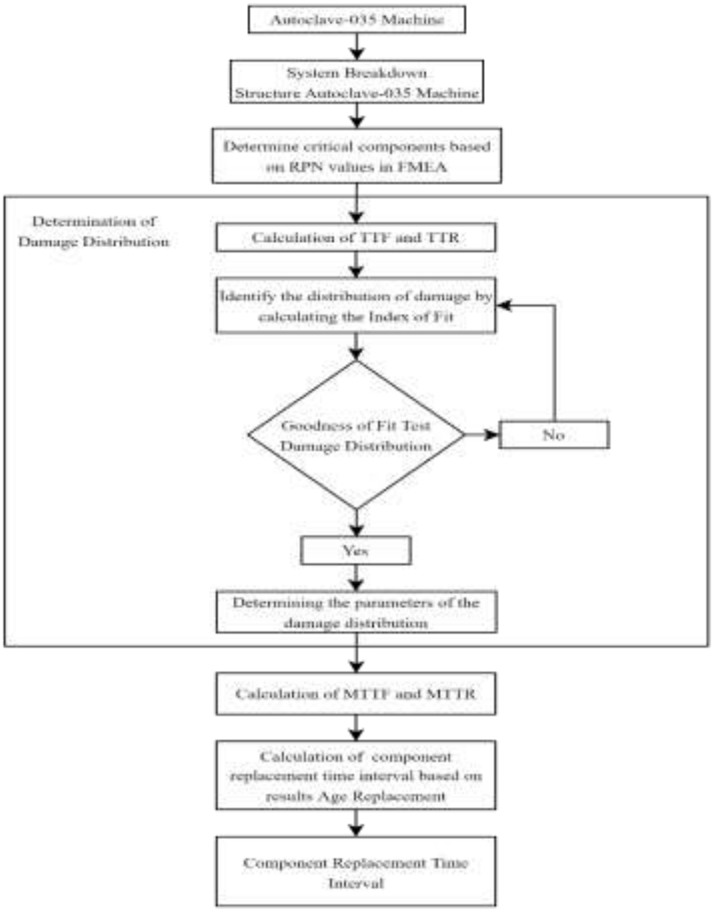

Figure 5. Research Methodology

The earliest pace in researching the Autoclave-035 machine is to create a system breakdown structure (SBS), the goal is to identify components, subsystems and within a system, breakdown subsystems into smaller components systematically and hierarchically and carry out a continuous improvement process for component identification (Nasution & Bazin, 2017). Furthermore, to determine the critical components on the Autoclave-035 machine using FMEA. Failure Mode and Effect Analysis (FMEA) is the process of identifying the failure of a component that can cause system failure (Mascia et al, 2020). One of the most widely used techniques for assessing system quality. FMEA includes identification, namely:

1. Failure Cause, the cause of the occurrence of the failure mode.
2. Failure Effect, the impact of the failure mode.

The application of FMEA is done first by looking for the values of severity, occurrence, and detection. The priority of the failure mode can be set according to the risk priority number (RPN) by multiplying the severity (1–10), occurrence (1–10) and detection rating (1–10). The Risk Priority Number is determined by the following equation:

$$RPN = S \times O \times D \quad (1)$$

After obtaining the most critical components in the Autoclave-035 machine, move to quantitative measurements, such as calculating Time to Failure (TTF) and Time to Repair (TTR). In determining the distribution of damage, it can be determined by the largest Index of Fit value, then tested with Goodness of Fit. According to Ebeling (1997), the method of identifying the distribution used to obtain the length of time for repair and failure time is by using least-square curve fitting. Least-square curve fitting is used to think of in connection with the distribution of a component using the largest index of fit value (Ulfah et al, 2021). The following equation shows the Least-square curve fitting formula (Walpole, 1995):

Median Rank:
$F(t_i) = (i-0.3)/(n+0.4)$ (2)

Index of Fit:
$$r = \frac{n\sum_{i=1}^{n} x_i y_i - (\sum_{i=1}^{n} x_i)(\sum_{i=1}^{n} y_i)}{\sqrt{\left(n\left(\sum_{i=1}^{n} x_i^2\right) - (\sum_{i=1}^{n} x_i)^2\right)\left(n\left(\sum_{i=1}^{n} y_i^2\right) - (\sum_{i=1}^{n} y_i)^2\right)}} \quad (3)$$

After determining the selected distribution, the distribution is tested using the Goodness of Fit test through Minitab 19 software. The goal is to ensure that the calculated distribution is in accordance with the existing theoretical value, then a verification and validation process is carried out using the Goodness of Fit test (Agu & Francis, 2018). Furthermore, the TTF and TTR data were determined by the selected distribution parameters using the AvSim+ 9.0 software. The calculation will proceed to Mean Time to Failure (MTTF) and Mean Time to Repair (MTTR). Mean Time to Failure (MTTF) is the average time interval of damage from the distribution of damage that is used to predict the occurrence of damage, while Mean Time to Repair (MTTR) is the average time interval of damage from the probability of repair time used to predict repairs when damage occurs (Eliska et al, 2017).

Normal Distribution:
MTTF / MTTR $= \mu$ (4)

Exponential Distribution
MTTF / MTTR $= 1/\lambda$ (5)

Weibull Distribution
MTTF / MTTR $= \eta\Gamma(1+1/\beta)$ (6)
Where:
λ = Failure rate
η = Distribution parameters
Γ = Gamma function
β = Weibull distribution parameters

Age replacement is a preventive replacement that is carried out depending on the life of the component and has the aim of knowing and determining preventive replacement based on the optimal age of the component. Calculation of the component replacement time interval by trial and error to get the lowest downtime (D(tp)) value (Prawiro, 2017). The following is an age replacement formulation with the criteria for minimizing downtime (Sukendar et al, 2020):

$$D(tp) = \frac{Tp \cdot R(tp) + Tf\left(1 - R(tp)\right)}{(tp + Tp) \cdot R(tp) + \{\left(M(tp)\right) + Tf \cdot \left(1 - R(tp)\right)\}} \quad (7)$$

Where:

D(tp) = Total downtime per unit time for preventive replacement
R(tp) = Reliability value at tp
M(tp) = Average time of occurrence of a damage if preventive action occurs when tp
tp = Preventive time interval
Tp = Downtime due to preventive measures
Tf = Downtime due to component failure

RESULTS & DISCUSSION

Results

Selection of Critically Component

The first stage is to find out the most fault-finding components in the Autoclave-035 machine by making a system breakdown structure first. System Breakdown Structure (SBS) is a method for analyzing, documenting and communicating the structure of a machine or equipment from the system, subsystem, and component levels in detail (Angelina et al, 2020). SBS Autoclave-035 machine can be seen in Figure 6.

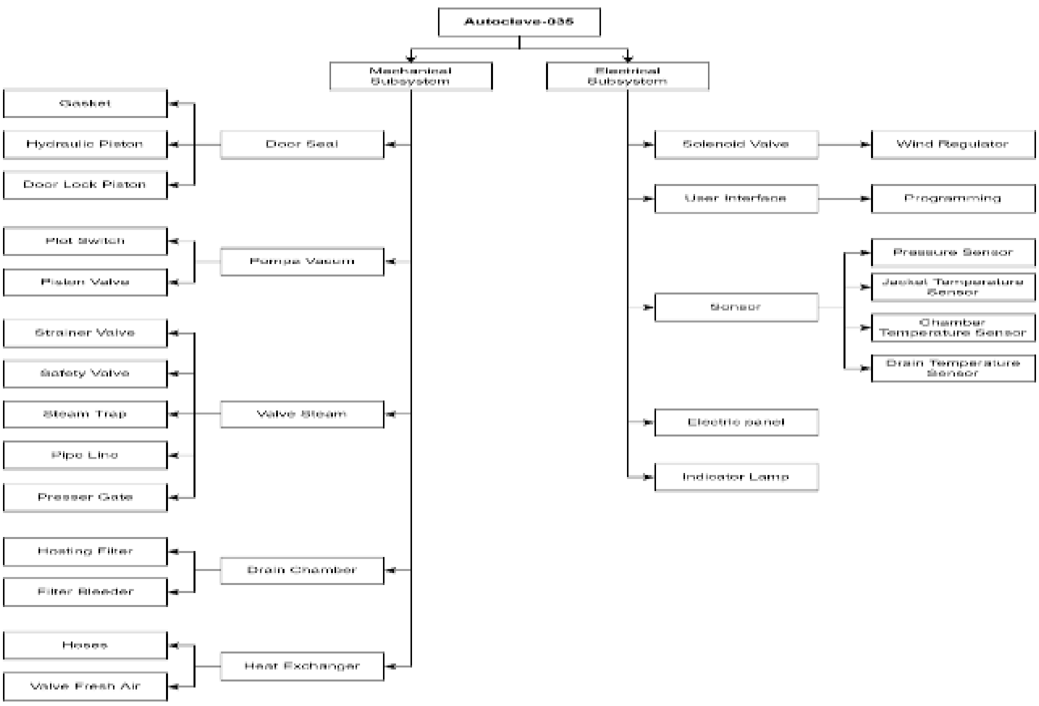

Figure 6. SBS Autoclave-35 Machine

The selection of critical components aims to determine what components will be the focus of research. The method used in determining these critical components is to make a Failure Mode and Effect Analysis (FMEA) and determine the Risk Priority Number (RPN) value for each component of the Autoclave-035 machine. The FMEA method was chosen because this method has the advantage that it can accurately analyze failures based on historical data (Aprianto et al, 2019). The RPN value consists of three criteria based on the failure mode, namely severity, occurrence, and detection (Pardiyono, 2020). The largest RPN value was then selected to be the most critical component in the Autoclave-035 engine. In this study, it is known that the highest RPN is in the Drain Chamber component of 200 and Door Seal of 210. Table 1. is an example of an FMEA analysis table and the RPN value for critical components on the Autoclave-035 machine.

Table 1. Failure Mode and Effect Analysis (FMEA) Autoclave-035 Machine

No.	Equipment	Function (F)	Function Failure (FF)	Failure Mode (FM)	Effect of Failure	FMEA			
						S	O	D	RPN
1	Door Seal	(1) Closing door to lock into the gasket and protect laboratory equipment that has entered the sterile room	(1) Door Seal doesn't lock tightly and often goes off track when closed	(1) Door Lock Piston is loose due to high frequency of use	(1) A leak occurs during the pre-vacuum process and cannot carry out the next sterilization process or is called Error Gasket Failure	7	10	3	210
				(2) Oil fluid and fluid fluid on the Hydraulic Piston is always dirty					
				(3) The connecting gasket					

				between the door seal and the engine body is broken					
2	Drain Chamber	(4) Channeling drying air in the chamber to carry out the drying stage	(4) Unable to supply cooling air to chamber	(1) Hosting filter in drain chamber is often dirty (2) The bleeder filter is brittle	(4) Unable to filter dirty air resulting from sterilization, causing sterilization not optimal and an error occurs during the sterilization process or called Error Sterile Timeout	5	5	8	200

Determining the Distribution and Parameters of TTF and TTR Data

Through the calculation of the Index of Fit, the distribution of TTF and TTR data on the Door Seal and Drain Chamber components can be determined. This method compares the largest Index of Fit values from the three distributions, to be specific the Normal distributions, Exponential distributions, and Weibull distributions. In the Door Seal and Drain Chamber TTF data, the largest Index of Fit value results in the Weibull distribution. In the TTR Door Seal and Drain Chamber data, the largest Index of Fit value results is the Weibull distribution. The results of the calculation of the distribution TTF and TTR data can be seen in Table 2., Table 3., Table 4., and Table 5.

Table 2. Calculation of the Index of Fit Distribution of Weibull TTF Door Seal

No	t_i	$x_i = \ln t_i$	x_i^2	$F(t_i)$	y_i	y_i^2	$x_i.y_i$
1	149,50	5,01	25,07	0,09459	-2,30888	5,33093	-11,56
2	2942,00	7,99	63,79	0,22973	-1,34318	1,80414	-10,73
3	408,50	6,01	36,15	0,36486	-0,78984	0,62385	-4,75
4	1702,50	7,44	55,35	0,50000	-0,36651	0,13433	-2,73
5	7751,50	8,96	80,20	0,63514	0,00819	0,00007	0,07
6	2,00	0,69	0,48	0,77027	0,38584	0,14887	0,27
7	4174,50	8,34	69,50	0,90541	0,85788	0,73596	7,15
TOTAL	**17130,50**	**44,43**	**330,5**	**3,50**	**-3,56**	**8,78**	**-22,27**
						$(\Sigma x_i)^2$	**1974,20**
						$(\Sigma y_i)^2$	**12,65**
						r	**0,38243**

Table 3. Calculation of the Index of Fit Distribution of Weibull TTF Drain Chamber

No	t_i	$x_i = \ln t_i$	x_i^2	$F(t_i)$	y_i	y_i^2	$x_i.y_i$
1	13034,17	9,48	89,78	0,06140	-2,75877	7,61082	-26,14
2	55,58	4,02	16,14	0,14912	-1,82333	3,32452	-7,33
3	1384,53	7,23	52,32	0,23684	-1,30826	1,71154	-9,46
4	1333,58	7,20	51,78	0,32456	-0,93549	0,87514	-6,73
5	570,83	6,35	40,29	0,41228	-0,63204	0,39948	-4,01
6	2213,17	7,70	59,32	0,50000	-0,36651	0,13433	-2,82
7	302,58	5,71	32,63	0,58772	-0,12098	0,01464	-0,69
8	743,58	6,61	43,71	0,67544	0,11803	0,01393	0,78
9	1747,92	7,47	55,74	0,76316	0,36489	0,13315	2,72

10	15,17	2,72	7,39	0,85088	0,64342	0,41399	1,75
11	103,17	4,64	21,50	0,93860	1,02614	1,05297	4,76
TOTAL	**21504,28**	**69,12**	**470,61**	**5,50**	**-5,79**	**15,68**	**-47,17**
						$(\Sigma x_i)^2$	**4777,12**
						$(\Sigma y_i)^2$	**33,56**
						r	**-0.50302**

Table 4. Calculation of the Index of Fit Distribution of Weibull TTR Door Seal

No	t_i	$x_i = \ln t_i$	x_i^2	$F(t_i)$	y_i	y_i^2	$x_i.y_i$
1	3,00	1,10	1,21	0,08333	-2,4417	5,9620	-2,6825
2	1,00	0,00	0,00	0,20238	-1,4867	2,2102	0,0000
3	1,00	0,00	0,00	0,32143	-0,9474	0,8975	0,0000
4	1,00	0,00	0,00	0,44048	-0,5436	0,2955	0,0000
5	25,00	3,22	10,36	0,55952	-0,1986	0,0394	-0,6392
6	2,00	0,69	0,48	0,67857	0,1266	0,0160	0,0878
7	0,50	-0,69	0,48	0,79762	0,4685	0,2195	-0,3247
8	5,00	1,61	2,59	0,91667	0,9102	0,8285	1,4650
TOTAL	**38,50**	**5,93**	**15,12**	**4,00**	**-4,11**	**10,47**	**-2,09**
						$(\Sigma x_i)^2$	**35,13**
						$(\Sigma y_i)^2$	**16,91**
						r	**0,10068**

Table 5. Calculation of the Index of Fit Distribution of Weibull TTR Drain Chamber

No	t_i	$x_i = \ln t_i$	x_i^2	$F(t_i)$	y_i	y_i^2	$x_i.y_i$
1	215,00	5,37	28,84	0,05645	-2,8455	8,0966	-15,2819
2	0,83	-0,18	0,03	0,13710	-1,9142	3,6643	0,3490
3	2,00	0,69	0,48	0,21774	-1,4042	1,9717	-0,9733

4	0,05	-3,00	8,97	0,29839	-1,0374	1,0762	3,1078
5	0,42	-0,88	0,77	0,37903	-0,7413	0,5496	0,6490
6	3,00	1,10	1,21	0,45968	-0,4852	0,2354	-0,5330
7	0,83	-0,18	0,03	0,54032	-0,2520	0,0635	0,0459
8	1,75	0,56	0,31	0,62097	-0,0303	0,0009	-0,0170
9	1,58	0,46	0,21	0,70161	0,1901	0,0361	0,0874
10	1,00	0,00	0,00	0,78226	0,4216	0,1778	0,0000
11	0,33	-1,10	1,21	0,86290	0,6867	0,4715	-0,7544
12	0,50	-0,69	0,48	0,94355	1,0558	1,1148	-0,7318
TOTAL	**227,30**	**2,15**	**42,55**	**6,00**	**-6,36**	**17,46**	**-14,05**
						$(\Sigma x_i)^2$	**4,64**
						$(\Sigma y_i)^2$	**40,40**
						r	**-0,52969**

After that, the results of the Index of Fit calculation can be verified and validated using the minitab 19 software with 95% confidence level. Table 6. and Table 7. shows the selected distributions for Time to Failure and Time to Repair of the Door Seal and Drain Chamber components.

Table 6. Goodness of Fit TTF test results

Component	Distribution	AD	P-Value	Preferred Distribution	Verification Results
Drain Chamber	Normal	2.204	< 0.005	Weibull distribution due to the small-scale AD value and the largest P-Value	Weibull distribution verified
	Exponential	1.933	0.008		
	Weibull	0.251	> 0.250		
Door Seal	Normal	0.422	0.225	Weibull distribution due to the small-scale AD value	Weibull distribution verified
	Exponential	1.159	0.060		

	Weibull	0.303	> 0.250	and the largest P-Value	

Table 7. Goodness of Fit TTR test results

Component	Distribution	AD	P-Value	Preferred Distribution	Verification Results
Drain Chamber	Normal	3.890	< 0.005	Weibull distribution due to the small-scale AD value and the largest P-Value	Weibull distribution verified
	Exponential	16.690	< 0.003		
	Weibull	1.460	< 0.010		
Door Seal	Normal	1.617	< 0.005	Weibull distribution due to the small-scale AD value and the largest P-Value	Weibull distribution verified
	Exponential	1.261	0.046		
	Weibull	0.640	0.080		

Furthermore, after all data has been verified and validated, then to determine the parameters of each TTF and TTR data for Door Seal and Drain Chamber components using AvSim+ 9.0 software. Table 8. and Table 9. shows the results of the selected distribution parameters:

Table 8. Result of TTF data distribution parameters

Component	Distribution	Parameter	
Drain Chamber	2-Parameter Weibull	η	1325.17
		β	0.581302
Door Seal	2-Parameter Weibull	η	2292.09
		β	0.365575

Table 9. Result of TTR data distribution parameters

Component	Distribution	Parameter	
Drain Chamber	2-Parameter Weibull	η	3.507
		β	0.492119
Door Seal	2-Parameter Weibull	η	4.03696
		β	0.785284

Calculation of MTTF and MTTR

Mean Time to Failure (MTTF) is the average time interval of malfunction from the distribution of damage that is used to predict the occurrence of damage. Table 10. shows the MTTF value.

Table 10. MTTF

Component	Distribution	Parameter		MTTF (Hours)
Drain Chamber	2-Parameter Weibull	η	1325.17	2080.5
		β	0.581302	
Door Seal	2-Parameter Weibull	η	2292.09	3088.61
		β	0.365575	

Mean Time to Repair (MTTR) is the average time interval of malfunction from the probability of repair time used to predict repairs when the damage occurs. Table 11. shows the MTTR value.

Table 11. MTTR

Component	Distribution	Parameter		MTTF (Hours)
Drain Chamber	2-Parameter Weibull	η	3.507	7,23
		β	0.492119	
Door Seal	2-Parameter Weibull	η	4.03696	4,64
		β	0.785284	

Age Replacement Calculation

After knowing the MTTF and MTTR values as well as the appropriate distribution with damage data and repair data for each component, then the Drain Chamber and Door Seal components are calculated using the Age Replacement model to determine and determine preventive replacement based on the optimal age of the component. Calculation of the component replacement time interval by trial and error to get the lowest downtime (D(tp)) value. The following is a calculation of the component replacement time interval using the Age Replacement method.

1. Door Seal
   - Preventive Maintenance = 1544,31 hours
   - Tp (2 x MTTR) = 9,28 hours
   - Tf (MTTR) = 4,64 hours
   - μ $= \frac{\sum_{i=1}^{n} ln(t_i)}{n}$ (9)
     $= \frac{44.43}{7}$
     = **6,35**
   - tmed $= e^{\mu}$ (10)
     $= e^{6.35}$
     = **571,03**
   - S $= \sqrt{\frac{\sum_{i=1}^{n} ln(t_i)}{n}}$ (11)

$= \sqrt{\frac{44.43}{7}}$

= **2,52**

- F(tp) $= \Phi\left(\frac{1}{S} ln \frac{tp}{tmed}\right)$ (12)

  F(157211) $= \Phi\left(\frac{1}{2.52} ln \frac{157211}{571.03}\right)$

  = **0,987104**
- R(tp) = 1 – F(tp) (13)

  = 1 – 0.987104

  = **0,012896**
- M(tp)+Tf $= \frac{Preventive\ Maintenance}{F(tp)}$+Tf (14)

  $= \frac{1544.3}{0.987104}$ + 4.64

  = **1569,1207**
- D(tp) $= \frac{Tp \cdot R(tp)+Tf(1-R(tp))}{(tp+Tp)\cdot R(tp)+\{(M(tp))+Tf\cdot(1-R(tp))\}}$ (15)

  = **0,001314120372122**

Table 12. Calculating the Age Replacement of Door Seal Components

tp (hours)	R(tp)	F(tp)	tp + Tp	M(tp) + tf	D(tp)
157000	0,012914	0,987086	157009,3	1569,1488	0,0013141204808429
157100	0,012905	0,987095	157109,3	1569,1355	0,0013141204022874
157200	0,012897	0,987103	157209,3	1569,1222	0,0013141203724368
157210	0,012896	0,987104	157219,3	1569,1208	0,0013141203721268
157211	**0,012896**	**0,987104**	**157220,3**	**1569,1207**	**0,0013141203721226**
157220	0,012895	0,987105	157229,3	1569,1195	0,0013141203723029
157230	0,012895	0,987105	157239,3	1569,1182	0,0013141203729648
157240	0,012894	0,987106	157249,3	1569,1168	0,0013141203741125
157250	0,012893	0,987107	157259,3	1569,1155	0,0013141203757459
				Min(Dtp)	**0,0013141203721226**

Based on Table 12. the minimum downtime or D(tp) value is 0.0013141203721226. The D(tp) is at tp = 157211 hours or the equivalent of 18,2 years.

2. Drain Chamber
   - Preventive MTC =1040,25 hours
   - Tp (2 x MTTR) = 14,46 hours
   - Tf (MTTR) = 7,23 hours
   - µ $= \frac{\sum_{i=1}^{n} ln(t_i)}{n}$ (16)

     $= \frac{69.12}{11}$

     = **6,28**

- S $= \sqrt{\frac{\sum_{i=1}^{n} \ln(t_i)}{n}}$ (17)
  $= \sqrt{\frac{69.12}{11}}$
  = **2,51**

- tmed $= e^{\mu}$ (18)
  $= e^{6.28}$
  = **535,57**
- F(tp) $= \Phi\left(\frac{1}{S} ln \frac{tp}{tmed}\right)$ (19)
  F(138361) $= \Phi\left(\frac{1}{2.51} ln \frac{138361}{535.57}\right)$
  = **0,986547**
- R(tp) = 1 – F(tp) (20)
  = 1 – 0.986547
  = **0,013453**
- M(tp)+Tf $= \frac{Preventive\ Maintenance}{F(tp)}$ +Tf (21)
  $= \frac{1040.25}{0.986547}$ + 7.23
  = **1061,6658**
- D(tp) $= \frac{Tp \cdot R(tp) + Tf(1-R(tp))}{(tp+Tp) \cdot R(tp) + \{(M(tp)) + Tf \cdot (1-R(tp))\}}$ (22)
  = **0,0025188133088059**

Table 13. Calculating the Age Replacement of Drain Chamber Components

tp (hours)	R(tp)	F(tp)	tp + Tp	M(tp) + tf	D(tp)
138330	0,013457	0,986543	138344,5	1061,6691	0,0025188133153481
138340	0,013456	0,986544	138354,5	1061,6681	0,0025188133118170
138350	0,013455	0,986545	138364,5	1061,6670	0,0025188133096391
138360	0,013454	0,986546	138374,5	1061,6660	0,0025188133088140
138361	**0,013453**	**0,986547**	**138375,5**	**1061,6658**	**0,0025188133088059**
138370	0,013453	0,986547	138384,5	1061,6649	0,0025188133093414
138380	0,013452	0,986548	138394,5	1061,6638	0,0025188133112209
138390	0,013451	0,986549	138404,5	1061,6628	0,0025188133144524
138400	0,013450	0,986550	138414,5	1061,6617	0,0025188133190355
				Min D(tp)	**0,0025188133088059**

Based on Table 13. the minimum downtime or D(tp) value is 0.0025188133088059. The D(tp) is at tp = 138361 hours or the equivalent of 16 years.

Component Replacement Policy based on Age Replacement

The calculation of the component replacement time interval using the age replacement method is based on the optimal service life of the component and is based on preventive maintenance activities carried out on the component. Table 14. shows the results of calculating the optimal replacement time for component.

Table 14. The Most Optimal Component Replacement Time Interval

Component	Preventive Maintenance		Component Replacement Time Interval (hours)	Component Replacement Time Interval (year)
Door Seal	1544.31 hours	2.2 month	157211	18.2
Drain Chamber	1040.25 hours	1.5 month	138361	16.0

In this research, it was found that the time to replace the most optimal component based on its service life was that the Door Seal component could work for 18,2 years. Meanwhile, the Drain Chamber component can work optimally for 16 years.

DISCUSSION

The RPN value in FMEA is obtained from determining the Severity, Occurrence, and Detection values. The order of results obtained from filling out the FMEA table and determining the highest RPN value is Door Seal with an RPN value of 210, Drain Chamber with an RPN value of 200, Vacuum Pumps with an RPN value of 192, Valve Steam with an RPN value of 128, and Valve Fresh Air with an RPN value of 60. Based on the results of the RPN value, the two components that have the highest risk priority are the Door Seal and Drain Chamber components. Door Seal has a function as a closing door to lock into the gasket and protect laboratory equipment to be sterilized. The malfunction that occurs in the Door seal component is that it cannot lock tightly on the gasket and goes out of line when closing due to the component has loosened due to age of use and the locking gasket is loose. This malfunction causes a leak in the sterile door during the pre-vacuum process and cannot increase the steam temperature or can be called Error Gasket Failure. Therefore, the Door Seal gets a Severity (S) value of 7 which means that failure will result in engine disturbances and/or decreased performance on the Autoclave-035 engine system. The Occurrence (O) value is 10, which means a high probability of failure during the machine operating time interval, which is about once a week. The Detection (D) value gets a value of 3 which means a high probability that defects will be detected. The Drain Chamber has a function as a channel for drying air in the chamber to carry out the drying stage. The malfunction that occurs in this component is that it cannot channel cooling air into the chamber caused by dirty air filters and sensors in the drain chamber. This malfunction causes an error in the middle of the sterilization process or can be called the Sterile Timeout Error. Therefore, the Drain Chamber gets a Severity (S) value of 5 which means that failure will result in a slight engine disturbance and/or a slight decrease in performance in the Autoclave-035 system. For Occurrence (O) get a value of 5 which means the probability of occasional failure during the machine operating time interval which is about once a month. For Detection (D) get a value of 8 which means a low probability that defects will be detected.

The Age Replacement model is a preventive replacement that is carried out depending on the life of the component with the criteria of minimizing the possibility of downtime that will occur. In the Autoclave-035 machine there are several components that compose it such as Sterile Door Seals, Vacuum Pumps, Steam Valves, Drain Chambers, and Heat Exchangers. After going through the secondary data identification stage, Failure Mode and Effect Analysis, Logic Tree Analysis, and Reliability Centered Maintenance II, it was found that there are only two components that are the most critical or the most frequent and most damaged, namely the Door Seal Sterile and Drain Chamber components. Therefore, the Age Replacement model is proposed only for these two components. Based on the results of a trial and error calculation using the Microsoft Excel application, it was found that the Door Seal Sterile component can work optimally within a period of 18.2 years with an estimated operating hour / day of 24 hours. Meanwhile, the Drain Chamber component can work optimally for a period of 16 years with an estimated operating hour/day of 24 hours.

CONCLUSION

The conclusion of this study is that based on analysis using Failure Mode and Effect Analysis (FMEA) by determining the value of the Risk Priority Number (RPN), the most critical selected subsystem of the Autoclave-035 machine is the mechanical subsystem with two critical components, namely Drain Chamber and Door Seal. Based on the results of data processing using the Age Replacement method, the most optimal component replacement time for the two most critical components, namely Drain Chamber can work optimally within a period of 18.2 years. And Door Seal can work optimally within a period of 16 years. After this time period has elapsed, the component must be replaced.

CONFLICT OF INTEREST

Concerning the research, authorship, and publication of this paper, the author(s) reported no potential conflicts of interest.

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