Building a foundation for proactive quality management

Analysis and improvement of a manufacturing process using Lean Six Sigma

Master's thesis in Engineering Mathematics and Computational Science, and Quality and Operations Management

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Gothenburg, Sweden 2020

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Acknowledgements

We would like to thank our supervisor Peter Hammersberg for his support and guidance throughout the project. Since the project utilized the Six Sigma methodology, his expertise and experience helped us greatly.

We would also like to direct a special thanks to our supervisor and company contact at the case company for his continuous help and support. Although busy, he always made time to help us when needed. Furthermore, we would like to thank all who participated, in one way or another, making this project possible. Especially the employees from Company A, who willingly shared and discussed their experience with us.

Finally, we want to thank our friends and family for their moral support throughout the entire project. This was especially important considering the abnormal circumstances caused by the Covid-19 pandemic.

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Abstract

Imagine a manufacturing process where there will always be material available with flawless quality at the right time in the process sequence. Imagine that each operational activity would be carried out once, on time, with no lag or issue in between. For most companies, this is often far from reality. This report will cover a company case where issues are dealt with as they occur, in a reactive manner. The company under investigation is experiencing disruptions in their manufacturing process, causing both standstill and rework. The purpose of this thesis is therefore to identify the potential root causes for operational waste, and to help build the foundation for proactive quality management.

The project was conducted using tools and theories from Lean Six Sigma and will contain a theoretical background, an explanation of the issue at hand, as well as an analysis of the current situation. Since the project was conducted using the DMAIC methodology, the current measurement system will be explained. Furthermore, the thesis contains an extensive analysis of both the currently identified process deviations and the underlying measurement system, as well as the identification of potential root causes for operational standstill, resulting in a new strategy for proactive quality management.

The project resulted in the identification of a large number of current and potential root causes for process standstill. Since the current measurement system was inclined towards a more reactive approach to quality management, this was also addressed. In order to help build the foundation for proactive quality management, and to increase the knowledge within the company of the present causes for standstill, the team recommend the implementation and continuous usage of Process Failure Mode and Effect Analysis (PFMEA).

Keywords: Six Sigma, PFMEA, LEAN, root cause analysis, process improvement

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1 Introduction

In this section, the project background as well as the problem formulation will be briefly explained. The chapter also includes an explanation of the purpose of the project, the objectives, and the delimitation factors.

In agreement with the company partner of this project, the partner will from here on and forward be referred to as “Company A” due to confidentiality reasons.

1.1 Background

Company A produces a series of machines, which in this report is referred to as M1, M2, M3, etc. Although some of these products have a shared platform of components, many parts differentiate the product range. These parts are, to a large extent, procured from several suppliers located across the globe. The majority of the suppliers are, however, located in Sweden or neighboring countries.

The production operations mainly consist of assembly and testing. Because of the size and complexity of the products, The company currently adopts a ”Stationary workstation” factory layout meaning that they bring people and components to specific workstations where they build one machine at the time. Once a certain amount of operations has been conducted at a workstation, the machine is moved to the next workstation.

In order to meet increased demands over the last few years, Company A has moved to a new production facility which allows for production scaling and facilitates a more streamlined production process. Each machine ideally takes roughly a few weeks to produce, however, Company A is experiencing disruptions in their production due to, for instance, lack of material availability or insufficient quality of parts for assembly. This means that, occasionally, the assembly operations halt, resulting in machine standstill and extensive rework. The result is higher operational costs due to longer throughput times, and the higher level of insecurity due to variation leads to higher bound capital in terms of stock buffers.

1.1.1 Purpose

Although there is a good general knowledge within Company A that there are issues affecting material quality and material availability, little research has been done regarding the extent or the effects of the individual deviations. However, data is being collected regarding events leading to standstill in the production process, but the data lack in quality and consistency of documentation. In some cases, symptom mitigating improvements are reactively being made, however, the issue remains. The purpose of this thesis is therefore to define and identify potential root causes for operational waste, as well as to help build the foundation for proactive quality management.

1.1.2 Objectives

The objectives of this thesis were to answer the following research questions:

- *What are the potential root causes of operational waste in the production process?*
- *How should the company adapt its current measurement system to become more proactive?*

1.1.3 Delimitations

The project group consisted of two students within the fields of Quality and Operations Management, and Engineering Mathematics and Computational Science. The project was therefore limited to primarily analyze issues within these areas. The project was also subject to a time limit as it was started on February 3rd and set to be finished on the 5th of June 2020.

The project was limited to only manage and analyze internal processes at Company A and not third-party processes that are outside of the company's reach.

The focus of the project was to limit waste of waiting from a manufacturing perspective, and not on limiting waste of waiting for customer orders. However, because of Company A's "customer first" policy, certain contributing factors cannot be altered as manufacturing operations comes secondary to the customer. Therefore, the project outcome could not improve upon operational standstill if the improvements would have a negative impact on the customers.

1.2 Ethical and Environmental Considerations

For any research, ethical and environmental aspects have to be considered. This section briefly describes these aspects from a project-specific view, addressing ethical and environmental considerations both in terms of the research process as well as the potential result of the research.

One thing to consider while doing research is how to, in the report, refer to the employees who participated, in one way or another, in the project. Although this project is formed as a case study, where the research revolves around presented facts rather than opinions, anonymity is preferred. Hence, the researchers will not name the participants or give obvious clues of who they are. Additionally, the case company wanted to remain incognito, so the anonymity approach is applied to the company as well. Because of this, the researchers will leave out information that might give away the identity of the company, as well as sensitive information that could be used to harm the company.

The company produces machines, that could potentially limit the need for employees for the customers. Improving Company A's process could, hypothetically, result in more employees being redundant in the future. This is a contemporary discussion, that the technology used by the company could one day cause many people to lose their jobs. However, the researchers believe that the technology used will not necessarily result in significant unemployment, but rather cause a shift in needed expertise.

Because this project aims at reducing waste in the production process, such a reduction could also result in unemployment. With a net reduction in needed workhours to produce the same output, less personnel would be needed to fulfill the same demand. However, it is believed that the demand will increase over time and that improving production capabilities would only lead to a higher ability to supply accordingly.

The researchers did not recognize that the result of the project would have any significant impact on the environment, neither positive nor negative. This is because the project is limited to the company's production process, where the researchers do not aim to change the operational activities. It could be argued that limiting operational waste could potentially increase system output, which in this case would be a larger number of machines produced. But because the technology behind the machines is rather new, it is difficult to determine the environmental effects of this. With sustainability in mind, however, the researchers avoided unnecessary travel to limit the environmental footprint of the study.

2 Theory

In order to determine what types of issues there were in the production process, the team utilized the definitions of categorical waste as described in the Lean management philosophy. Thus, this section briefly presents the Lean definition of waste in production processes.

2.1 Lean

The theoretical framework used in this project was the management philosophy called Lean production. The, today, well-known philosophy originated from Kiichiro Toyoda in 1930 and was called Toyota Production System. The philosophy combined quality movements with mass production to create efficient production without reducing product quality. The expression "Lean Production" first made its appearance in "The Machine That Changed the World" written by Womack, Jones, and Roos in 1990 (discussed by Sadriu and Larsson, 2017).

There are many different definitions of what Lean is and many different perceptions of the Lean cornerstones. One of the more prominent definitions of Lean synchronization is that it "aims to meet demand instantaneously, with perfect quality and no waste" (Slack, Chambers, and Johnston, 2010, p.429). Waste is regarded as activities other than those that add value to the customer. More specifically, waste is activities that add costs without adding value to the product or service provided to the customer. According to Chambers et al (2010), a very slight part of activities performed within a company is considered value-adding. One reason for this is that some activities are needed in the process to complete the product, even though some of these might not add value to the customer. These activities are called "necessary waste" and must remain in the system although they are not value-adding. However, much of the waste can, and should, be eliminated to increase operational flow and decrease throughput time.

In the original Toyota Production System, seven "Mudas" (wastes) where identified; Waste of Overproduction, Waste of Inventory, Waste of Movement, Waste of Transportation, Process Waste, Waste of Waiting, Waste of Over-Processing.

Overproduction is considered waste. This is true for individual operational steps as well as the entire process. The outcome of a process should not exceed the demand of the subsequent process nor the customer demand. In other words, lean production is opposed to buffers in production lines as well as stock keeping. In Lean production, these two are separated into two different wastes. Stock keeping and mismatching external demand are called "waste of inventory" whereas mismatching internal demand and buffers are considered "waste of overproduction".

Unnecessary movement is also considered as Muda. There are two different forms of unnecessary movement: "waste of movement" and "waste of transport". Waste of movement is simply unnecessary movement required by, for instance, an operator at a workstation having to walk across the room to get the appropriate tools. Waste of transportation is unnecessary movement required to move items or material from one place to another. This waste is related to facility layout, means of transportation, and workplace organization. (Gremyr, Bergquist, Elg, 2019).

Two of the Mudas are related to disruptions in the flow of operations. They both have close links to variation in material quality or lack of availability of material. Variation in material quality such as defects is disruptive in, for instance, the assembly process, as some parts do not meet set requirements for installation. Therefore, additional activities must be performed for production to continue. This can be considered as "Process Waste" as defined by Carreira and Trudell (2006). The same waste can be denoted as "Waste of Defects" (Porta, 2019). The other main waste caused by the aforementioned issues is "Waste of Waiting". This waste relates to activities other than those that are value-adding that comes as a result of

not being able to perform value-adding activities, e.g. waiting for components to assemble (Carreira and Trudell 2006).

The final waste is “Waste of Over-Processing”. This waste occurs when certain process steps are done extensively without adding significant value to the product or service. Spending resources and time on elements that are indifferent to the customer is a waste and should be avoided. It is therefore vital to understand the customer needs and relate operational activities to meet those needs.

3 Methodology

The project is a case study that has followed the Six-Sigma DMAIC methodology (Define, Measure, Analyze, Improve, and Control). This type of methodology is useful when the company has identified an existing problem but no obvious solution. The DMAIC process aids the researchers to logically process the problem by providing a set of tools with the goal to end up with a sustainable solution (Shankar, 2009).

The combination of Lean and Six Sigma has been a popular way of working ever since General Electric first combined the two methodologies during the late 90s. Research has, since then, shown that the two methodologies are complementary to each other. The reason for this is that the focal point of Lean is to reduce waste by slimming down the process to only value-adding activities whilst Six Sigma focuses on reducing variation and enhancing the efficiency of value-adding activities.

The problem formulation indicates that there are variation-related performance issues for the company, which hinders the performance of the production line. As explained, the company has knowledge of these issues but has difficulties identifying its root cause. Six Sigma has many different purposes, which, as mentioned in *Six Sigma: Definition and underlying theory* (Shroeder, Linderman, Liedtke and Choo, 2008), includes finding and eliminating root causes upstream, meaning that the root causes of the issues must be resolved rather than the effects or symptoms of the root causes. In general, Six Sigma is a framework for understanding variation that may lead to a reduction of time, defects, and other metrics related to both process performance and customer expectations.

Six Sigma was developed by Motorola in 1987 and has since then become one of the more prominent methodologies for improvement work, according to Bergman and Klefsjö (2010) (discussed by Sadriu and Larsson, 2017). One of the reasons for this is the structural approach to improvement work, with clear methods and efficient tools for defining, measuring, analyzing, improving, and controlling the process under investigation. This is done using the DMAIC methodology, with the aforementioned steps acting as phases in the structured improvement work.

A process or a process step has input-factor(s) and some type of output(s) as can be seen in Figure 3.1. Additionally, there are also noise factors (N), that might affect the measurement and management of variation and waste. This is because these factors can disturb the process and/or the identification of waste and improvement areas. The goal of Six Sigma is to mitigate the negative effects of variation in the system on the quality characteristic Y. This can be done, either by reducing variation in input-factors (x) or by increasing the robustness of the process to handle the incoming variation, both from x and noise. Important to acknowledge is that Six Sigma can be performed on each process step, as they will have an individual set of inputs(s), output(s), and noise factors.

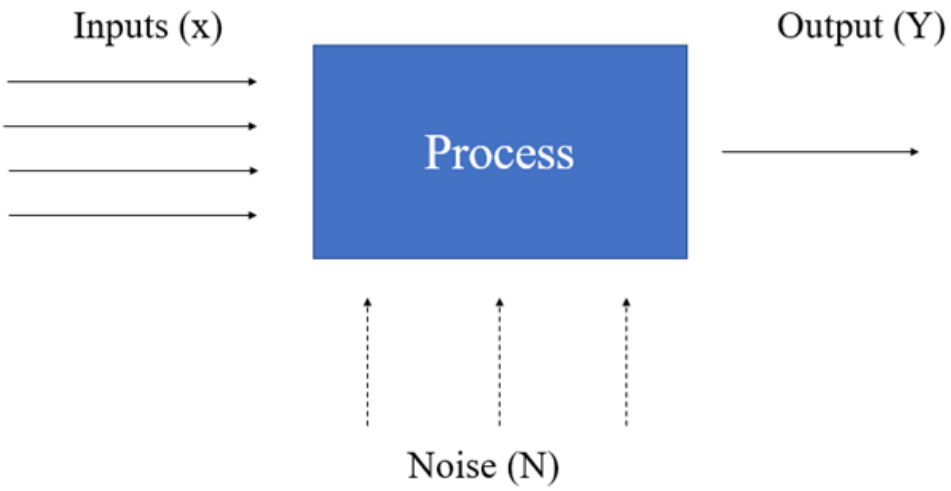

Figure 3.1 Visual representation of inputs, noise, and output in the Six Sigma process.

3.1 Empirical Study Utilizing DMAIC

In the initial step, the "Define Phase", it is key to identify the appropriate process for the improvement work. This was done by analyzing where the problem was suspected to be from an output perspective, where the effects of the issues are, and where it is possible to facilitate change.

When the process was identified, it was possible to identify the customer/user of the identified process's output as well as a suitable quality/performance characteristic. The Y should be of value to the customer and simultaneously be affected by the process variation. For the improvement work to be possible to quantify, the quality or performance characteristic must be able to be measured, utilizing y as a variable. Having a set process also enables the identification of system inputs. The define phase also included the identification of the ideal state for the defined process. This implies when the process is working ideally with respect to Y. To determine the extent of the identified issue, the team conducted a current state analysis, mapping out the process and its current performance in relation to the ideal state.

The second phase, "Measure", is all about gathering data and measuring the current state of operations. This provided the investigators with information regarding the current knowledge and measurement of the issue at hand. More specifically, the measure phase included a compilation of the current data at hand, as well as a description of how the data was gathered, modified, and used by the research team. The Measure phase facilitates the subsequent phase, "Analyze" by gathering and compiling extensive data for further analysis.

During the Analyze phase, the data was broken down and analyzed. Due to the purpose partly being to help the company to be more proactive, the currently available data were analyzed with the aim being to identify how the data is used today, as well as to find areas of improvement in both data gathering and usage of the available data.

The other main target in this phase was to define and identify potential root causes for operational waste, avoiding sub-optimization. Although a set of x's can be identified in an earlier stage, the data from the measure phase and the tools in the analyze phase enables investigation of x's factors upstream within the scope. By using the data at hand, the team analyzed what the current data could reveal in terms of x-factors' impact on y. In other words, the data from the measurement phase was analyzed to determine the

pre-identified causes effect on the performance metric. In order to further identify potential root causes for operational waste, the team also conducted an extensive root cause analysis.

The last two phases, “Improve” and “Control”, involves the mitigation of the effect of variation on the y-measurement as well as initiating quality management principles to ensure that changes in the process can be sustained over time. Hence, the team introduced a suitable framework for proactive quality and performance management. This was done with the purpose being to ensure that the company gathers the correct data and proactively uses the data with the focal point being the root causes for operational waste. Finally, an implementation plan regarding specific changes and responsibilities was presented to facilitate for implementation of suggested recommendations.

3.2 Data Collection and Research Design

This project was conducted as a case study utilizing the DMAIC Six Sigma methodology. A case study was deemed suitable as a research method as it allows for a comprehensive analysis of a contemporary issue, applied in a real-life situation. Case studies result in, according to Merriam (2009), a rich and holistic account of a phenomenon. In other words, a case study should result in a comprehensive analysis of the company, allowing for the research questions to be answered.

Throughout the project, the research team conducted qualitative analysis utilizing various tools from the Six Sigma toolbox. The qualitative analysis in the define phase also included unstructured and semi-structured interviews. These were held with various individuals with different positions in the company, with different relations to the specified issue. According to Bryman and Bell (2015), a semi-structured interview is good in order to explore the subject in-depth without limiting the interviewee to standardized questions. Because of this, the interviews can be used to generate ideas, increase learning and understanding, and to find unexplored correlations from various standpoints. In order to gather implicit data points for analysis, the team also conducted observational studies. Bryman and Bell (2015) claim that such a study is important as it can be used to capture data that is not captured with direct methods. Additionally, the team conducted quantitative data analysis. According to Desai (2010), data analysis is an important step that enables the project to confirm or reject hypotheses throughout the process, as well as to validate possible findings with qualitative evidence. The combination of qualitative and quantitative research methods can, according to Dempsey, Farquharson, Waller (2016), be beneficial as it can illuminate the issue from different angles, allowing for a more nuanced investigation of the topic.

4 Define

The define phase marks the initial step in the DMAIC process and is of great importance to find and understand issues in the production process. This chapter will describe the various tools that have been used to identify the problem and form an understanding of Company A's current state in relation to the theoretically ideal state of operations.

4.1 Effective Scoping

By interviewing functional managers, employees from production, and purchasing, as well as conducting observational studies and general observations, the researchers established an Effective Scoping matrix. Effective scoping (Hammersberg, 2019) is a tool that has evolved from SIPOC, which enables the user to describe the process and map the investigation perspective and objective in a clear and structured way from a pull-perspective, in accordance with Lean philosophy, before the underlying system has been framed. The purpose of the tool is to follow the process upstream and identify the area of influence, setting up the scope of the investigation and identify how to characterize and develop the process, i.e. the driving metric of the process development under the constraints to consider. The tool facilitates for identification of several factors, including output, customer, quality characteristic Y, measurement y, availability of data, delimitations, the jurisdiction of changes, and input characteristics. The information was gathered using unstructured and semi-structured interviews, document analysis, and observations. The tool itself consists of a number of fields that needs to be filled in a certain order, starting from the output of the system and finishing with the inputs. A summary of the outcome of the effective scoping can be seen below.

Q1 - Output

The output of the manufacturing operations is the machines. Company A's product portfolio currently contains five different machines, (here denoted as M1-M5). Different customers require different machines, although Company A wants to prioritize later machines (M4 & M5) and phase out the earlier models, primarily M1.

Q2 – Output user

Company A base their recourse planning and production on forecast, and produce their products mainly to stock. Because of the production not being a conventional pull system, the output user is not directly the customer, but rather Company A itself. In some cases, however, the customer places an order on a specific machine that is not forecasted. In those cases, the company will add that machine to the production plan.

Q3 – What is required from the user? (Y)

After conducting semi-structured interviews and observations, it was concluded that Company A wanted to ensure production flow without interruption and with a more predictable series of operations as it is easier for the company to plan resources and produce products more consistently with more predictable throughput times. This makes it possible to optimize stock and its turnover, time, and resources so that they can produce more with less. Company A is still in relatively early stages, meaning that they require a certain amount of flexibility to alter the production to adapt to customer demands. However, disruptions in production flow due to unwanted input and/or process deviations have to be reduced to a minimum.

Q4 – Measure (y)

In order to measure the continuity in the production flow, the variation of production lead time for each machine type should be measured. Variation in production time within the same machine type could be a

suitable measurement for production inconsistency as it would show how standstill affects the predictability of manufacturing operations. Standstill caused by deviations seems to be the main reason for the variation within the machines. Thus, measure y is the standstill for the machines. Standstill is, in this project, defined as the total time a machine is not being worked on in accordance with the pre-defined operational activities. This includes the time it takes to conduct rework activities to be able to proceed with normal operations.

Q5 – Baseline of y, measurements

As of today, Company A continuously monitors and document their production deviations in a shared excel file. In this file, each machine that is being, or has been, produced is documented if it has experienced any deviations. The document includes what machine was affected, where the deviation occurred, how long time the deviation affected operations, and what the likely cause was amongst other data. As of today, this data is being used to assign actions to personnel depending on the type of deviations.

Another baseline for y is data stored in Company A's ERP system. From there, it is possible to gather data on the start and end date for each produced machine. This will show the overall lead time of each machine, hence the throughput time in the system. This specific data is not being used to a large extent today.

Q6 – What other Y cannot be lost in the process?

After communicating with staff involved in the process it has become clear that the reliability and lead time of customer orders are of great importance and are therefore not allowed to suffer due to improvements in the production flow. In addition to this, the project is not allowed to have a negative impact on the quality and safety of the products nor processes. Lastly, Company A must have a certain degree of flexibility to meet customer demands and allow for continuous learning through testing. Thus, improvements to Y cannot suffocate flexibility.

Q7 – Jurisdiction of changes

The research team has the jurisdiction to change activities and procedures within the company. The changes must however fall in line with company general directives and norms. Although it is not possible to alter processes outside of Company A, the team can suggest add on(s) to second-party audits of suppliers if needed. This means that, theoretically, it is possible to decrease system-related variation or mitigate the effects of these within the company control span. It is also possible to affect certain forms of incoming variation through, for instance, certificate demands and increased quality control of supplier activities.

To do this, the team needs a wide variety of functions and roles. Mainly Six Sigma related competences as well as statistical and mathematical knowledge is required for the analysis. To implement changes, however, the team needs the support of functional managers from the affected departments.

Q8 a– Inputs to the system

The main inputs to the system are the parts that build up the products. Each machine type has a set number of included parts specified in the Bill of Materials (BoM). The parts have different levels of integration, meaning that some parts are parts of a subassembly whereas some parts are mounted directly to the final assembly.

In addition to this, employees are needed throughout the majority of the manufacturing process. Each build is generally assigned to an operator who is responsible for that particular build. Another input in the system is instructions for different operational steps which describes how activities are supposed to be carried out.

Q8 b – Who supplies the input

The majority of the parts are sourced from several suppliers. These suppliers are generally located in Sweden or neighboring countries, however, some are located further away. The distance accompanied by the type of shipping is directly connected to the lead time of the inputs. Some suppliers construct the parts in-house while some suppliers source including parts from yet another supplier. The number of suppliers involved in the separate supply chains also correlates to lead time.

The employees are, to a large extent, consultants from a large consulting firm. They generally have long contracts. The instructions are usually constructed by manufacturing engineering in consultation with production personnel who conduct the work.

Q9 – Input requirements

Incoming parts have to meet quality requirements, meaning that they should have sufficient quality so that they can be used in production. Company A has recently set up a list of components that are Critical to Quality (CQ) and Critical to Safety (CS). These parts are especially important in terms of their quality as they will directly affect the quality and/or safety of the machines if they do not meet the standards.

Another requirement on the inputs is that there has to be a trustable lead time. Parts with unreliable lead times and parts completely without lead times will result in poor resource management.

Another key requirement is that the suppliers must be able to deliver according to the lead times. Company A must be able to count on the suppliers to deliver according to their promise if they want to have continuous production flow.

4.2 Value Stream Mapping

In order to fully understand the system of operations and to get a perception of the process cycle time, a simplified Value Stream Map (VSM) was made, see Figure 5.1. The VSM was established after conducting a walk-in Gemba, starting from the process output and walking the process upstream. In addition to this, interviews were held with the functional managers to fully understand the process. Figure 4.1 shows the system of operations with lead times and cycle times excluded. Even though this VSM is simplified, it creates a better overall perception of system relations and where improvement work should be focused. The tool consists of functions tied together with information transfer (dashed arrows) and physical transfer (solid arrows).

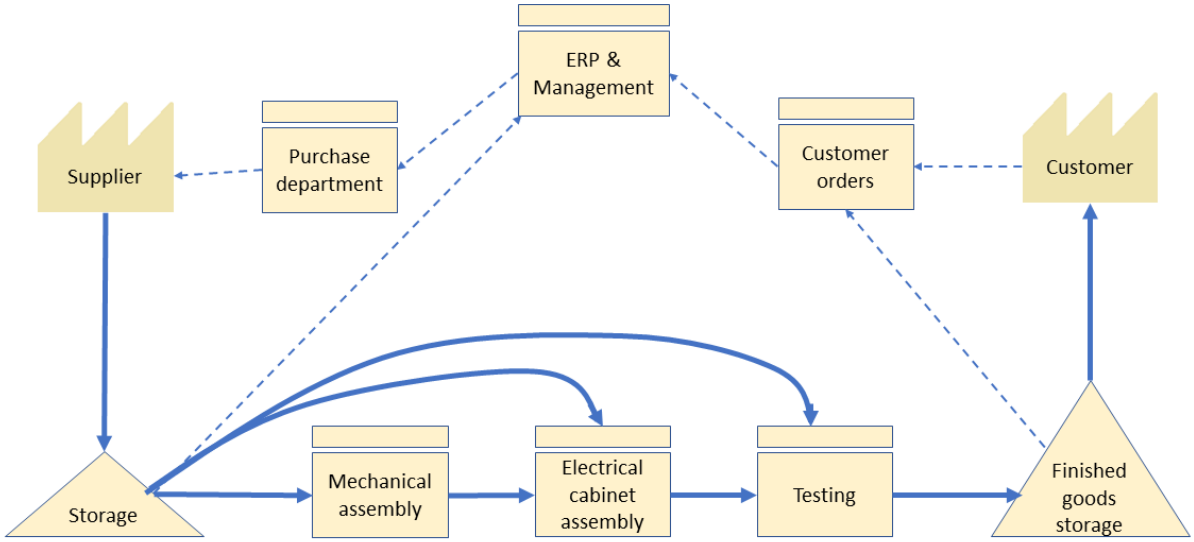

Figure 4.1 Value stream map visualizing a simplification of the material (thick line) and information flow (dashed line) within the company.

The system starts with a forecast made from previous data and general industry indexes. The management estimates how many of each machine will be sold each year, partly from dialogue with current customers and potential customers, and partly from analyzing the industry growth. The difficulty with this is that it is not only hard to estimate the number of machines that will be sold, but also what type of machines that will be sold. According to an employee involved in the production process at the company, having different machines for sale as well as differentiating factors within each machine type makes it almost impossible to forecast. Nevertheless, this information initiates a building plan for these machines, with resources allocated accordingly. This is done by management and the Enterprise Resource Planning unit (ERP). There is currently an ERP software in place that helps the company allocate resources and plan the procurement of sourced material. However, this software will be replaced in the near future.

Once a machine build has been initiated in the ERP system, the components specified in the BoM for that machine are allocated for the build, which updates the current stock balance. All material in the BoM is not updated simultaneously, but rather so that it somewhat matches the operational procedure. This means that the components in the BoM are taken from the balance roughly when they are expected to be used. If the balance of a component is, at some point in time, below the safety stock it will be put on the purchasing requisition list. The purchase department is thus notified that the component(s) has to be purchased, and will initiate a purchase order to the supplier. The majority of parts are kept in stock, while some are just in time (JIT) orders, meaning that they are ordered to arrive at the exact date when they are needed for assembly.

Once the parts are needed for production, they are taken from the stock and assembled in accordance with the figure. The process begins with a mechanical assembly where several steps are carried out at the first workstation. For some machine types, there are some pre-assemblies necessary before the mechanical assembly. When the mechanical assembly is carried out, the machines are moved to the second workstation. In this zone, the electrical cabinet assembly is performed. The last station is referred to as “testing”, meaning the machines are tested in terms of performance and calibrated to suit the customer's needs. Throughout the manufacturing operations, material is moved to the workstations from the storage.

Once a machine has passed the testing, the machine is packaged and moved to the finished goods storage or sent directly to the customer.

Not all machines are build based on forecast. In some cases, machines can be ordered directly from the customer. In most cases, there is either a finished machine that can be allocated to the customer or a machine that is already being planned to be built that the customer can have once finished. But sometimes, a customer orders a machine that is not in stock nor the build plan. In these cases, the customer order function places an order in the ERP system. Management will then have to decide on how to alter the current plan to fulfill the customer need.

4.3 State Analysis

To get a better perception of the extent of the issues, a state analysis was performed. This involves investigating the entire process in its theoretically perfect state, the "Ideal State", and compare the current state of operations to that. This section will thus include a description of the process in its ideal state and an analysis of the current state in terms of the quality characteristic, y.

4.3.1 Ideal State Analysis

The ideal scenario would be a continuous production flow with no disruptions. There will always be material available with sufficient quality at the right time in the manufacturing sequence. In the ideal state, each operational activity would be carried out once, on time, with no lag or issue in between. In short, the ideal state could be calculated as the sum of all necessary operations in sequence with no lag. Company A has estimated how long time each operation would take to carry out and summarized it in an excel file. For each machine type, there is data on time for operations, allowing an ideal throughput time to be calculated. This time can be seen in *5.1 Throughput time data.*

4.3.2 Current State Analysis

The ideal throughput time does not seem to be the norm, however. It seems that there are many sources for variation in throughput time caused by deviations. In the context of lean production, Company A's issues mainly fall into two categories of waste, process waste, and waste of waiting. More specifically, there seems to be a large number of material defects that cause the operations to a halt, idling machines. Process waste due to defective components can, according to Porta (2019), be denoted as waste of defects, which refers to the waste of rework caused by faulty components. Similarly, parts with insufficient quality can cause an urgent lack of components, ultimately causing operational standstill, i.e. waste of waiting; the other main waste in the company's manufacturing process. Lack of material is another common cause, it is claimed, for standstill in production. This is in itself waste of waiting.

In order to capture the extent of the issue, without relaying solidly on qualitative methods, the ERP system data was checked. It was possible to capture data that showed the start date and the end date of each produced machine since 2019, see *5.1 Throughput time data.* Utilizing tools in Excel, the net workdays between each date could be calculated, showing the actual throughput time for each individual machine. Important to acknowledge is that the throughput time includes the entire process, from the first operation step to when the machine enters the finished stock or is shipped to the customer (whichever happens first). In Table 4.1 below, the actual average throughput time for each machine type can be seen, as well as the ideal throughput time.

Table 4.1 In this table the number of produced machines, ideal throughput time, and the average throughput time is presented.

Machine type	Produced machines (st)	Ideal Throughput time (days)	Avg Throughput time (days)
M1	**37**	**19,2**	**34,5**
M2	**14**	**20,2**	**60,5**
M3	**11**	**26,0**	**38,2**
M4	**30**	**27,4**	**62,0**

What can be seen is that the actual average throughput time differs significantly from the ideal case for all machines. This is especially true for M2 and M4. For M2, the actual average is almost 300% the ideal time, meaning that two-thirds of the total average is categorical waste. Figure 4.2 shows this more vividly.

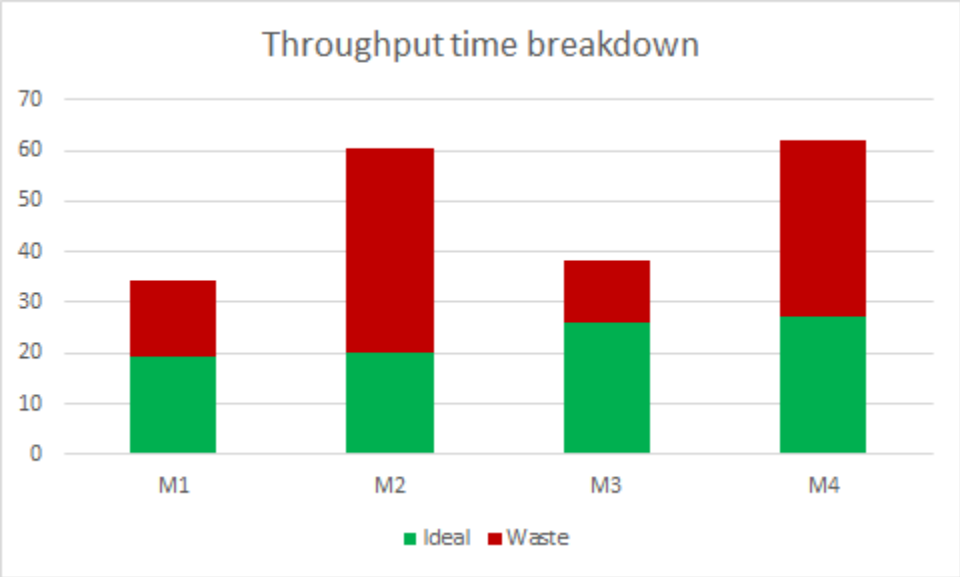

Figure 4.2 Throughput time breakdown. The green symbolizes the ideal throughput time in days and the red constitutes of the time difference between the ideal case and the actual average. In Lean terms, the red symbolizes the waste in the system for each individual machine type.

Important to acknowledge is that the aforementioned data is based on averages, and the Lean Six Sigma philosophy claims that decisions should not be made on averages alone, as it might give a skewed representation of reality. Thus, each individual machine was analyzed further. The throughput for each M4 machine can be seen in Figure 4.3. Each dot represents one machine, and the throughput time can be seen on the y-axis.

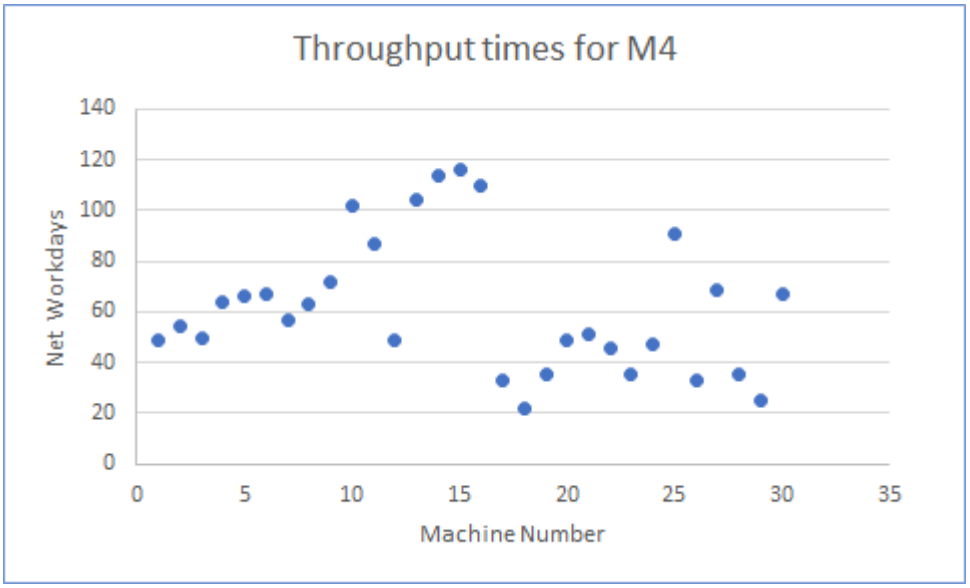

Figure 4.3 Throughput times for machine M4. Each dot represents the M4 machines produced since 2019 with their corresponding throughput time on the y-axis.

While analyzing the net workdays for each machine, it becomes clear that there are major differences in throughput time between machines of the same type. Through a semi-structured interview with an employee involved in the production process, it was concluded that some of the machines were loaned out for testing, although not put as finished in the system. This could explain some of the extraordinarily high throughput times that can be observed for some of the machines. Through the aforementioned interview, it was also concluded that it is not possible to directly connect the variation in production time to the different types of waste as the processes are not completely connected and the data stored in the ERP system is subject to noise and contains different conditions that make it hard to know what is being measured. The company might argue that some of the activities that cause a higher overall throughput time are not caused by issues, but in fact, conscious decisions, and should not be regarded as waste. This could be considered as necessary waste within Lean Philosophy. However, the researchers couldn't identify and quantify the different types of waste individually.

To further visualize the spread of throughput times for each machine type, a box-whisker plot was constructed, see Figure 4.4.

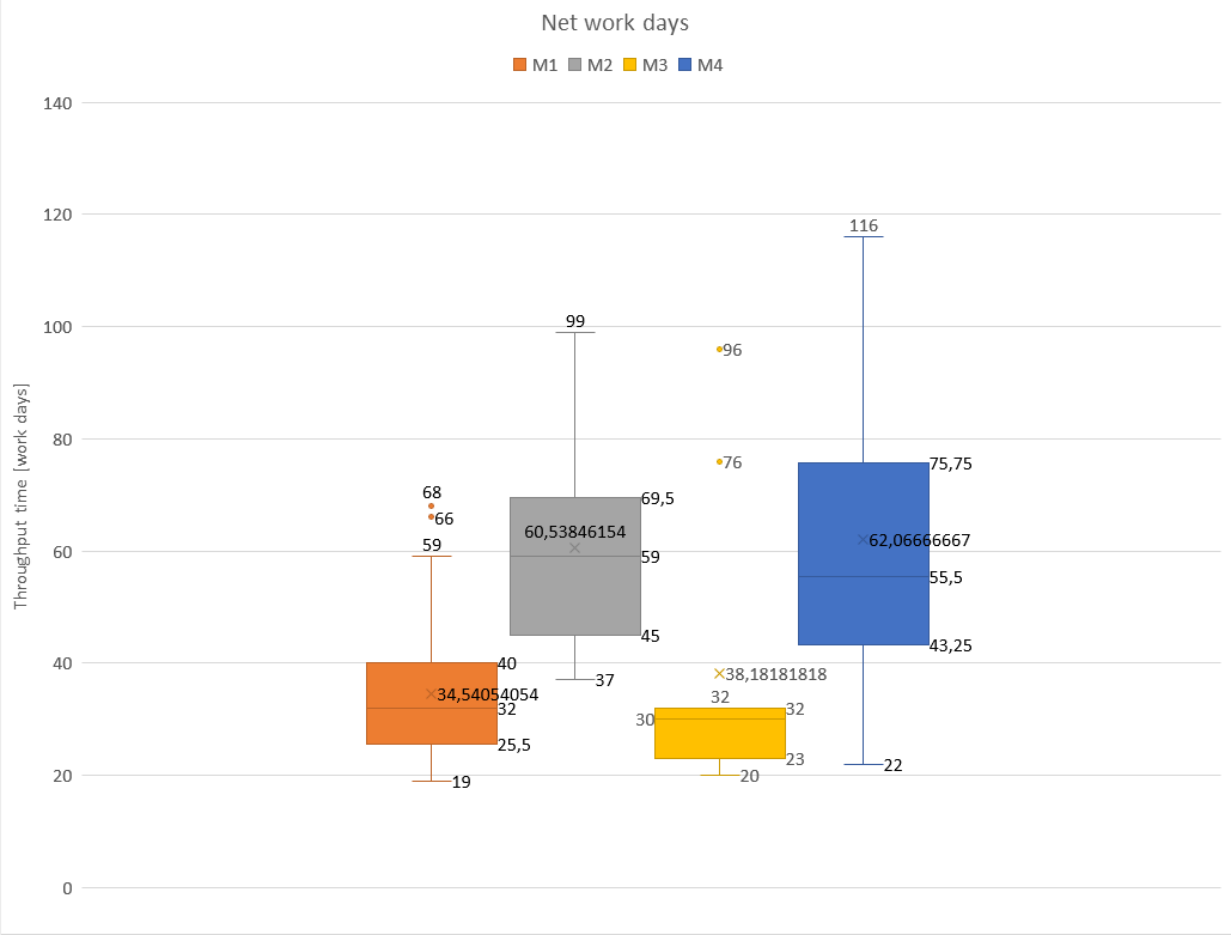

Figure 4.4 Box-Whisker plot showing the data spread, mean, and median values for each machine type. In the plot, it is also possible to see the highest and lowest value in the data set as represented with the whiskers as well as possible outliers. The box is limited by the first and third quartile of the data.

This box plot visualizes the data distribution in relation to the median throughput time for each machine type. This tool gives a full overview of the spread of data, including potential outliers. What can be seen is that the mean values are higher than the median values for all machines. This indicates a skewed data set, meaning that the throughput times for all machine types have a larger spread of higher throughput times. This makes sense as the throughput times can only be as low as the ideal throughput time whereas there are no limitations on the high end. M1 and M3 have a substantially lower spread of data between the 1st and 3rd quartile compared to M2 and M4. This means that the throughput times for M1 and M3 could be more predictable in terms of variation compared to M2 and M4.

M3 is especially interesting in this aspect, as there are two potential outliers in the data, which could be the cause for the mean value being higher than the highest recorded value, not counting the outliers. For this machine type, the highest value, aside from the outliers, is 32 workdays, with the median value being 30 workdays. This would indicate that the M3 machine is indeed relatively stable compared to the others.

For M1, M3, and M4 the lowest throughput time is close to the ideal throughput time, indicating that it is in fact possible to reach the ideal state in some instances. For M4, this value is in fact lower than the ideal

throughput time. It was concluded, through interviews, that some machines were being pushed out very quickly to meet a sudden customer demand. This means that the company put more people on the machine in order to complete the machine as quickly as possible. This would not be considered as the ideal case, however, as the ideal throughput time is calculated based on "normal" operations. Another possibility is that a false data entry was mistakenly included in the data set. This could happen, as some data entries are denoted as "test", i.e., not being actual machines. These values have been removed manually, but the probability exists that such a data point has been included in the data set.

For M2, the lowest recorded throughput time is far away from the ideal case. Its lowest throughput time is almost 200% the ideal case. This indicates that Company A has not been able to produce such a machine without issues occurring, causing the machine to experience standstill.

M4 has the highest spread of data, both for the 1st and 3rd quartile, as well as for overall spread. Because of the high overall spread, potential outliers could not be mathematically identified for this machine type, resulting in a span of throughput times from 22 workdays to 116 workdays. This data does probably include machines that have been loaned out for testing, which is not considered as unexpected standstill due to deviations as per the definition in this report. However, when examining deviation data in *6.2 Deviation analysis*, indications are made that the throughput time for this machine type suffers due to deviations, and being one of the latest machines in the product portfolio, this is something that needs addressing.

4.4 Expanding Knowledge

Company A seems to have general knowledge regarding the issue of standstill and the contributing factors that causes it. The reason for this is that the people within the company are continuously getting exposed to the issues and deviations, and has to find a way to limit the immediate standstill that comes as a result of the deviations. As a fast-growing, medium-size company, Company A is continuously trying to find ways to keep up with increasing demand, scale up production while simultaneously solve the issues that occur. This phenomenon is common for this type of company, and is often referred to as "firefighting". The term describes a state when the company is "putting out the flames", i.e. solving the immediate issues rather than putting out the "fire" from its source. This often results in short term sub-optimizations and mitigation of symptoms rather than the elimination of root causes.

The purpose of this project is, again, to help the company towards more proactive quality management, and improving its operations based on the elimination and/or mitigation of root causes for standstill. This means help provide ways to find and eliminate root causes but also build a framework that can help sustain the improvements. The most important part is to, in a structured way, increase the knowledge within the company of the present causes for standstill, and to create a sense of urgency for change. One vital part of increasing knowledge is to investigate the current measurement system and its role in facilitating or hindering proactive measures. Thus, the next step in the DMAIC cycle was initiated, the measure phase.

5 Measure

Measure is the part of the project where most data about the production process is collected. This chapter will describe how data was collected and how it can be used to identify root causes for waste.

Due to the pandemic outbreak of the COVID-19 virus in 2020, Company A closed the factory in March and the project was from there on forward unable to continue its progress from the production site. This limited the ability to gather data and information as personnel at Company A had to shift their focus to maintain the situation.

5.1 Throughput time data

To get a better and more extensive understanding of the process, data that describes the ideal process time for each process step for the machines was collected from Company A. The data is an estimation of the time consumption of each process step. The process steps has been devided between what is described as area 1, area 2a, area 2b, and packaging area. The data was collected by the company, thus, no new measurements had to be conducted. This data could then be used to extend the simplified VSM with the process times as can be seen in Figure 5.1 which contains the throughput time for machine M4.

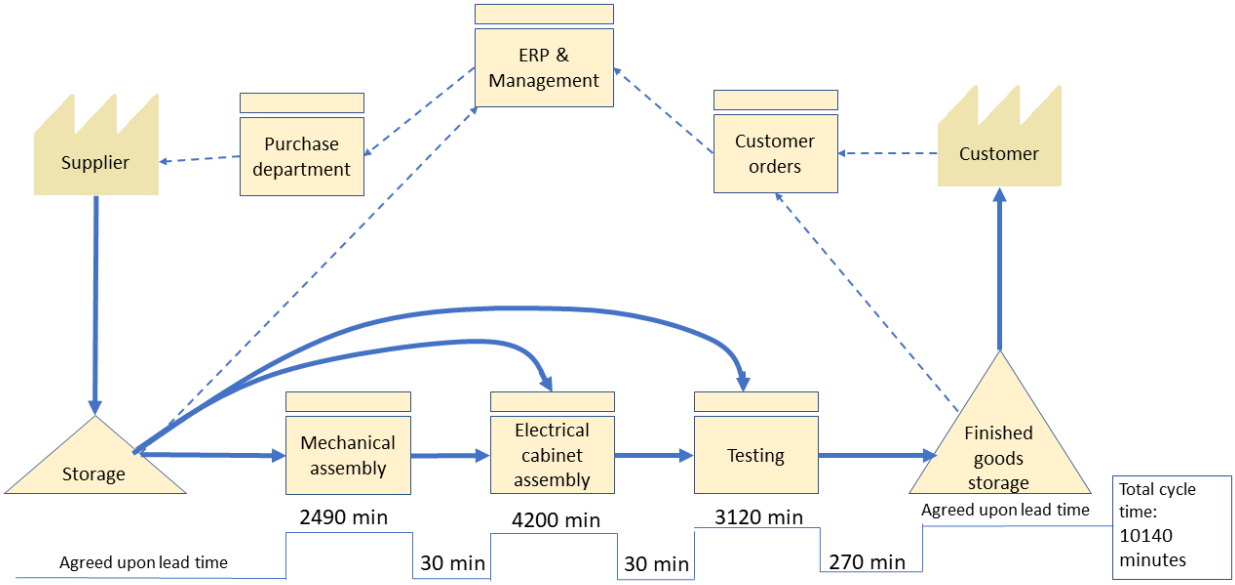

Figure 5.1 Value stream map visualizing a simplification of the material (thick line) and information (dashed line) flow within the company with the throughput time added for machine M4.

In addition to the process step time, data from the company's ERP system that describes the actual throughput time for each produced machine was collected. The actual throughout time describes the time it takes from when the operators start building the machine to when it is ready to be sent to a customer.

By having these two sets of data, the true cycle time was comparable to the sum of the process step durations. By doing this it should be possible to determine how many of the produced machines that had gone through the building process without delay. However, when conducting semi-structured interviews indications were made that machines were often moved aside from the process to be used as a testing platform. This means that those machines were intentionally moved aside and therefore had a prolonged

production time. It was also concluded that it is not possible to directly connect the variation in production time to the different types of waste as the processes are not completely connected and the data stored in the ERP system is subject to noise. This is important to keep in mind when comparing to the estimated process step time.

5.2 Deviation document

Company A is currently collecting data that describes when the production is experiencing disruptive flow in an excel chart which we will refer to as the "deviation document". The data used from this document was limited to data regarding machine M4 that was collected during the year 2019. This was done to fit the project into the time limit and to use data that was relatively up to date. In addition to this, data regarding the testing phase of the machine was excluded in agreement with Company A as the testing phase has experienced issues that are not desired to be handled by the project team. The testing phase was defined as processes coming after step 230, taken from the document describing the estimated time consumption for each process step which was discussed in *5.1 Throughput time data.* In this data, the processes coming after step 230 are described to be in area 2b.

The column headers in the document are supplied with the following instructions:

- Machine nr
  - Fill with the current machine serial number [XXXX]. If the deviation refers to multiple machines register one deviation per machine.
- Nr
  - Fill with the next number of occurrences of deviations on the current machine. The number of occurrences always starts at 1 for each specific machine number. For example; the first deviation on machine 1234 gets occurrence number 1, the second deviation on machine 1234 gets occurrence number 2, etc. This allows us to in a simple way refer to a specific deviation on a specific machine by for example referring to deviation "1234-2".
- Type
  - Choose from the drop list which machine type the deviation applies to.
- Date
  - Fill with the date of deviation discovery by the following format [YYYY-MM-DD] for example 2019-01-30.
- Started by
  - Fill with your name using four letters, the two first of your first name, and the two first of your last name [FFLL], for example, "Anders Andersson" = [ANAN].
- Area
  - Choose from the drop list in what area the deviation was discovered.
- OP step
  - For M2 and M3 machines: choose from the drop list in what operation step the deviation was detected
  - For M4 machines: leave the cell empty
- Deviation type
  - Choose deviation type from the drop list
  - Material defect
    - Physical defects on the item. For example, missing sub-part, damaged surfaces, etc.
  - Material shortage

        - No material in stock. In this category, material that has been borrowed by other later machines is also accounted for.
    - Staff shortage
        - Responsible machine operator is not available to work on the current machine because of other activities. For example, troubleshooting another machine.
    - Human error
        - Errors that occur because of human mistakes. In this category mistakes that are caused by lack of instructions for the operation are included.
    - Instructions
        - Unclear or error in operation instructions that can lead to incorrect build.
    - Software
        - Errors that occur when using the machine's software and applications. For example, error when auto-calibrating the machine.
    - Safety
        - Incidents or risk observations that stop the machine until the deviation has been fixed.
    - Structure
        - An error that makes the logistics department unable to deliver the correct item in the correct quantity to the specified operation even though they deliver according to “TO”.
    - Testing
        - Not approved test that leads to actions and rerun of the test.
- Problem description
    - In short, describe the problem using relevant information.
- Activity
    - In short, describe what actions have been made to solve the problem in both the short term and long term. For example, material is taken from stock.
- Cause
    - In short, describe the probable cause for the problem. If unknown, leave the cell empty.
- Responsible
    - Fill with the name of the responsible person who closes the deviation by the same format as “Started by” [FFLL].
- Comment
    - Optional. Use this cell to leave other relevant information that does not fit under any previous header.
- Finishing date
    - Fill with the date when the deviation is closed with a long-term solution by the following format: [YYYY-MM-DD]
- Time consumed
    - Fill with the time that the machine has been in a standstill as a cause of the deviation. Use the format [hh:mm]. For example, 02:30 for two hours and 30 minutes and 00:15 for 15 minutes.
- Prio
    - Mark this box with an X if the deviation causes a stop in production. (Standstill for descendants).

Since the raw data contains an extensive amount of information it was compiled in different ways to make it more understandable. The first compilation separates all the different deviations listed in the document and sums up the accumulated standstill time as seen in 6.*2 Deviation analysis*, Table 6.1. In addition to this, the number of occurrences of each deviation type was counted as can be seen 6.*2 Deviation analysis*, Table 6.2, and a box and whisker chart was made in order to visualize the spread of the standstill time for each deviation type.

5.3 Shortage List Compilation

Every weekday a list describing the current item shortages for manufacturing and customer orders is emailed to some of the employees. These lists have been collected and compiled for data from 2019-01-01 until 2020-02-19 in order to investigate if any items stand out, or if there is any pattern in how the shortages appear over a period of time.

When processing the lists, the main focus was to make sure that the data could be separated by customer orders and manufacturing orders, and also to show how the amount of shortages differs over time. Therefore, each shortage list was added to a common list with the shortages marked as customer order shortage or manufacturing order shortage as well as the date for when the shortage occurred. The list could then be used to count the number of shortages, note that this is not the number of items in shortage but the number of distinct items in shortage, for each date in each of the two categories to allow for a simple comparison of occurrence. The list was also compiled to show which items had been in shortage for both customer and manufacturing orders at the same time. An effort was also made to pair the items with their respective supplier.

6 Analyze

With the data gathered, it was possible to analyze the current deviations by compiling the standstill data in the deviation document, historically visualize the shortages found in the shortage lists, and to conduct a root cause analysis. The goal of the analysis was to identify critical x-factors and investigate how they are measured and documented today, as well as to find relevant potential root causes that can be measured and documented in the future. Therefore, this section will contain a deviation analysis of the current state of affairs, and a root cause analysis.

6.1 Measurement analysis

When working with the gathered data it became clear that it could vary in its accuracy. Therefore, an analysis of how the data can be used was made.

6.1.1 Deviation document analysis

The deviation document contains a substantial amount of information that can help to point towards the existing issues within the production process. Most importantly, it allows for a simple way to supervise disturbance in the production process and the possibility to go back and review the deviations. However, through a personal conversation with an employee at the production department, it was explained that the measurement of standstill can vary between different recordings depending on who recorded the standstill time. The document also contains incomplete data points that lack helpful information which makes the registered data hard to interpret. There were 90 out of 303 deviations registered during 2019 without any standstill time which made it hard to judge their impact on the production time. Also, 187 deviations out of 303 were registered without any description of the cause. However, in some data points, the cause can be interpreted from the problem description. In some cases, the cause was described in other columns than the designated “cause column” which made it complicated when trying to figure out how to get any consistency of data compilations. Overall, when examining the data in the document it is difficult to determine the actual root cause for many of the deviations. This leads to the conclusion that the document allows for a better understanding of what types of deviations that occur but also that there seems to be a need for a common language when filling the document so that every employee that uses the document has the same understanding of the instructions.

Another interesting part of the data is that it might describe if there has been an issue with a specific item when a deviation occurs. The information is however embedded within the problem description of the deviation as there is no specific instruction to include the description of the item. To be able to use this information the item number has to be extracted from the text string by using excel code. This method is not flawless and was therefore deemed too unreliable to use. Information about problematic items might however be useful to investigate in order to track their occurrence. By having a separate column for the problematic item(s), it would be easier for Company A to keep track of these problematic items.

6.1.2 Shortage lists analysis

Today the shortage lists are being used as indicators that show what items are in shortage. They allow for an overall view of the current state of shortages and if they are directly caused by a manufacturing order or a customer order. However, the purpose of the lists is not to highlight potential root causes for shortages. This means that the lists are then being used more reactively to handle the shortages. To conclude, the lists are enabling a historical view on the shortages and the current state, however, they are not being used in this manner today. Also, they do not contain much information about the potential root cause of shortage.

6.2 Deviation analysis

In order to investigate the current state of deviations during the production process, the deviation document provided by Company A was explored as mentioned in *5.2 Deviation Document.* As the document had some instances of missing data regarding the standstill time, the data compilations in this chapter were made with data that had these data points removed. In Table 6.1 the total sum of standstill time for each deviation type is shown. The testing phase is excluded as discussed in 5.2 *Deviation document* and is therefore colored red. As can be seen in the table, the M4 machine had a total standstill of 909 hours, which adds up to about 140 workdays of 6,5 hours. Compared to a year consisting of 250 workdays this can be translated to that there has been a machine on standstill for about 56% of the total production time during the year 2019. In addition to this, the number of occurrences for each deviation type is displayed in Table 6.2.

Table 6.1 Summations of standstill for each deviation type for machine M4 during 2019.

Deviation	Standstill	Deviation	Standstill
Item deviation	00:00	Material shortage	371:55
Documentation	00:00	Material defect	327:25
ERP/IT	01:00	Software	11:40
Misplace	00:00	Staff shortage	00:00
Instructions	05:45	Safety	00:00
Quality	00:00	Structure	19:20
Human	163:30	Equipment/Storage space	08:30
Material	00:00	Testing	305:00

Table 6.2 The table shows the number of occasions respective deviation has occurred for machine M4 during 2019.

Deviation	Occasions	Deviation	Occasions
Item deviation	0	Material shortage	21
Documentation	0	Material defect	109
ERP/IT	1	Software	7
Misplace	0	Staff shortage	0
Instructions	7	Safety	0
Quality	0	Structure	28
Human	24	Equipment/lack of space	3
Material	0	Testing	7

The result presented in the tables indicates that there has been a substantial amount of standstill occurring during 2019 for machine M4. To get a better idea of the spread of standstill time for each deviation a box and whisker chart was made using the standstill time for each occurrence as can be seen in Figure 6.1 and Figure 6.2. The charts display the same data, the only difference is that Figure 6.1 also shows the potential outliers in the data. Only the deviations that had occurred 10 times or more are displayed in the figures. The figures contain many features of the data. The x marks the mean, the box is limited by the first and third quartile, the line marks the median, and the whiskers mark the lowest and highest occurring value that is not considered to be a potential outlier. The figures show that material defect, material shortage, and human deviations have rather extreme outliers which might be the cause for pushing up the mean

value above the third quartile. As can be seen in Figure 6.2, the mean values for all of the displayed deviations are higher than their median values which might indicate that the data is skewed to the right (the median value for “human” is coinciding with the value of the first quartile, which is 1).

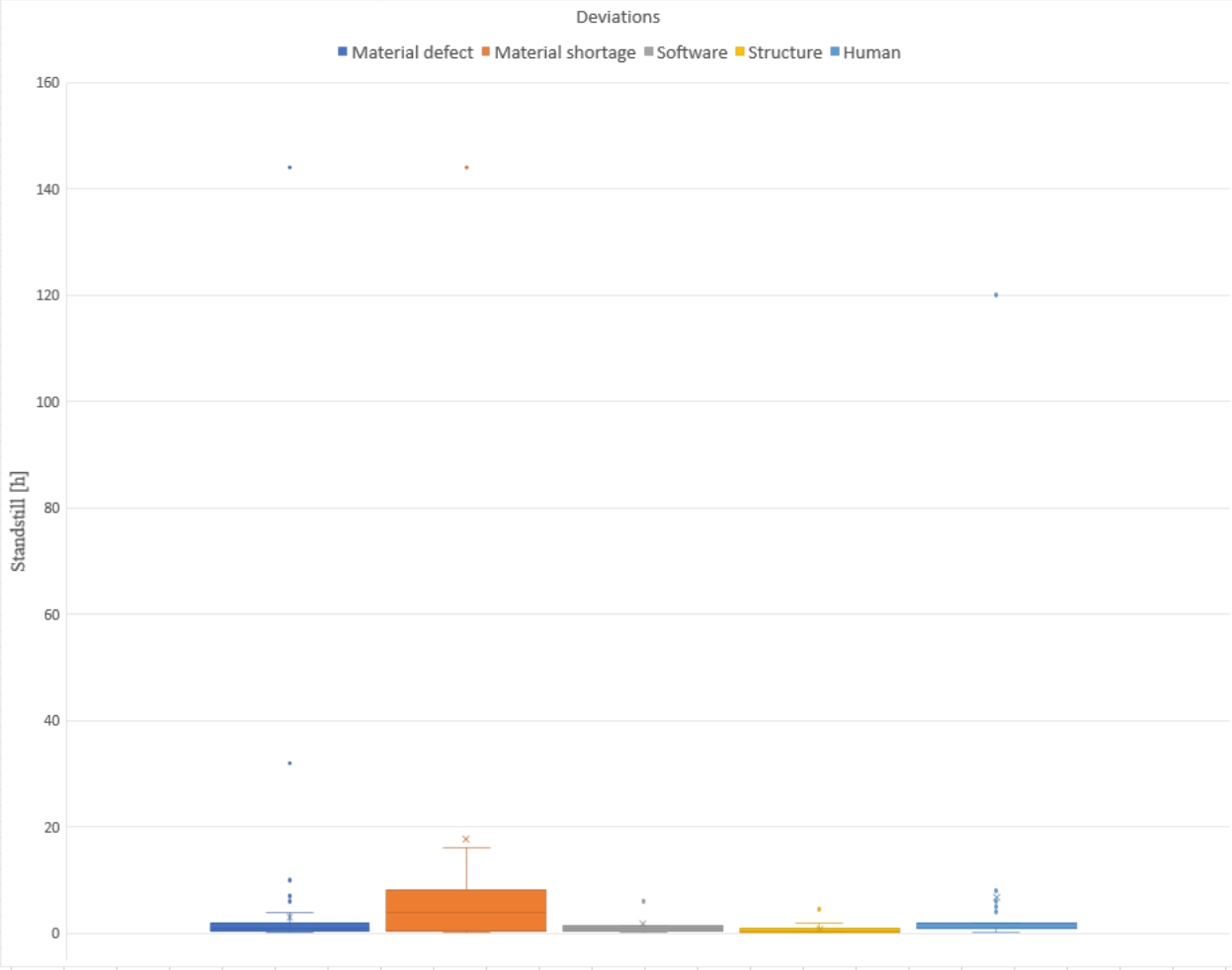

Figure 6.1 Box and whiskers plot of standstill for deviation types with 10 or more occurrences. In this figure, the outliers are included.

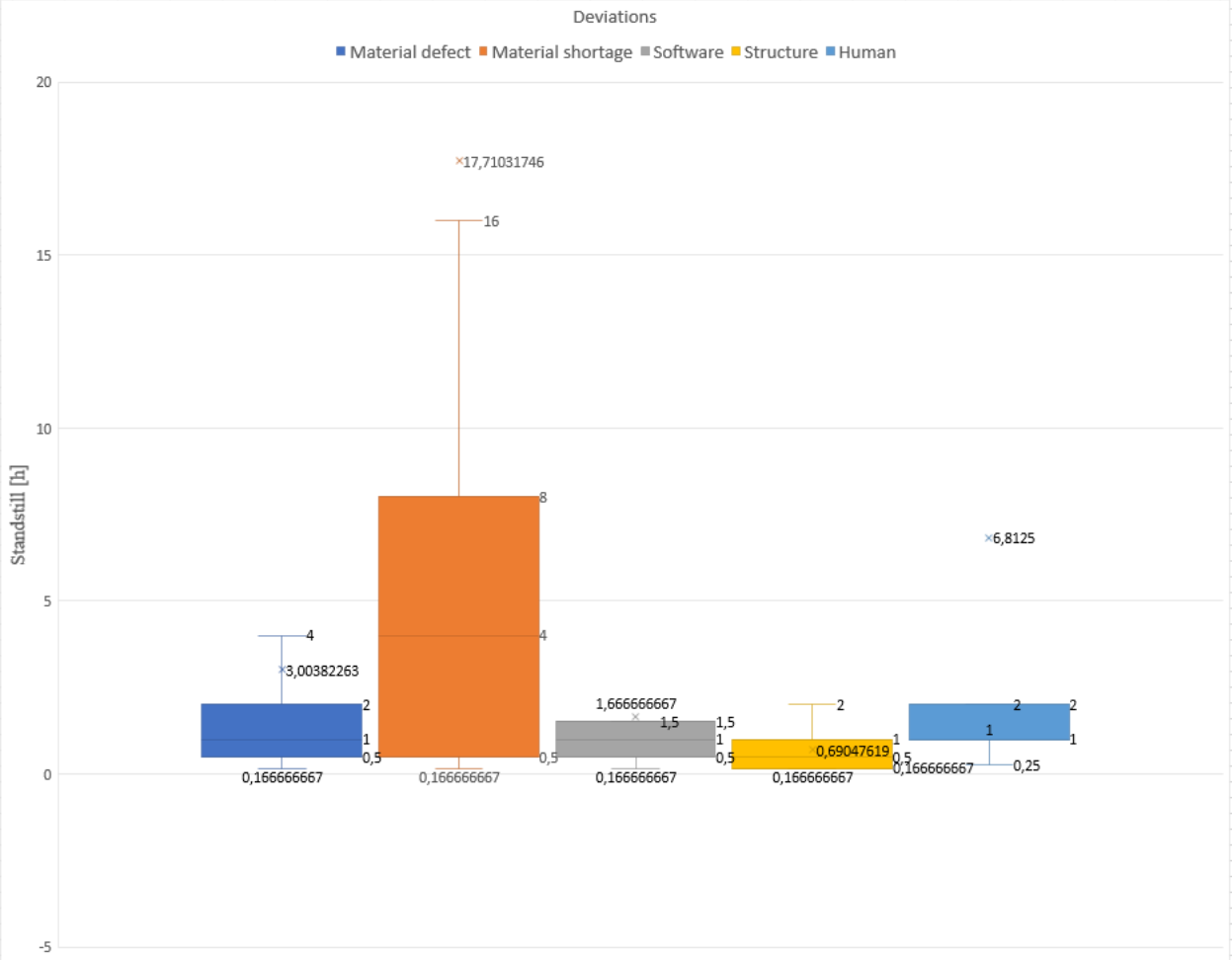

Figure 6.2 Box and whiskers plot of standstill for deviation types with 10 or more occurrences. In this figure, the outliers are not displayed.

The compilations above give an indication of the issue at hand but it also indicates the importance of how data is collected. It is however important to keep in mind that the data used to conduct the compilations is flawed as mentioned in *6.1.1 Deviation document analysis*. If the input data is not accurate and is missing information it is going to affect the output data and make it less reliable. The results above should therefore be viewed as approximate indicators of the current state of deviations rather than the absolute truth. Hence, the current method of data collection regarding deviations needs to be reviewed.

6.3 Root cause analysis

Based on qualitative methods and the measurement data provided in *5. Measure*, a root cause analysis on the critical x-factors was performed.

6.3.1 Affinity Interrelationship Method

Together with the functional managers for production, logistics, and purchase, as well as employees from customer orders, the team conducted an analysis using the Affinity Interrelationship Method (AIM), with the purpose to qualitatively map the organization's current understanding of the structure of the problem with operational standstill due to Material Shortage. AIM is a tool that is performed in 10 consecutive steps, with the aim to map potential causes and their interrelationship, as well as their respective contribution to a stated issue. (Gremyr et.al, 2019) In this case, the issue was formulated as: "What are the

main contributing factors for standstill in manufacturing due to material shortage?". The result of this analysis can be found in Appendix *A AIM*. With the contribution from a representative sample of individuals from different functions within the company, it was ensured that the analysis was not skewed towards one particular part of the company. This is important because different functions might have different knowledge and views regarding particular issues. However, the analysis was split up into two occasions. The first occasion, where the raw data was collected and the grouping was made, had all representatives from the above-mentioned departments while the second occasion, where the interrelationship was determined, was only attended by one employee from the purchasing department. Due to the unfortunate low attendance on the second occasion, the analysis could potentially lose credibility regarding the potential cause-interrelationship. However, since the majority of the data collection was conducted during the first occasion, the results were deemed to be representative of all functions.

6.3.2 Fishbone Diagram

In order to structurally identify and document the potential causes for standstill, a fishbone diagram was made. A fishbone diagram, also referred to as an Ishikawa diagram, is a tool that allows for a structured and visual representation of the cause and effect relationship of a problem. The tool got its name from the esthetical similarities to a fishbone, with the bigger bones representing main causes, and the smaller bones representing different levels of subcategories of causes. In this case, the effect of the issue is standstill and rework, and the causes are a wide variety of different factors as shown in Figure 6.3.

The diagram was conducted during a brainstorming session utilizing qualitative analysis, including interviews and observations, the AIM analysis, as well as quantitative analysis using data from the deviation document regarding machine M4 during 2019. Most branches were generated from the gathered data while some were defined to extend the current definitions of deviations.

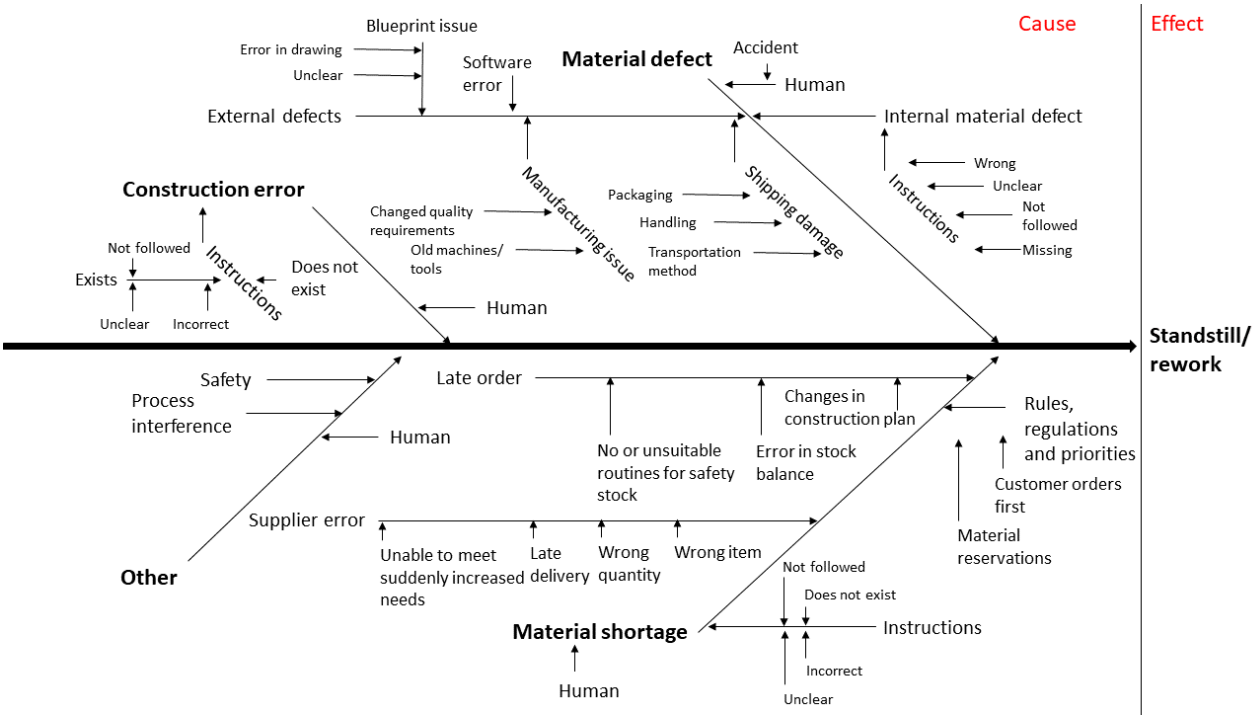

Figure 6.3 Fishbone diagram displaying the cause and effect relationship of the standstill problem. Bones connected to the spine of the diagram represent different levels of the potential causes for standstill and rework.

The full analysis showed that the lion part of the causes contributing to standstill in manufacturing operations can be grouped into three main categories of factors, material defects, material shortage, and construction errors. Additionally, there are a few factors that could not be categorized as neither of the aforementioned main categories of factors, denoted as “Other”.

6.4 Material defects

The first main category of factors that were identified was material defects. A material defect is any deviation related to the state and quality of the procured material. This means material with insufficient quality, which forces the production to a halt or causing the operators to perform rework. Rework includes changing parts, throwing away a part, repairing parts, or similar activities that would not have been needed if the part met quality requirements.

Material defects are currently being logged in the deviation document when they are detected. The current documentation does tell what went wrong and what was done to fix the immediate issue but lacks information and categorization of causes. When it comes to standstill, the most important action to delimit the effect of material deviation is to reduce the amount of rework needed to fix the issue. In general, the amount of rework increases with the number of steps performed where the defective part was present. The worst-case scenario would be if a defective part was included in the system at an early stage and only detected during testing at the end of operations, or even worse, if sent to a customer. If the part is deeply integrated, it could result in extensive rework just to be able to change the defective part.

The root cause analysis showed that there are two categories of material defects, or rather, two types of causes for material defects, namely external defects and internal defects.

6.4.1 External Material Defects

External material defects are all material related defects that come as a result of external factors. In other words, the part is already defective when it arrives. As explained earlier, it is crucial to find these defective parts as early as possible to avoid extensive rework and possible safety risks. To avoid this, the company has recently compiled a list of parts that are critical to quality and parts that are critical to safety. The purpose of this is to ensure that certain parts meet quality requirements and to ensure that these parts have robust quality assessment criteria. This also makes it possible to communicate these requirements and criteria to the suppliers. A more precise specification would, in theory, reduce the incoming variation of material quality, while imposing more extensive quality controls would make the system more robust for incoming variation. The drawback with more extensive quality controls late is that it is time-consuming and costly, and could be considered as waste according to the principles of Lean Production and Six Sigma. Quality control should be controlled with standardized monitoring systems in the early phases, which would reduce the post-monitoring of deviations to a minimum. It is therefore important to limit quality controls to vital components and components that have a high rate of defects as early as possible in the process.

Three sub-factors of external defects were defined; Shipping Damage, Supplier Manufacturing Issues, and Blueprint Issues.

6.4.1.1 Shipping damage

Shipping damage is, as the name suggests, damage sustained during transportation of the material. This can be caused by inappropriate handling, insufficient or inappropriate packaging, or by utilizing transportation modus that is not suitable for transporting the specific component(s). The shipping damage can often be assessed upon arrival. For instance, if a steel plate is correctly manufactured, but scratched, bent, or cracked, it is possible that the damage was sustained during shipping. By assessing the packaging and the mode of transportation, this could be confirmed. Depending on the contract with the supplier, this can either be addressed to the supplier or investigated internally together with the shipping company.

6.4.1.2 Supplier Manufacturing issue

The second external factor that can cause material defects is caused during the supplier manufacturing process. Old tooling or machines can be a cause for a high rate of defective components. This can be assessed using second-party supplier audits, investigating if the current supplier manufacturing process meets requirements.

Another reason for the supplier failing to meet quality requirements can be that Company A is changing quality requirements. As a step in continuously improving product quality, tolerances are narrowed and requirements are sequentially increased. This can result in the supplier having issues to meet the new requirements with their current manufacturing process. If this happens, Company A could either help the supplier to meet expectations or, if necessary, change the supplier.

6.4.1.3 Blueprint issue

Another cause for external material defects can originate from Company A itself. This type of issue can be referred to as “Blueprint-related” issues. The company is continuously improving its machines, and thus, changes the measurements, tolerances, materials, etc. in their blueprints. These changes can be followed using a revision-based system, meaning that each new change will have a newly assigned revision number attached to the order. However, altering revisions can confuse the supplier, as there might be old revisions in the supplier’s manufacturing system. The result can be that the supplier manufactures according to the old revision, meaning that they are following outdated blueprints.

Blueprints can also be unclear, yet correct. In some instances, the blueprints can seem self-explanatory from Company A's point of view, but might still be misinterpreted by the supplier. In most such cases, the supplier will communicate this and ask for a blueprint update, but if the supplier proceeds without knowing, the result can be defective parts.

The last blueprint-related external material defect is that the blueprints are incorrect. This can be a result of a human error along the line. This means that the supplier received incorrect blueprints. Because there are several different launches for the machines, it could be a possibility that such a thing could occur. Overall, it should be rather simple to backtrack a blueprint related material defect.

6.4.1.4 Software error

This category covers issues that occur due to software-related problems detected in the production. These issues can, for instance, be due to faulty calibration or insufficient programming. These types of issues are likely detected through testing, as visual inspection is usually very time consuming if even possible.

6.4.2 Internal deviations

The other main factor for material defects, aside from external factors, is the internal factors. Internal defects constitute the internal handling and processing of the material. It could range from internal logistics or faults that occur during the manufacturing process.

6.4.2.1 Instructions

Many of these types of issues seem to be related to instructions for the different operations. If operational activities result in a lesser quality of the material used, it can be due to several reasons. Either, the instructions of the operation are unclear so that it can be interpreted wrong, hence causing material damage. This should be rather easy to follow up since the operator can point out the unclear instructions. Another case would be that there are no instructions at all for the activity. This can result in material deviations, especially considering employee turnover rate. With new operators joining Company A, activities that had been considered common knowledge might not be trivial enough to avoid operational errors. If a certain operational step causes many material defects, instructions for that activity should be established.

If there are correct and clear instructions, but they are not followed, material defects can occur. This type of issue is serious, as it is not a structural issue, but rather a disciplinary issue. One example of a case where instructions tend to be overlooked is when it is not aligned with best practice. The operator then proceeds with what he/she considers to be correct, without following the written instructions. To avoid this, it is important to continuously update the instructions in consensus. Another possible example of instructions not being followed even though they exist is that they are not communicated properly. There might be instructions written, but they are not followed since the operator does not know of their existence. Hence, communication is also key when it comes to instructions.

The last instruction-related internal material deviation is that the instructions are followed, but they are not correct. Faulty instructions can be a result of new product launches or updates to existing machines with instructions not being up to date. Such errors might be spotted before they are followed, but if they are not, it can result in material defects.

6.4.2.2 Human error

Not all operations have, or will have, instructions. This is because some operations, such as moving one component from one place to another, are trivial enough to be understood without instructions. Yet, the material can be dropped, scraped, cracked, etc. during such operations as well. These errors can be referred to as Human errors, or simply "mistakes" and they can occur in all of the main categories. If

certain mishaps are reoccurring often, the company should consider implementing guidelines. There is a balance between instructions and guidelines. The former tends to take ownership from the operator, whereas the latter embower the operator taking the daily decisions. Additionally, instructions tend to be static and can easily become obsolete whilst guidelines are dynamic and can be self-organizing if they are matched against the right standard and know-how.

6.5 Material shortage

Material shortage is another main cause of standstill in manufacturing operations. Not having access to material when needed is indeed disruptive, as it is impossible to proceed assembly without the material. When analyzing material shortage in the system, it is clear that it is logged differently across the different functions. Primarily between the purchasing department and in production. It is also clear that it is perceived differently between functions, as the purchasers see the ordering and supplier-related issues whilst the production department experiences the results of material shortage. The deviation document is filled in on the production floor, and because of this only includes the results of the deviations rather than the causes. In order to bridge the perception gap between the departments, meetings are held between purchasers and production employees so that the production department can get a better understanding of why the material is not present and when the material is expected to be delivered. While this is good, it would not be necessary if the material shortage issues in the deviation document were updated frequently and by the purchasing department.

Material shortages can be caused by a few different main factors, namely a supplier error, a late order placed by the purchasing department, or by hindrance caused by supporting and secondary information processes, i.e., planning, policies and regulations, and system flaws.

6.5.1 Supplier error

A supplier error is any issue caused by the suppliers that result in material shortage for production. This means that the supplier is responsible for the shortage and the standstill that comes as a result of the deviation.

There are several different examples of supplier errors. Perhaps the most obvious is the case when the supplier fails to meet the delivery date. The reasons for this type of deviation are many, and will not be covered in this report as Company A has no direct influence over the supplier's business. However, it is important to measure both the delivery precision of the suppliers and to monitor their performance over time. If a supplier fails to meet the delivery date on several occasions, the costs for Company A could be significant. It is therefore vital to have trustable lead times and that the company can trust that these lead times will be held.

During interviews with several employees from the purchasing department, it was established that the current lead times were taken directly from the supplier, meaning that the supplier had set the lead times of the sourced parts. It was also revealed that some parts did not have a lead time at all. This makes it difficult to predict when certain components might arrive, and will also make it difficult to conduct proper resource planning. Currently, there is a KPI in place to measure the delivery performance of the suppliers. However, in many cases, material is ordered within lead time to meet unexpected needs, meaning that many orders are placed not in accordance with pre-determined agreements. The current way of measuring delivery performance is, therefore, "delivery according to promise". The way this works is once an order is placed the supplier must respond within 48 hours with a confirmation of the order and the suggested date of delivery. If the company cannot manage to deliver according to the suggested date, they might suggest a new date in the confirmation. This date is the set delivery date. This date is then referred to as the "promised date". The company must be able to trust that the goods will arrive on that particular date.

Once a delivery has been received, the dates are checked and logged. This means that this KPI shows the ability to meet the promised date, not the actual lead time. However, in some cases, the supplier can encounter issues that force them to postpone the delivery. This can result in a lack of material without the KPI showing it, as long as the supplier can meet the promised date.

Figure 6.4 shows the supplier delivery precision according to the promised date during one year running. It becomes clear that the delivery precision, as it is measured, generally exceeds the 18-month target of 90% on-time delivery. Note that the sudden drop in April 2020 is due to an agreement with the suppliers to postpone delivery. This is a result of the COVID-19 pandemic and should be considered as an outlier value deviating from the normal process behavior. A sourced component is deemed to be delivered on time if it has arrived within 4 days of the promised date. This means that the delivery can either be < 4 days early or < 4 days late and still considered to be on time. If a component is, e.g. 3 days late, it could result in 3 days of standstill (hypothetically), and it would not show in the current KPI. Although the KPI is functional in the sense of measuring the reliability of the suppliers, it is not trackable to lead time. A supplier can deliver poorly according to lead time but follow their promised dates to a large extent. The issue with this is that there is no current method of knowing if the lead times are reliable or even held. If orders are placed based on lead time, this can become a problem. The material can be expected to come in accordance with the set lead time, but in reality, they are coming in late. This makes it difficult to track and manage resources and might result in a lack of resource availability.

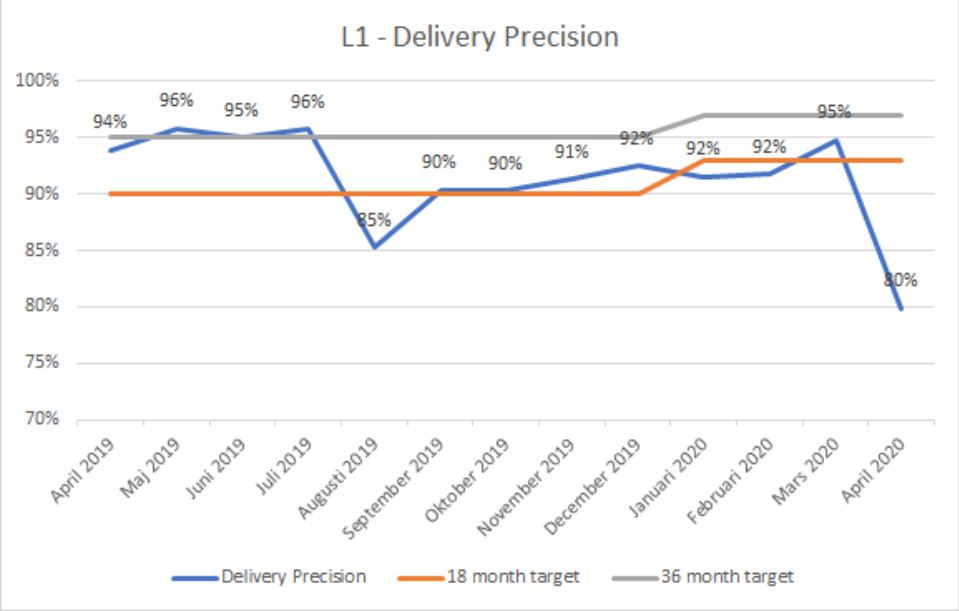

Figure 6.4 Key performance index describing the delivery precision of suppliers. If a delivery has arrived within 4 days of the promised delivery date it is said to be delivered on time.

One reason for the supplier not being able to deliver according to promise or lead time is that, on some occasions, the supplier cannot manage changes in demand. As Company A is scaling up production, the demand is continuously increasing. Some suppliers might encounter issues in managing to meet the new demand. The issue is not being able to handle the new order quantity on the expected lead time. This is solved today by ordering in smaller quantities with delivery spread out across the year. However, on some occasions, a sudden change can cause a sudden increase in demand, perhaps due to a large customer order draining the stock. Because of the flexibility Company A has for its customer, they must be able to expect a similar level of flexibility from their suppliers. In order to increase the robustness in such a situation is

having second sourcing or even multiple sourcing. This means that if the main supplier cannot manage the sudden demand, additional suppliers are available. However, having many suppliers can be costly and difficult to manage, so investigating which components and suppliers need multiple sourcing is key to keeping down costs. An initial investigation was made to determine which items are often in shortage by compiling the shortage lists described in *5.3 Shortage List Compilation*. The compilation shows what items are more often than others in shortage along with its supplier. The compilation also shows if an item has been in both customer order shortage and manufacturing order shortage at the same time which might be an indicator that customer orders and manufacturing orders are causing shortages for each other. However, the shortage lists do not contain cause for the shortages. To proceed with the information in the shortage lists it is important to investigate causes in order to determine the correct actions.

If the supplier manages to deliver on time, there can still be supplier-related errors that cause operational standstill due to material shortage. The supplier can deliver the wrong items or the wrong quantity. When ordering a large number of different parts from a supplier in one big order, it is not unlikely that something goes wrong. This is easily trackable as the delivery is checked when it arrives at the company, but can, in the worst-case scenario cause material shortage in production, especially if the lead times are long.

6.5.2 Rules and regulations

One other cause for material shortage is regulations, priorities, and system errors. These are internal system and operational related priorities or issues that ultimately can cause material shortages.

In the system, there are two main categories for logging lack of material, either it is missing for production due to manufacturing orders or it is missing to a customer (customer order). The difference is that the manufacturing orders are material needed for direct operations on currently assigned builds, whereas customer order can be a variety of different needs from a customer perspective. For instance; it could be a subsidiary wanting to refill stocks, a subsidiary having a customer who needs a specific part, one of the company's customers needing a spare part, etc. The company has a service agreement in place, where they promise their customers that if a machine is not working, they will get it up and running within 48 hours. This means that spare parts can be needed in an instant, depending on the reliability of the delivered machines. This is believed to be one of the reasons that material suddenly becomes missing for production. The process of customer order procurement can be seen in Figure 6.5. Note that the only difference from the entire process VSM, in a practical sense, is that the manufacturing operations and the finished goods storage are excluded.

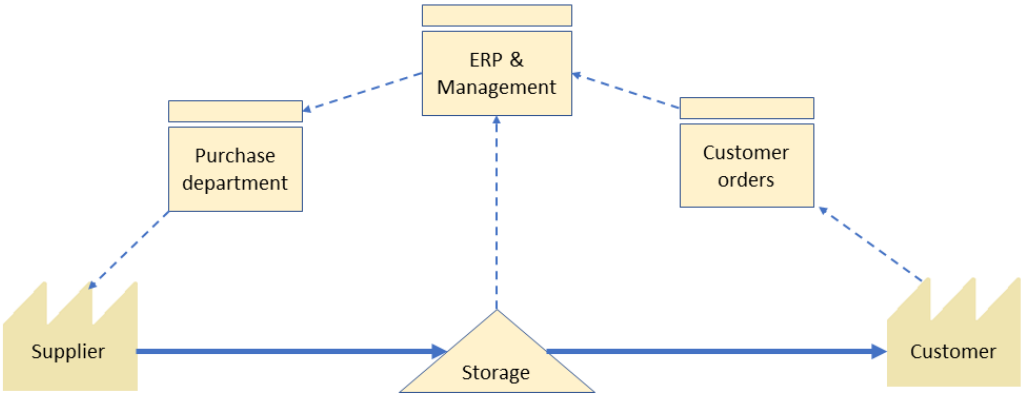

Figure 6.5 Value stream map showing a simplified image of customer order procurement.

Because both value streams coincide, the customer orders can drain the material, ultimately causing a manufacturing standstill due to material shortage. This is a known issue within the company, and there has been a suggestion to separate the stock for manufacturing orders and customer orders and spare parts. The positives with this are that resource management could potentially become much easier, as planning resources based on historical data is much more predictable in manufacturing than in spare parts. It is easier to establish a stock that is suited for machine planning rather than forecasting what spare parts will be used in the future. This would not only potentially decrease the standstill caused by material shortage for production, but could also allow for a lower overall safety stock for machine components. In order to investigate the relevance of this, data was analyzed regarding simultaneous shortages of both customer orders and manufacturing orders. Although this does not cover all the instances where customer orders drain the stock, it can give a perception of the extent of the problem.

Figure 6.6 shows individual articles on the x-axis and the number of occurrences when the article was both missing for manufacturing order and customer orders. For confidentiality reasons, the item numbers have been erased. Note that this does not indicate individual occurrences but rather the extent of the issue of simultaneous shortages. This is because this data shows how many times the articles appeared on the ERP system as a shortage both on customer orders and manufacturing orders. This means that the articles in question can have been a shortage for consecutive days, or on many different occasions for shorter periods. Nevertheless, the data shows that there are a substantial number of cases where customer orders and manufacturing orders are lacking the same material. Since customer orders are prioritized, it is not unlikely that large customer orders have caused material shortage for production on many of these occasions. For parts with a large number of occurrences in the figure below, a new strategy of stock-keeping should be considered.

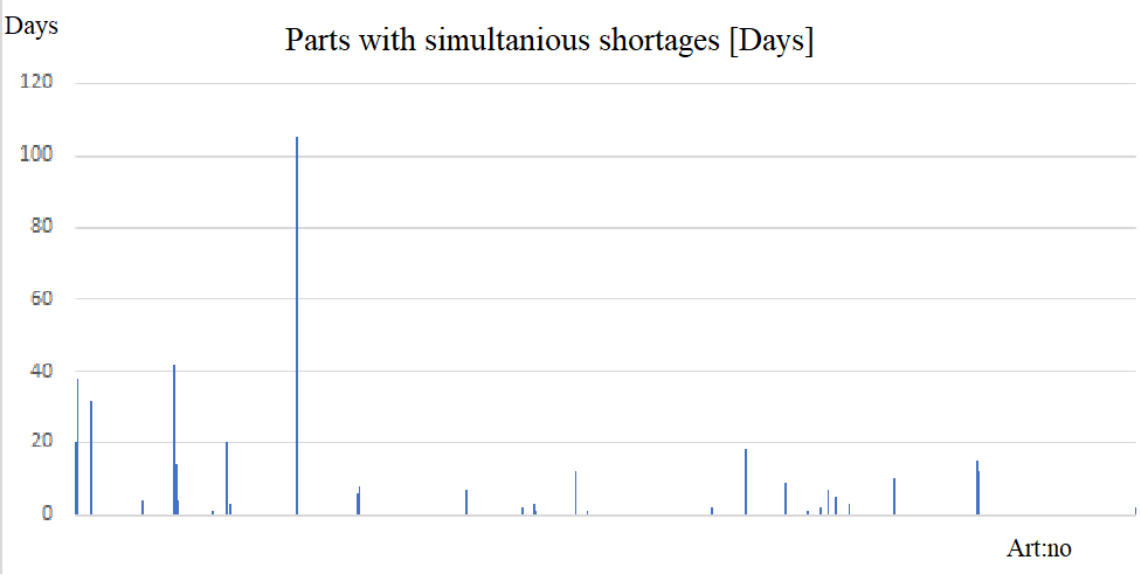

Figure 6.6 Each bar represents an item. The number of days the item was in both customer order and manufacturing order shortage simultaneously is displayed on the y-axis.

Figure 6.7 shows the distinct number of items that have been registered as a shortage in the system over the year. The x-axis shows each consecutive day and the y-axis represents the number of unique entries in the shortage list. This indicates when there are shortages for manufacturing orders and customer orders respectively. There seems to be a larger number of manufacturing shortages in the first half of the year, whereas customer shortages seem to be higher in the latter part of the year. Both customer and manufacturing shortages increased substantially at the end of the summer. One reason for this is the fact that many of the suppliers are located in Sweden, where the summer vacation causes companies to reduce production or even close operation for a period of time whereas many of the company customers are located abroad where operations continue. Another reason could be that companies want to fill up their storage after the summer and that this is causing shortages in both manufacturing and customer orders. However, this data should be analyzed with care, as the company moved to a new facility after the summer of 2019.

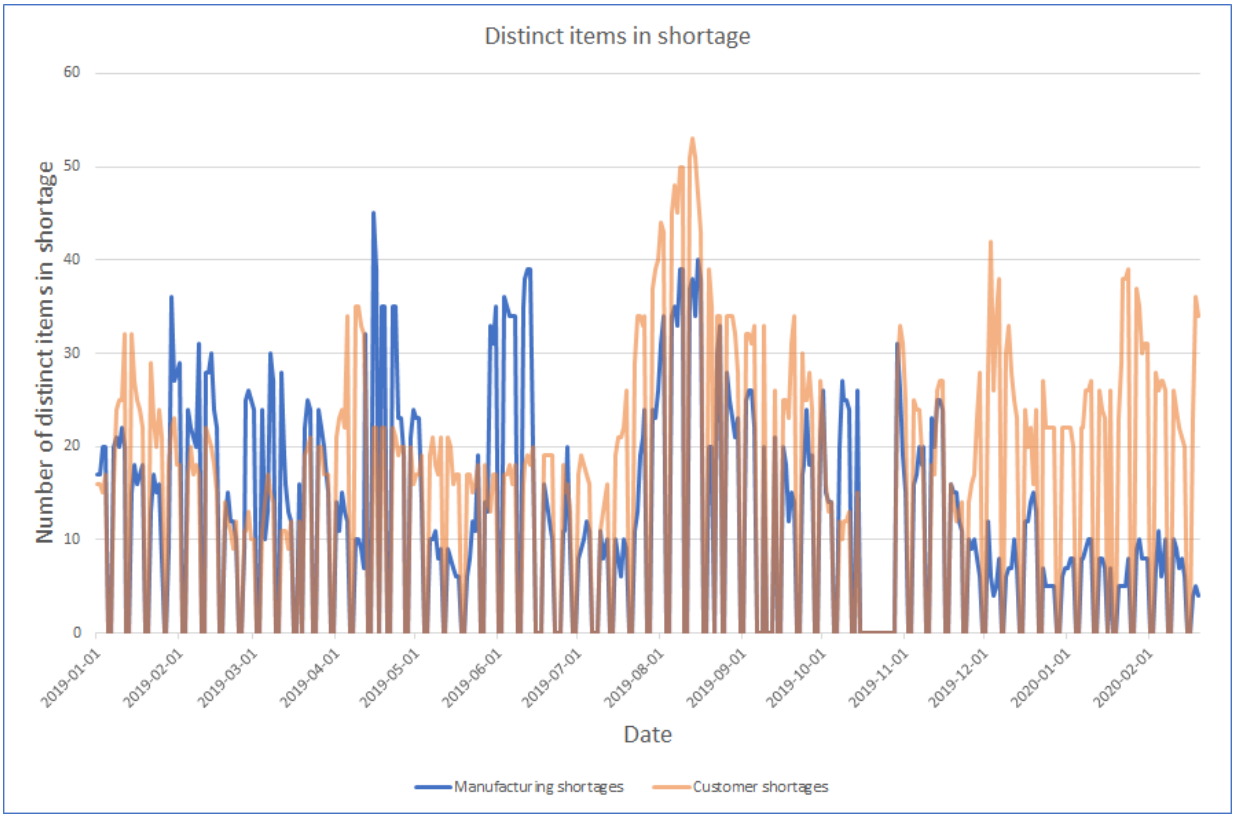

Figure 6.7 The graph shows the number of distinct items in shortage for each day. The blue line describes manufacturing shortages and the orange describes customer shortages. The value goes down to zero when data is missing, mostly during weekends as the shortage lists are received on weekdays.

Another issue that was brought up during the AIM analysis was the fact that the system can show the wrong amount. If a machine is started in the system, the material needed to build that machine is booking material. This means that the material that needs to be used within the next few weeks will be allocated to that build. If for some reason a build is canceled or changed, the material can still be booked by the machine, although it is not needed. The issue with this is that the material is unavailable in the system, but is de facto available in stock. In order to avoid this, the system needs to be checked and updated regularly to ensure that there are no "ghost" machines in the system. Although this is not a true material shortage by definition, it can cause the belief that there are shortages, and if no inventory checks are being made, it is difficult to assess the availability of material.

6.5.3 Late order

The last second-order cause for material shortages is late orders. A late order is an order placed within the set lead time and is thus caused internally. This means that, even though the supplier manages to deliver according to lead time, the delivery will be too late from the production point of view. There are several reasons why an order can be placed too late. One such reason could be that there is an error in the stock balance. Similar to the presence of "ghost machines" in the system, there are cases where the balance shows that there are parts in stock, but in reality, the balance is zero. The reason for this could, for instance, be that parts have been taken out without logging it. The issue with this is that system will not notice the purchasers that parts need to be ordered, ultimately resulting in a situation where the issue will only be noticed once the material is needed. Depending on the lead times of the affected parts, the

standstill can be severe. In such cases, the company will try to get these components delivered as soon as possible, placing orders within the lead time, i.e. placing a late order.

Another cause for later orders can be that there are no reliable routines for updating safety stock. As explained, some components do not even have a safety stock logged in the system, and some safety stocks are just set to avoid getting noticed from the system to order. The current process of setting safety stocks is estimations made by the purchasers. However, with no routines for updating the safety stocks, components might be too low to cope with increasing demands, thus causing the order to be late. Due to the fact that Company A has scaled up production, and shifted their productional focal point from one machine type to another, the turnover rate of certain components has and will change over time. For example, a component with an annual consumption of, say, 40, has doubled over the last year, yet the safety stock stays the same. If the consumption is due to larger singular outtakes, the safety stock may be too low to act as a buffer. The purchaser can either increase the frequency of orders, or material shortages will occur. The problem will be further enhanced if the lead time is high, and if the minimum order quantity does not allow for more frequent orders. Because of this, it is recommended that when the company decides to update safety stocks, the consumption data, minimum order quantity, and lead times are investigated. This is not only relevant for parts that historically have caused operational standstill, but also parts that have decreased in turnover over time. Having more suitable safety stocks can not only limit material shortage but also lower the tied capital.

Because the stock is shared for parts for manufacturing and spare parts, it is important to consider what parts should be allowed as spare parts. Or more precise, what level of parts should be considered spare parts. What is meant by this is that parts are included in a level of integration, i.e. subassemblies. It might be too costly to have each individual part in stock, and available as a spare part. It is recommended to investigate the turnover rate over the last year and assess the reasonability to sustain certain parts as spare parts. This is in itself an extensive task but is deemed necessary.

Another cause for late order is sudden changes in the construction plan. Because of the level of flexibility the company has, sudden changes can be made in order to meet customer demands. This can include adding machines to the build plan, and rearranging the build plan so that it better suits the more immediate customer needs. This will inevitably result in sudden demands of sourced components, sometimes within lead times of certain parts. This is, in itself, a cause for late orders. Note that sudden changes in the build plan can result in the supplier not being able to deliver the wanted quantity, even if the order is placed based on lead time. This is, however, an external supplier issue rather than a late order. This project had a delimitation that it should not restrict the company’s ability to be flexible towards the customer, hence, changes in the build plan are to be expected. However, it is important to communicate the planned changes as early as possible in order for each function to be able to act proactively. Perhaps, if it is a commonly reoccurring reason for late orders and thus material shortage, the company should take action to mitigate the negative effects of changing the production plan. One example of such an action would be to analyze the quality of the production forecasts.

6.6 Construction error

In some cases, standstill can occur due to errors other than those that involve material defects or material shortage. Despite having sufficient material at hand, the production can come to a standstill due to construction errors. This type of error relates to mishaps or errors that occur during manufacturing operations. Such errors can often relate to the instructions of the activity.

If there are instructions for the operational step where a mishap occurred, it could either be because the instructions were not followed, that they were unclear and misinterpreted, or that the instructions were

wrong or outdated. The other possibility is that there were no instructions available for the activity, which causes operators to operate differently. If it is observed that construction errors occur repeatedly on one particular operation, the way to solve this is to write, update or clarify the instructions, or to conduct operator training. Certainly, there are cases where there are construction errors due to human mistakes, but having data that can show the occurrences of these errors can help differentiate a real issue from a mistake.

6.7 Other

Although material defects, material shortages, and construction errors should cover the majority of the deviations (as it stands today), there will be cases where the production calls to a halt due to other reasons than the aforementioned. Safety is of big concern to Company A, and the safety of the operations is key in the company culture. Thus, there might be cases where unexpected events cause standstill because it is not considered safe to proceed according to plan. Note that the other main causes can result in a situation that is not considered safe, but then the cause of the standstill should be denoted to that particular cause, and not Safety. For instance, if a construction error has caused the machine to leak vacuum, it might not be safe to continue with operations and there will be a standstill. The cause of that standstill is not safety, but rather construction error. In some cases, however, there might be a reason to put safety as the cause of standstill. If there is a leakage in the roof, causing water leakage, that might affect the machines, the cause for standstill is considered to be safety.

The final cause for deviation that was identified was standstill caused by process interference. The rather broad cause cover unexpected aspects of the process that results in standstill for the machines. Temporary employee shortage or sudden loss of power could be two examples of process interference. These are considered to be a type of natural variation that is hard to predict and difficult to eliminate.

The Lean Philosophy expresses the importance of the continuous flow of operations, not only for each machine but for the system as a whole. The reason is that, because of the layout that the company adopts, standstill downstream in the operational flow can cause process interference and standstill upstream. This means that even though one machine is ready to be moved to the next workstation, if that workstation is occupied by a machine that is experiencing issues the standstill will be doubled due to queuing. This phenomenon is important to acknowledge, since the issue for one machine, ultimately can affect the throughput time for several. The company is due to experiencing this issue if the production volume reaches a high enough level, mainly due to the bottleneck that is the testing phase. The positive with having a workstation-based factory layout is, however, that it is possible to move the stationary machines aside and continue work on other machines without having it severely backing up the operational flow.

7 Improve & Control

In order to help build the foundation for proactive quality management, and to increase the knowledge within the company of the present causes for standstill, the researchers recommend the implementation and continuous usage of Process Failure Mode and Effect Analysis (PFMEA). This chapter will thus cover an explanation of the tool as well as an implementation strategy for the company.

7.1 Process Failure Mode and Effect Analysis

For a smaller company, a test-and-fix approach to quality might be sufficient to ensure quality at acceptable costs. However, when scaling up its operations, the approach might become too time-consuming and too costly to sustain. Sorting out issues as they occur and try to mitigate the negative effects is a reactive approach that does not solve the issue from its source. Hence, a more proactive approach to quality management is recommended for Company A. They have indeed reached another level of operational intensity over the last few years, and the current reactive approach is causing a lot of rework and standstill, which is ultimately very costly for the company. In order to initiate the shift towards a more proactive approach, the implementation of Failure Mode and Effect Analysis (FMEA) is recommended.

Failure Mode and Effects Analysis is a method designed to:

- Identify and fully understand potential failure modes and their causes, and the effects of failure on the system or end users, for a given product or process.
- Assess the risk associated with the identified failure modes, effects, and causes, and prioritize issues for corrective action.
- Identify and carry out corrective actions to address the most serious concerns.

(Carlsson 2012).

There are many different versions of the FMEA tool, however, they all focus on increasing knowledge of a given potential or recognized issue, and to provide a robust structure for continuous improvement work. Depending on the application of the tool, the content can differ. For the PFMEA, the expected entries usually include failure mode, effect, severity, cause, occurrence, detectability, risk priority number, recommended actions, and responsibility.

The failure mode is a description of the manner the requirements and intended function of a process step is failed to be delivered. The potential failure mode can be described in many ways depending on the definition of failure mode.

The effect is a result of the failure mode for which it can have more than one effect (Carlson, 2012). The effect is further discussed in *7.1.1.4 Potential effect(s) of failure*. For each effect, there should be a severity number attached. The severity number is supposed to indicate the sverity of the effect. This number is often decided based on a pre-determined scale. This will be further investigated in *7.1.1.5 Severity*.

Each failure mode will also have a more specific cause, describing how the failure mode occurred, or could occur, in a more specified manner. The causes should be as concrete as possible so that it is possible to identify suitable actions if necessary. As explained, having issues that are difficult to detect could, for example, result in a prolonged standstill and more extensive rework or a malfunctioning product being sent to a customer. Thus, this must also be included in the PFMEA. The way this is done is by the detectability number. Like the severity number, the level of detectability is a number that is based

on a pre-determined scale where the highest number represents issues that are very difficult to detect, and the lowest number represents issues that are almost impossible to miss.

Some issues rarely occur while other are present more often. In the PFMEA, this is logged with yet another scale-based number, “occurrence”. To be able to track the occurrence, the number should be based on failure modes that are due to specific causes. This number either needs to be filled in by experienced professionals that have extensive knowledge of the process and the issues and with the help of historical data.

In order to help with prioritization of what issues require immediate action, a Risk Priority Number (RPN) is calculated. The RPN is a combination of the effect severity, the cause occurrence, and the failure detectability. It represents a collective risk of the explained failure mode and is used in the PFMEA as a way of prioritizing what issues to primarily attend to. The RPN is calculated as the product of the three described factors. Once the tool is continuously being used within a company, standards can be set on what is considered to be acceptable RPN and what is deemed too high and will require corrective actions. It is however worth noticing that the RPN might miss to prioritize a failure mode or effect if it has a high severity but low occurrence or detectability rankings. The PFMEA user have to be aware of that if a high severity rankings occur this should also be prioritized in order to avoid catastrophic failures.

The right side of the PFMEA matrix is related to corrective measures with the first one being “Action(s)”. Actions refer to the recommended activity needed to mitigate one or several of the aforementioned factors. In order for the actions to be materialized, responsibility for the action is also determined here as well as a date for completion.

Once a corrective action is carried out, the three factors are recalculated based on the new circumstances to see if the action(s) have been successful. If data needs to be gathered for this to happen, the result of the changes can only be seen in the PFMEA once sufficient information is available. If the factors are based on more qualitative measures, the effect can be estimated at the point of action completion.

As cited by Carlson (2012) “PFMEA has the potential to be a very powerful tool to achieve high reliability in processes, and when done well, it is remarkably effective. […] If the tool is effectively used throughout the product life cycle, it will result in significant improvements to reliability, safety, quality, delivery, and cost.”. In the suggested version that is described in *7.1.1 Strategic Implementation of PFMEA* the focus will be to improve upon reliability in the production process.

7.1.1 Strategic Implementation of PFMEA

In order to increase reliability of the production process, implementation of a modified PFMEA is suggested. In the following chapters, an implementation method is suggested by supplying instructions on how to fill the PFMEA document. In addition to this, mock data is used to provide a visual example of what the PFMEA might look like, see Appendix *B Mock Data*. The data in Appendix *B Mock data* has been made up and does not represent any real events and thus only have the purpose to serve as an example on how to fill the PFMEA. The columns have the following instructions:

7.1.1.1 Process step

Depending on the purpose of the PFMEA the process step can be represented by small actions or larger steps. It is suggested to initially apply the tool to the process steps described in the data discussed in *5.1 Throughput time data* to cope with current deviations. The column should be filled with the step number and a description of the operation.

7.1.1.2 Function(s)

The function of the process step should be described in this column. The description should describe the operation, and parts and tools that are being used. It is worth noticing that for a process step, there may be multiple functions.

7.1.1.3 Potential failure mode(s)

The failure mode is a description of the manner the requirements and intended function of a process step is failed to be delivered. The potential failure mode can be described in many ways depending on the definition of failure mode. For example, poor performance could be a potential failure mode. Company A has to choose how to define the failure modes. According to Carlson (2012) each function can have multiple failure modes. See mockup data found in Appendix *B Mock data* for examples.

7.1.1.4 Potential effect(s) of failure

The effect is a result of the failure mode for which it can have more than one effect (Carlson, 2012). Carlson also mentions regarding PFMEAs that "the team should consider the effect of the failure at the manufacturing or assembly level, as well as the system or end-user" (Carlson, 2012, chapter *3.5.3 Effect)*. Many of the causes that have been described in Figure 6.3 will have rework or standstill as an effect but it is important that all effects are being recorded, for example, safety concerns. As mentioned above, a failure mode might have multiple effects. For instance, a material defect might have the effect of standstill but can also cause a safety issue. It is important to pay attention to all effects. See mock data in Appendix *B Mock data* for examples.

7.1.1.5 Severity

The severity is a number from a scale that is supposed to reflect the severity of the effect. The scale is supposed to make sense to the company applications and should therefore be determined and reviewed as needed (Carlson, 2012). Also, the scale should be set without regard to detection and occurrence. A modified example of the criteria for severity from *Effective FMEAs: Achieving Safe, Reliable, and Economical Products and Processes using Failure Mode and Effects Analysis* (Carlson, 2012, section 3.5.5 Severity, Figure 3.4), is shown in Table 7.1. Note that in the scale for this example, the criteria for 8 is not described as double the amount of time of criteria 4. It is important to be aware of the chosen scaling in order to be able to better interpret the ratings. According to Carlson (2012), "Using scales that have too many ranking levels for a given application can result in the FMEA team spending excessive time deciding which level on the scale represents the risk without adding value. Using scales with too few ranking levels can result in the FMEA team missing important risk differentiation." These scales can then be updated in the future based on data that has been gathered over time in order to get more exact scales.

Table 7.1 The table shows an example of what the criteria for severity might look like.

Effect	Criteria: Severity off effect on the product (Customer effect)	Rank	Effect	Criteria: Severity of effect on the process (Manufacturing/ assembly effect)
Failure to meet safety and/or regulatory requirements	Machine operation not safe to handle due to potential failure mode and/or machine not being able to meet regulations. No warning is given	10	Failure to meet safety and/or regulatory requirements	Risk of endangering operator without any warning
	Machine operation not safe to handle due to potential failure mode and/or machine not being able to meet regulations. With warning.	9		Risk of endangering operator with warning
Main function(s) not working or experiencing performance issues.	Machine is not working.	8	Major disruption	Rework/standstill, > 1 workweek
	Machine works but is unable to perform main function(s) in an acceptable manner.	7	Significant disruption	1 workweek> Rework/standstill, > 3 workdays
Secondary function(s) bot working or experiencing performance issues.	Main function(s) of machine working but secondary function(s) not functioning.	6	Moderate disruption	3 workdays > Rework/standstill, > 1 workday
	Main function(s) of machine working but secondary function(s) unable to perform in an acceptable manner.	5		1 workday> Rework/standstill, > 3 hours
Annoying defects.	Main function and secondary function(s) are working but major visual or audible defects present.	4	Moderate disruption	3 hours > Rework/standstill, > 2 hours
	Main function and secondary function(s) are working but significant visual, audible, or annoying defects present.	3		2 hours > Rework/standstill, > 1 hour
	Main function and secondary function(s) are working but moderate visual, audible, or annoying defects present.	2	Minor disruption	1 hour > Rework/standstill, > 0.5 hours
	Main function and secondary function(s) are working but minor visual, audible, or annoying defects present.	1		0.5 hours > Rework/Standsill

7.1.1.6 Cause

The cause, which is the reason for failure, is not always easy to identify and is one of the investigations that are necessary to conduct in order to have useful data for the PFMEA. The resulting failure mode in a PFMEA is caused by assembly or manufacturing failure according to Carlson (2012). Carlson also mentions a technique called the "five whys" which basically means that the team should ask why the failure occurred five consecutive times to get to the actual cause. There can be multiple causes for a single failure mode. See examples in the mockup data found in Appendix *B Mock Data*.

7.1.1.7 Occurrence

The likelihood of a failure mode and its cause being present at production can be described by the occurrence which is a ranking number and should not be determined with regard to the likelihood of detection or severity (Carlson 2012). The scale should be agreed upon before taken into use. It is desirable if the ranking is objective hence, it can be a good idea to document the occurrence of the failure mode and its cause to get data that can describe how often the failure mode and its cause are present. This data could then be used to establish an occurrence. scale from 1 being very unlikely to occur and 10 which represents a very high occurrence. An example of this scale can be seen in Table 7.2.

Table 7.2 The table shows an example of what the criteria for occurrence might look like.

Likelihood of failure	Criteria	Rank
Very high	1 failure per 2 units	10
	1 failure per 5 units	9
High	1 failure per 10 units	8
	1 failure per 15 units	7
	1 failure per 20 units	6
Moderate	1 failure per 25 units	5
	1 failure per 30 units	4
	1 failure per 35 units	3
Low	1 failure per 40 units	2
Very low	1 failure per 45 units	1

7.1.1.8 Controls

This column should be filled with the active detection and/or prevention type control methods that are currently being used. The detection control is applied before the machine is leaves the factory and is used to detect the cause or failure mode. The active prevention type control methods are used to prevent failure mode, cause or effect (Carlson, 2012). Detection control methods are then suggested to be reviewed when setting the detectability rank as described in *7.1.1.9 Detectability*. The detection control methods could also aid when suggesting recommended action to mitigate the risk connected to detection. If the prevention type control method is properly defined it can also be considered to aid as input to the ranking regarding occurrence. It could also aid in determining what kind of recommended action to apply to mitigate the risk connected to the frequency of occurrence (Carlson, 2012). When describing the control method(s), it is suggested to define if it is a detection or prevention type method.

7.1.1.9 Detectability

Detectability is also a number based on ranking which Carlson (2012) describes as "the likelihood that the current detection-type controls will be able to detect the cause of the failure mode" (from section 6.2.10). The scale can be set from 10 which represents no current detection-type control and almost impossible to detect failure mode and cause, to 1 being very likely that the detection-type control will detect failure mode and cause. Table 7.3 shows an example of what the high and low rankings might look like. In this

PFMEA it is suggested to establish a scale and review all detection-type controls for each failure mode and its cause to be able to set a scale with criteria and assign a suitable number to describe the detectability.

Table 7.3 Example of high and low ranking criteria for detectability.

Opportunity for detection	Criteria: Likelihood of Detection by Process Control	Rank	Likelihood of Detection
No opportunity for detection	No control method(s) are in use	10	Almost impossible
...	...	...	…
High opportunity for detection	Highly reliable control method(s) are in use.	1	Very likely

7.1.1.10 Risk priority number

The RPN is simply the product of the individual ranking numbers for Severity, Occurrence, and Detectability. It is supposed to rank the risk of potential failure modes and their causes (Carlson 2012). The RPN is supposed to help to prioritize what issues require immediate action. A high RPN is supposed to be prioritized however, it is not a perfect measure for risk. According to Carlson, it is important to address both high RPN as well as all high severities. This is because an issue might have a high severity ranking but low RPN ranking, this means that the end-user and the company can still be subject to high risk even though the RPN ranking is low. In the mock data found in Appendix *B Mock data*, an example is given of a failure mode with a moderate level of RPN ranking but the highest severity ranking. Such an issue should be prioritized even though it does not have the highest RPN ranking.

7.1.1.11 Recommended actions

These are the actions that Company A has to develop to reduce or remove the risk of the potential causes for failure (Carlson, 2012). When determine actions, the existing controls should be considered as well as the cost of the action and the prioritization of the problem (Carlson, 2012). These actions must be determined by experienced personnel after the causes of the failure modes have been identified. It is possible that there can be multiple recommended actions for the causes (Carlson, 2012).

7.1.1.12 Responsible

A suitable person should be assigned the responsibility to ensure that the recommended actions are being properly used. For example, the responsible person for material shortage might be an operational buyer or someone within logistics who are aware of the cause for the failure mode.

7.1.1.13 Actions taken

These are the actions that was taken to lower the risk to what is considered to be an acceptable level. The action taken should be connected to the recommended action (Carlson, 2012).

7.1.1.14 New severity, occurrence, detectability, and RPN

After actions have been taken to cope with the cause for a failure mode, the detectability, severity, and occurrence ranking should be updated on the right-hand side of the PFMA if the action has changed the current state of these measurements. This can be hard to determine right after completion and might require data that has been collected after the recommended actions have been applied in order to determine the new occurrence, severity, and detectability.

7.1.2 Continuous work

A PFMEA can be used on different levels. When the tool has been implemented and utilized, it is also possible to adapt the tool to closer analyze the specific production steps individually and further

investigate possible root causes. This would allow for continuous improvement by eliminating process waste. By initially analyzing the causes and effects of the entire process, the company can get a wider knowledge of where in the process the next FMEA might be needed.

7.2 Implementation plan

In order to ensure that the recommendations from this report can be materialized, an implementation plan is suggested. This includes what should be done, and by whom. Note that this plan covers what is suggested to be done to implement the recommended changes to the current way of dealing with deviations, and will not be definitive due to the lack of mandate for the researchers to alter the company's current way of working. Further discussions will have to be held between the researchers and the managers of Company A in order to reach a consensus on an implementation strategy.

7.2.1 Measurement system changes and responsibilities

Due to the current measurement system and its current usage not being geared towards categorizing root causes, the researchers suggest certain changes that would allow for a more comprehensive data analysis in the future.

As discussed in *6.1.1 Deviation document analysis* there is a need for additional instructions that describe how to fill the deviation document. These are the following subjects that have to be specified:

- Instructions that describe what is considered to be standstill time.
    - The standstill is suggested to be defined as the total time a machine is not being worked on in accordance with the pre-defined operational activities. This includes the time it takes to conduct rework activities in order to be able to proceed with normal operations. The standstill time should include all time lost from normal operational procedures, and should thus not include time where the machine would otherwise not have been worked on.
- New column for problematic item numbers
    - The item number should be isolated without text
- New column for cause definition
    - This is suggested to further increase the ability to categorize deviations. The categorization is suggested to follow the causes found in the Ishikawa diagram seen in Figure 6.3. For example, a deviation could be caused by material defect due to external deviation which in turn could be caused by shipping damage due to insufficient packaging. The cause definition should then be set as the following: Material Defect - External Deviation - Shipping Damage - Insufficient Packaging. If other causes than those found in Figure 6.3 are found they can be considered to be added to the diagram.

The person responsible for the document has to make sure that everybody that is supposed to use the deviation document to record disruptions has the same view of the instructions supplied with the document. This person should also have the responsibility to make sure the document is being filled correctly.

For the PFMEA to be used successfully there is a need for ownership, i.e. someone who is suitable to review the instructions for the document and making sure that all employees who use it are aware of these instructions. This person also has the responsibility to make sure that the document is being filled correctly.

In order for these changes to be possible, there might be a need for redefining existing work descriptions and freeing time for employees to be able to handle the tasks mentioned above. If no work descriptions are covering the tasks and no time is freed to handle the tasks, there is a risk that the suggestions will be disregarded and no one has time to make a change.

8 Conclusion

The purpose of this thesis was to define and identify the potential root causes for operational waste and help build a foundation for proactive quality management. The production process at Company A experiences a noticeable amount of deviations that are causing extensive rework and standstill of machines. Regarding the identification of root causes it has become clear that there is a good general knowledge about the deviations within the company and the data that they collect. Therefore, some of the main causes of standstill and rework could easily be identified. However, some root causes for deviations still remained unknown due to the variation of data precision and incomplete data collection. It is concluded that the deviation document that is currently used, needs to be revised to increase measurement accuracy. This includes updating the current instructions on how to fill the deviation document, and what data needs to be included in the file. It was also concluded that the responsibilities of those who need to fill in the document need to be spread out over the different company functions to provide a more precise and holistic perspective of the occurring deviations.

The project also resulted in defining a large number of potential root causes for current deviations. The researchers conclude that such an analysis is important for the company, as it allows for a shift towards a more proactive approach to quality management, and facilitates continuous improvements towards waste elimination. The PFMEA framework, as presented in the report, is considered to be a valuable tool for materializing the possibilities of improvement as it allows the company to continuously manage the causes for failures in production.

9 References

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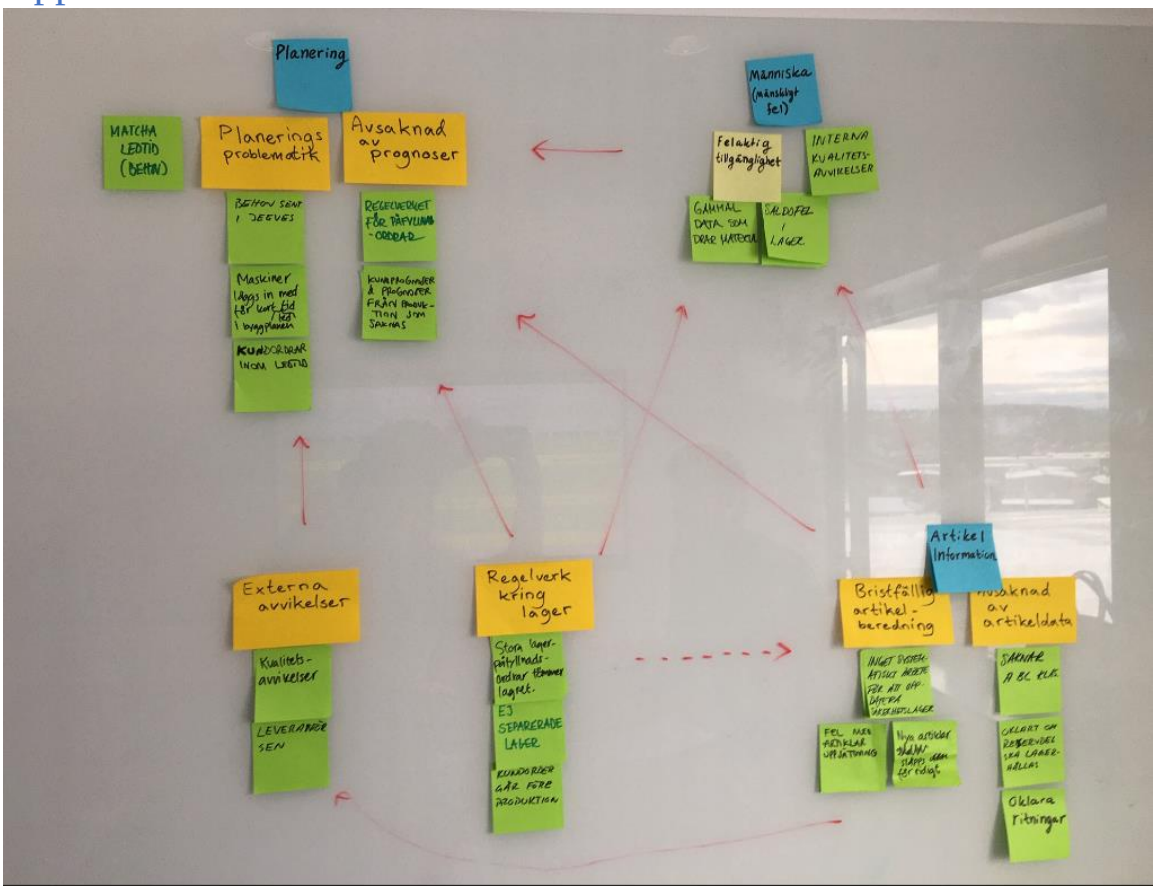
Appendix A AIM



Appendix B Mock data

Process step	Function(s)	Potential failure mode	Poential effect(s) of failure	S E V	Cause(s)	O C	Controls	D E T	RPN	Recommended actions	Responsible	Date for completion (target)	Date for completion (actual)	Actions taken	NEW S E V	NEW O C	NEW D E T	New RPN
Step 5: Mount part A onto part B using method C.	Mount part A onto part B securely in order to function as protection for the machine according to specifications.	Visual defects on surface on part A.	Standstill and/or rework. Potential scrapped.	3	Not sufficient packaging when shipping causing shipping box to scratch surface of part A.	7	Detection control: Visual inspection upon arrival	3	63	Contact supplier/transport company to suggest additional protective packaging	[SVSV]	2020-05-10	2020-05-03	Supplier A was contacted and asked to add another layer of protection at the critical area. They agreed and will update their routines.	3	3	3	27
Step 5: Mount part A onto part B using method C.	Mount part A onto part B securely in order to function as protection for the machine according to specifications.	Part A is missing.	Standstill. Unable to complete assembly. Blocking upcomming machines.	8	Part A did not arrive upon lead time due to supplier being unable to meet increased demand	4	Detection control: Continuous communi-cation with supplier	5	160	Find second sourcing for Part A. Also extend communication with supplier to detect issue earlier.	[ERER]	2020-05-15	2020-10-15	Communication routines with supplier updated: late delivery will be notified earlier by the supplier to the purchasing department. Affected personnel has been notified and supplied with instructions that state when communication is needed. Lead times were also updated to better match the current state of delivery time. Also, second sourcing supplier found that can supply part A if a late delivery is detected.	5	3	3	45
Step 7: Assemble parts from collection A using screwdriver	Parts from collection A are assembled using screwdriver according to instruction C to fulfill criteria D	Part A1 is missing.	Standstill. Unable to complete assembly. Blocking upcomming machines.	6	Item is present in stock but not available in system due to item booked to another machine which got cancelled, no rutines for removing cancelled machines	4	No current control method	10	240	Person responsible for cancelled machine must correct the system status when machine is cancelled, new instructions needed that are communicated to those affected. Also the system should be reviewed continously by machine planner.	[AVAV]	2020-05-12	2020-05-12	New instructions introduced to describe routines of actions if a machine is cancelled or postponed. These instructions have been communicated to those affected. Also, continuous review of machine planning by [DNV] was added as control method.	6	2	6	72

															NEW			
Process step	Function(s)	Potential failure mode	Poential effect(s) of failure	S E V	Cause(s)	O C C	Controls	D E T	RPN	Recconmended actions	Resposible	Date for completion (target)	Date for completion (actual)	Actions taken	S E V	O C C	D E T	New RPN
Step 7: Asseble parts from collection A using screwdriver	Parts from collection A are assembled using screwdriver according to instruction C to fullfill criteria D	Screwdriver unable to perform assembling function (*insert short description of function).*	Standstill. Cannot continue assembly work.	6	Screwdriver filled with dirt coming from assembly procedure which is causing the screwdriver to be unoperable (the screw head won't turn). Cleaning instructions are considered to be unclear which leads to cleaning procedure not being done correctly.	6	**Prevention control:** There exists instructions of how to clean the screwdriver after performing assembly procedure.	8	**288**	Review current instructions of how to clean the screwdriver with operators and improve to make them clear. Make sure that instructions are available at the process step and known to operators by letting them know it has been updated.	[AXAX]	2020-05-20	2020-05-19	Unclear instructions regarding cleaning of screwdriver at process step 7 has been reviewed together with operators. The unclear instruction was found and has been edited to be clear. Instructions are always available at the process step workstation and all operators has been notified of the update within the instruction.	6	2	8	96
Step 14: Test run of machine in order to verify function A.	Verification of function A by doing a real life scenaio test. Verification so that it fullfills criteria B	Function A fails fullfill part B1 of criteria B	If sent to customer, risk for potential injury on user.	10	Faulty installation of item C1 during process step 9 due to faulty inerpretation of instructions by operator. The instructions were unclear	5	**Detection control:** Testing of machine in testing phase	3	**150**	Review current instructions with operators and improve to make them clear. Make sure that instructions are always avaiable and known to operators. Also add prevention control at installation of item C1 at process step 9 so that it has been installed correctly.	[SVSV]	2020-05-15	2020-05-12	Unclear instructions regarding installation of item C1 at process step 9 has been reviewed together with operators.The unclear instruction was found and edited to be clear. Instructions are always available at the process step workstation and operators are instructed to always review them before beginning a process. Prevention control added at installation of item C1 at process step 9 by having a second operator verifying that the installation of item C1 has been done correctly.	10	1	3	30
All steps assigned to affected operator	Operator is supposed to performed the intended operations at her/his workstation.	Operator not available. No one available to perorm intended operations.	Standstill. The process step that was intended to be carried out by the operator can no longer be performed.	7	Operator sick/abscent, no available workforce	2	No current control method	10	**140**	Create routines/instructions for how to reorganize worktasks among available operators to avoid unnecessary standstill.	[AXAX]	2020-05-20	2020-05-20	New instructions/routines were created to be better prepared. (*Insert short description of instructions/routine here*)	5	2	10	100

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