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Quality Control Analysis on 100ML Bottle Products with Fault Tree Analysis Method Approach and Failur Mode and Effect Analysis

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ABSTRACT

This study analyzes quality control implementation for 100ml bottle production at PT. X using Fault Tree Analysis (FTA) and Failure Mode and Effect Analysis (FMEA) methods. Data collected from February 15-29, 2021, revealed a 1% defect rate (7,110 bottles) from total production (788,700 bottles). Pareto analysis identified three dominant defects: Thick-Thin Walls (30%), Oil Stains (28%), and Fraying (13%), accounting for 71% of total defects. FTA root cause analysis traced these defects to human factors (operator errors), machine issues (uneven cavity temperature, misaligned components), and material problems (plastic mixing inconsistencies). FMEA assessment prioritized corrective actions based on Risk Priority Numbers (RPN), highlighting critical failures: uneven cavity diameter (RPN=432), oil-contaminated blue cores (RPN=384), and faulty thermo-couples (RPN=280). Proposed improvements include scheduled cavity maintenance, compressor overhauls for clean air supply, and thermo-couples calibration during product changeovers. The integrated FTA-FMEA approach demonstrates effectiveness in pinpointing systemic quality issues in blow molding processes, providing actionable insights to reduce defects by 40-50%. This research contributes to operational excellence in plastic manufacturing by combining defect visualization (Pareto) with causal-depth analysis (FTA) and risk quantification (FMEA).

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1. Introduction

The industrial world currently plays an important role in the production era in Indonesia. In the face of fierce competition in the industrial world, companies compete with each other in providing good service and quality of their production. Companies that have high competitiveness that can survive in the business of increasing profits (Latifah & Rosyidi, 2018). In the industrial world, product quality and productivity are the key to success for various production systems, both of which are very important corporate performance criteria for profit-oriented companies (Prihandoko et al., 2020) .

PT. X is one of the manufacturing companies engaged in the processing industry of plastic seeds into various products made of plastic. It has 5 factories spread across Indonesia, China and Singapore, namely in Pandaan-East Java, Cikarang-West Java, Tangerang Banten, Shanghai Paragon Plastic Packaging Co. Ltd. (Shanghai), and Hefei Paragon Plastic Packaging Co. Ltd. (Hefei). This industry is a job order industry that manages plastic seeds through the production process into a product desired by customers. The molding of plastic products is carried out in two ways, namely blow molding is the process of processing plastic seeds into a product by blowing air in the plastic to be printed. Meanwhile, injection molding is the process of processing plastic seeds into a product by injection. The products produced are toothbrushes, gallons, bottle caps, spool handsaplast, poison bottles and so on. The marketing method of PT. X is done directly, namely producing according to orders from customers which until now have not been limited to only domestic and also accepting orders from abroad.

Based on the data obtained by the author during the TanggaL from February 15, 2021 to February 29, 2021, PT. X has quality-related problems, namely in 100 ml bottle products. In these products from February 15, 2020 to February 29, there was a defect of 7,110 (1%) 100 ml bottles out of a total production of 788700 (100%) 100 ml bottles.

The types of defects that occur in the bottle product are Thick Thin, Dirty Oil, Hair, Dirty Material, Gate Spotting, Deformation, Folding, and so on. Therefore, in this defect problem, it is necessary to make improvements with the aim of optimizing the quality of the 100 ml bottle product. There are several quality control methods that can be used to reduce defective products. One of the methods that can be used is FMEA (Failure Mode and Effect Analysis) and FTA (Fault Tree Analysis). FMEA (Failure Mode and Effect Analysis) is a method used to define, identify, and eliminate defects and problems in the production process, both known and potential problems in the system (Yuamita, 2022). Meanwhile, FTA (Fault Tree Analysis) is an analysis method that can analyze system failures, can look for aspects of the system that are involved in major failures, and find the causes of product defects in the production process (Alfianto, 2019). For this purpose, an analysis of the defect was carried out in this study with the aim of knowing in detail the cause of the defect in the 100 ml bottle product using the FMEA (Failure Mode and Effect Analysis) and FTA (Fault Tree Analysis) methods.

Based on the description above, the formulation of the problem that will be studied in this study is whether the largest type of defect that occurs in 100 ml bottle products at PT. X ?. What are the factors that cause the largest defect in 100 ml bottle products at PT. X ?. What are the consequences of the failure of the 100 ml bottle product process with FMEA at PT. X ?

Based on the formulation of the problem above, the research objective to be achieved is to identify the largest type of defect in 100 ml bottle products through seven tools at PT. X. To find out the factors that cause the largest defect in 100 ml bottle products through FTA at PT. X. Identify the consequences of the failure of the 100 ml bottle product process with FMEA at PT. X.

Based on the research objectives above, the benefit of the research obtained is that the Company can find out the largest type of defect in 100 ml bottle products through seven tools at PT. X. The Company can find out the factors that cause the largest defect in 100 ml bottle products through FTA at PT. X. The Company can find out the consequences of the failure of the 100 ml bottle product process with FMEA at PT. X.

1. Literature Review

FTA (Fault Tree Analysis).

The FTA (Fault Tree Analysis) method is an analysis technique, analyzing the environment, and operations to find a way/solution to the problems that arise (Yagturi & Hartati, 2022). FTA (Fault Tree Analysis) is a graphical model of parallel variations and combinations of errors that arise as a result of defining an existing problem (Dwiano et al., 2021). This method is carried out with a top-down approach, which begins with the assumption of failure from the top event and then details the causes of a top event to a root cause.

FMEA (Failure Mode and Effect Analysis).

FMEA is an engineering technique used to determine, identify, and eliminate known failures, problems, errors, and the like from a system, design, process, and/or service before reaching consumers (Hanif et al., 2015). FMEA is used to identify the sources and root causes of a qualitative problem. A failure mode is anything that includes a defect or failure in design, a condition outside the specified limits, or a change in a product that causes the impaired function of the product (Rahman & Perdana, 2021). There are several reasons why it is necessary to use FMEA, including that it is better to prevent failures than to correct failures, increase the chances of being able to detect a failure, identify the biggest causes of failure and eliminate it, reduce the chance of failure and build the quality of products and processes. The three main variables in FMEA (Failure Mode and Effect Analysis) are as follows:

a. Severity, is a way to identify the potential impact of a failure by grading the failure according to the consequences it causes..
b. Occurrence is the possibility that the cause may occur and result in a form of failure during the lifetime of the product's use. Determining the Occurrenceance ranking is ranked 1 to 10. Rank 1 is a low incidence rate (not frequent) and rank 10 is a high incidence rate (frequent).
c. Detection is a way (procedure), test, or analysis to prevent failures in a service, process, or customer. In determining ranking detection, it consists of rankings 1 to 10. Rank 1 is the level of control that can detect failure (always can) and rank 10 is the level of control that cannot detect failure.

RPN (Risk Priority Number) or risk priority number is a mathematical product of the severity of the effects, the possibility that the occurrence of causes will cause failures related to effects (Occurrence), and the ability to detect failures before they occur to the customer (Detection). The RPN (Risk Priority Number) equation is shown by the following equation:

$$RPN = Severity \times Occurrenceance \times Detection$$

1. Methodology

Research Object and Location

This research was conducted on a 100ml bottle production line at PT. X which is located in Pandaan, East Java. The object of the study was focused on the blow molding process by analyzing product defects during the period of 15-29 February 2021. The selection of the location was based on a high defect rate of 1% (7,110 bottles) of the total production of 788,700 bottles.

Data Types and Sources

The research uses a mixed-method approach, the data used in this study are:

a. Primary data, in the form of direct observation results of the blow molding process including the type of defect and the amount of production. In addition, interviews were also conducted with the machine operator and the QA team to formulate potential causes and recommendations for necessary corrective actions.

b. Secondary data, in the form of technical specifications of AISA blow molding machines, and Standard Operating Procedures (SOP) of production

Research Tools and Instruments

a. Check Sheet for defect recapitulation
b. Pareto Chart (Using the 80/20 principle):
Sorting from the highest frequency

$$Persentase\ kumulatif\ = \left(\frac{\sum Defect\ tertinggi}{Total\ defect}\right) x\ 100\%$$

c. Fault Tree Analysis (FTA) with AND/OR gate logic
d. Failure Mode and Effect Analysis (FMEA) with the calculation:

$$RPN\ = Severity\ (S) \times Occurrence\ (O) \times Detection\ (D)$$

Rating scale:
Severity (1-10): Impact of the defect on the product
Occurrence (1-10): The frequency of occurrence of the cause
Detection (1-10): Detection capability before reaching the customer

1. Results and Discussion

In collecting this data, there are two parts of the outline, namely about the company's data and the data to be analyzed. The data collected for use in data processing are total production data and 100 ml bottle defect data. The data was obtained from the Quality Assurance (QA) Section of PT. X during February 15-29, 2020. The following is the data that has been collected which covers production data and defect data of 100 ml bottles as follows:

Table 1. Total Production Data and Defect Data of 100 ml Bottles on February 15-29, 2021.

Tanggal	Total Produksi	Total Defect
15	48400	709
16	55000	435
17	55000	465
18	50600	875
19	55000	535
20	52800	462
21	57200	390
22	51700	308
23	55000	433
24	52800	579
25	51700	557
26	50600	440
27	47300	328
28	51700	330
29	53900	264
Total	788700	7110

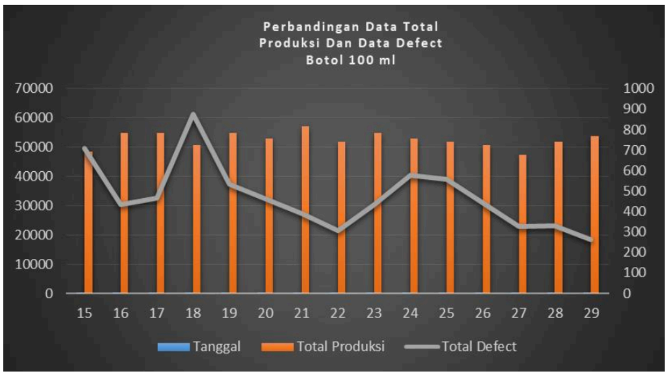

Figure 1. Comparison of Total Production Data and 100 ml Bottle Defect Data

a. Proportion of Total Production Data And Defect Data 100 ml Bottle

The proportion of total production data and total defect data of 100 ml bottles, the author calculates the percentage of comparison between total production data and total defect data of 100 ml bottles during the period of February 15, 2021 – February 29, 2021 which is presented in the form of pie diagrams, which are as follows:

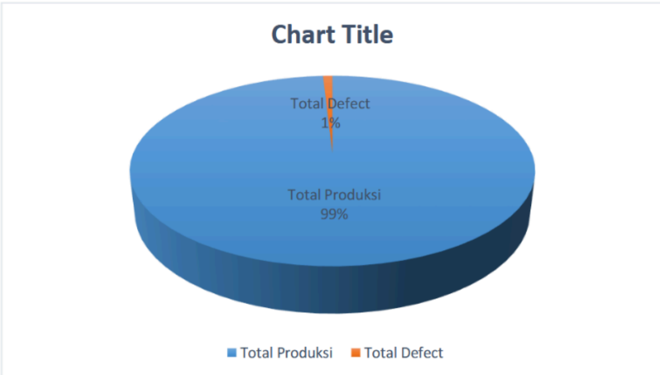

Figure 2. Proportion of Total Production Data and Defect Data of 100 ml Bottle Date 15 February 2021 – 29 February 2021

Based on the pie diagram, it can be seen that the total defect data of 100 ml bottles for the period of February 15, 2021 – February 29, 2021 reached 1% of total production.

b. Pareto Chart

The data on the type of defect in the 100 ml bottle that occurred during the period of February 15, 2021 – February 29, 2021 is as follows:

Table 2. Data on Defect Type in 100 ml Bottles on February 15, 2021 – February 29, 2021

Jenis Defect	Jumlah Defect	Persentase (%)	Akumulasi (%)
Tebal tipis	2155	30%	30%
Kotor Oli	2017	28%	59%
Ngerambut	893	13%	71%
Kotor Material	810	11%	83%
Gate Menclek	630	9%	91%
Deformasi	330	5%	96%
Melipat	275	4%	100%

From this data, it is then processed using a Pareto Diagram with the aim of finding out the highest defects contained in the 100 ml bottle for the period of February 15, 2021 – February 29, 2021, which is as follows:

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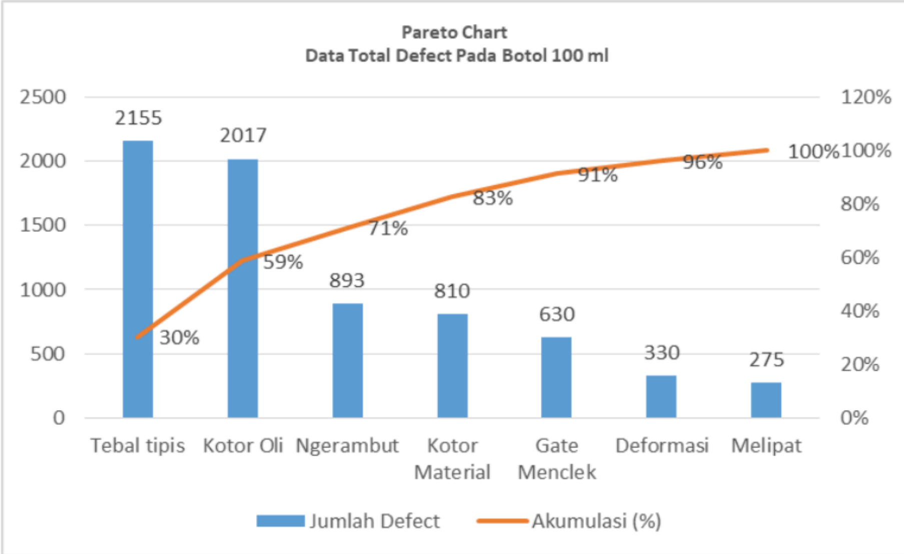

Figure 3. Pareto Chart Total Defect Data On 100 ml Bottle

Based on the Pareto Chart principle known as the 80/20 principle, which means 80% of the consequences are caused by 20% of the causes. So, of the 7 defects, there are 3 types of defects with the highest cumulative total percentage, namely Thin Thick defects with a weight of 30%, Dirty Oil defects with a weight of 28%, and Ngeranbut defects with a weight of 13%, so the main repairs are focused on the three types of defects.

c. Analisa FTA (Fault Tree Analysis)

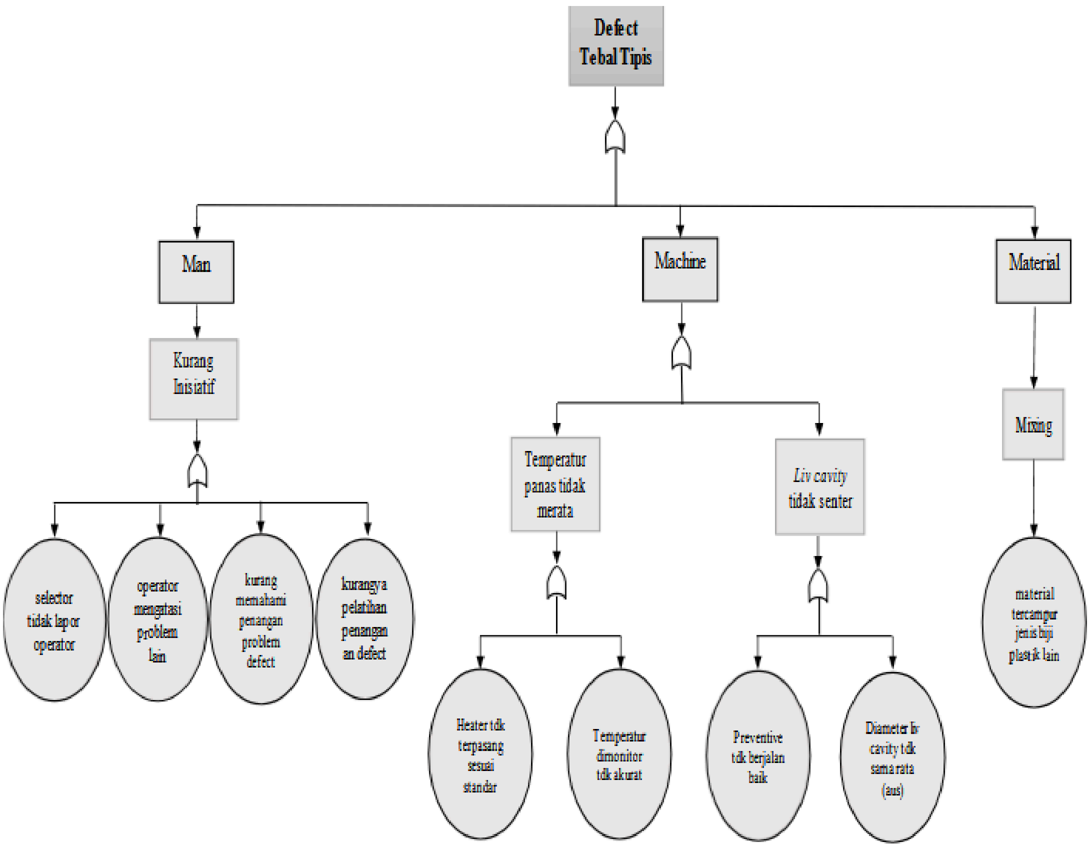

Figure 4. FTA (Fault Tree Analysis) Defect Thin Thickness

From the results of the analysis that has been carried out using FTA (Fault Tree Analysis) in figure 4. So, the factor causing the problem of thin thickness defects in 100 ml bottle products at PT. X is caused by the man, machine, and material factors. These factors are as follows:

1. The Man Factor.

   The human factor is one of the factors that plays a very active role because humans are actors in this case as selectors, operators and so on. This can be influenced by several reasons, namely lack of initiative, this is because the selector does not report the operator, the operator handles other problems, lacks understanding of handling defect problems, and lacks defect handling training.

2. Machine Factor.

   The engine factor is one of the important factors because the machine is an auxiliary tool used to carry out production activities. This is influenced by several reasons, namely uneven heat temperature, Liv cavity is not flashlight.

3. Material Factors.

   The material factor is one of the important factors because material is the main raw material that will be used to produce a product. This is influenced by a cause, namely Mixing, this is because the material is mixed with other types of plastic seeds.

d. Analisa FMEA (Failure Mode and Effect Analysis)

Based on the FTA (Fault Tree Analysis) that has been made previously, it will then be an input in the creation of an FMEA (Failure Mode And Effect Analysis) table which functions to provide weighting to the Severity (S), Occurrenceance (O), and Detection (D) values based on the potential effect of failure, the cause of failure, and the RPN (Risk Priority Number) value. From the data from the FMEA (Failure Mode and Effect Analysis) analysis, the RPN (Risk Priority Number) value was obtained from the largest to the smallest. The following are the results of the FMEA (Failure Mode and Effect Analysis) analysis of the defects of Thick, Thin, Dirty Oil, and Hair products in 100 ml bottles, which are as follows:

From the FMEA (Failure Mode and Effect Analysis) analysis, the defect of the Thin Thickness of the 100 ml bottle product which has the largest RPN (Risk Priority Number) value, namely the Liv Cavity Diameter is not even or worn with the result of the RPN (Risk Priority Number) value of 432.

From the FMEA (Failure Mode and Effect Analysis) analysis, the defect of Dirty Oil of 100 ml bottle products which has the largest RPN (Risk Priority Number) value, namely there is oil in the Blue core with an RPN (Risk Priority Number) value of 384.

From the FMEA (Failure Mode and Effect Analysis) analysis, the defect of the 100 ml bottle product which has the largest RPN (Risk Priority Number) value, namely the Thermo Couple part, does not match well with the result of the RPN (Risk Priority Number) value of 280.

Table 3. FMEA (Failure Mode And Effect Analysis)

No	*Cause Of Failure Mode*	*Severity Rating* (S)	*Occurance Rating* (O)	*Detection Rating* (D)	*Risk Priority Number* (RPN)
1.	Diameter *Liv cavity* tidak sama rata (aus)	8	9	6	432
2.	Bagian *Heater* tidak terpasang sesuai standart	8	8	4	256
3.	Temperatur dimonitor tidak akurat	7	7	4	196
4.	*Preventive* tidak berjalan baik	6	7	4	168
5.	Selector tidak lapor operator	6	5	4	120
6.	Operator mengatasi poblem lain	6	5	4	120
7.	Kurangnya pelatihan penanganan defect	6	5	4	120
8.	Kurang memahami penanganan problem defect	6	4	4	96
9.	Material tercampur jenis biji plastik lain	6	5	3	90

Based on the results of the RPN (Risk Priority Number) from the FMEA (Failure Mode and Effect Analysis) analysis. So, from the results of the largest RPN (Risk Priority Number) value, repairs are then made with the aim of reducing the defect.

Table 4. Proposed improvements

Jenis Defect	Faktor Penyebab Potensial	Usulan Perbaikan
Tebal Tipis	Diameter *Liv Cavity* tidak sama rata atau aus	Melakukan *maintenance* secara berkala pada *Liv Cavity* dan *Mould*
Kotor Oli	Udara pada kompresor kotor dan *blue core* terdapat oli	Melakukan *maintenance* pada kompresor agar *suplay* udara bersih dan *blue core* bebas dari oli
Ngerambut	*Thermo Couple* tidak terpasang dengan baik	melakukan pengecekan *Thermo Couple* pada saat akan *sett up* atau pergantian produksi jenis botol agar temperatur akurat di monitor

2. Conclusion

Based on the results of research that has been conducted on 100 ml bottle products at PT. X, the conclusions that can be drawn from this study are as follows:

Based on the Pareto Chart principle known as the 80/20 principle, which means 80% of the consequences are caused by 20% of the causes. So, there are 3 types of defects with a total cumulative percentage of 80%, namely Thick Thin defects with a weight of 30%, Dirty Oil defects with a weight of 28%, and Hair defects with a weight of 13%, so that the main repairs are focused on the three types of defects.

Based on the analysis that has been carried out using FTA (Fault Tree Analysis), the factors that cause the defects are Thick, Thin, Dirty Oil, and Hair in 100 ml Bottle products at PT. X, namely the man, material, and machine factors.

The proposed improvements that can be made to carry out the process of repairing Thick, Thin, Dirty Oil, and Ngermbut defects based on the largest RPN (Risk Priority Number) from the results of the FMEA (Failure Mode and Effect Analysis) analysis are as follows:

a. The proposed repair of the Thin Thickness defect is to carry out periodic maintenance on the Liv Cavity and mold.
b. The proposed repair of the Dirty Oil defect is to maintain the compressor so that the air supply is clean and the blue core is free of oil.
c. The proposed repair of the Ngeramabut defect is to check the Thermo Couple at the time of changing the production of bottle types so that the temperature is accurate on the monitor

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