

**Streamlining Information and Part Flow by Re-designing
Process Flow to Aid Root Cause Analysis**

by

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Bachelors of Science in Mechanical Engineering
University of Illinois at Urbana-Champaign (2016)

Submitted to the Department of Mechanical Engineering
in partial fulfillment of the requirements for the degree of

Master of Engineering in Advanced Manufacturing and Design

at the

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

September 2017

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Abstract

Waters Corporation is a world leading analytical instrument manufacturing company, with an overarching goal of achieving and maintaining high product robustness. Analysis of the challenge identifies the problem of lack of root cause analysis. This is further attributed to the inefficient process flow of information and parts: there is a lack of tracking mechanism for parts which is induced from lack of ownership and value at each stage of the root cause analysis phase. A new process flow is designed around the current process to address gaps and inefficiencies. This process flow redesign is done for both information flow for hot parts list and the movement of parts; this will streamline the overall root cause process and secondarily help save cost and eliminate redundancies. A layout improvement solution is developed, and a plan for implementation recommended. The new process flow is designed to increase visual control of the process and to effectively move the material. Each phase of the project has been reviewed and discussed to encourage stakeholder involvement in order to develop a continuous improvement culture.

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Acknowledgments

I would like to take this opportunity to express my gratitude to the people who made this possible. First and foremost, thanks to my family for their unconditional love and support. I would not have accomplished anything without them.

Many thanks to Professor David Hardt and Professor Duane Boning for being such an excellent advisor by giving extremely helpful feedback on our work and progress. Also I would like to thank Jose Pacheco for making this project possible and always being a great help throughout the program.

Special thanks to Francis Kim, Jim McPherson, Randy Koester, Randy Ryder, John Webber, Steve Zicollela, and Barbara Millers for allowing me to carry out this project. I appreciate generous sharing of your experience and patiently answering my copious questions. A thousand thanks to everyone at Waters for your generosity, enlightenment, and efforts in helping me and my teammates with the necessary resources and assistance.

Last but not the least, a huge shout out to my teammates, Basma Aiouche and Gokce Solakoglu, and all my friends who made this journey at MIT worthwhile. I learned a lot from you and it was pleasure meeting you all.

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Chapter 1

Introduction

The mission of this thesis is to develop and validate a streamlined process flow of information and parts at Waters Corporation. This thesis is based on research conducted at Waters Corporation, an analytical instrumentation company located in Milford, Massachusetts. The scope of the thesis focuses on the root cause analysis processes of the company. The end goal is to have an improved process which leads to a robust product.

1.1 Background Information

Waters Corporation is an industry leader in the field of liquid chromatography (LC), mass spectrometry (MS) and its related products. Their business is divided into two main divisions: biochemical and chemical analysis - HPLC, UPLC-MS; and physical testing - thermal analysis, rheometry, and calorimetry, where the former constitutes the majority of the revenue. Waters Corporation designs, manufactures, and provides services in analytical instruments for its core customers in markets such as chemical, clinical, environmental, food, life sciences and forensics. They have \$2.1 billion in annual revenue in 2015.



Figure 1-1: Waters Corporation [1]

1.2 Milford Facility

Waters Corporation has three major facilities, each dedicated to a particular instrument and function. They include: Milford, Massachusetts - LC instruments and accessories; Wimslow, England - MS instruments and accessories and Wexford, Ireland - Quadrupole MS instruments. Milford is the global headquarters of Waters Corporation which employs approximately 1500 employees. Furthermore, it is also the distribution center for Waters, which means it handles all the shipments for the company.

1.3 Products

Waters Corporation product line is divided into two main categories: Liquid Chromatography and Mass Spectrometry. This section includes details about the two product lines, including the science behind them.

1.3.1 Liquid Chromatography

When the separate parts contained in a mixture react differently to a mobile and stationary phase, the mixture may be broken up into its components. This method is called liquid chromatography. A liquid solvent is usually set up as the mobile phase whereas an absorptive solid called the stationary phase is used to break up the mixture. First, a pump is used to make sure that the solvent flows at a steady pressure so that the sample may be injected into the solvent stream. Then, the resulting mixture is made to flow through the column. As a result, the sample components may be broken up. The final step is to use the detector to measure the various quantities. Figure 1-2 shows the procedure required for liquid chromatography.

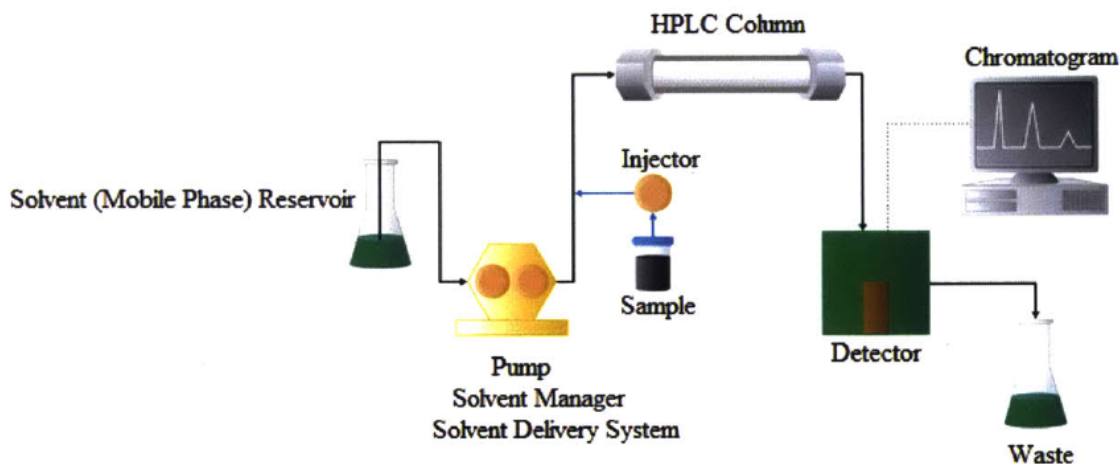


Figure 1-2: Pictorial representation of liquid chromatography procedure [2]

Different types of this process are used; the pressure at which the solvent flows varies depending on the process in use. Low pressure liquid chromatography sets the pressure at approximately 3 bar, whereas ultra-high pressure liquid chromatography uses 1000 bar as the pressure setting.

1.3.2 Mass Spectrometry

Chemicals can be ionized and the ions may be differentiated according to their mass-to-charge ratio. This process of identification is called mass spectrometry [3]. It may be utilized to identify mixtures as well as pure chemicals.

Mass spectrometry ionizes specimens by striking the specimens with electrons, breaking some of the specimens into charged parts. Then, the ions are sped up through magnetic and electric fields which allows them to be sorted according to their mass to charge ratio. The various ions are, then, caught and identified using electron multipliers or similar methods. Finally, the ions can be identified by showing their relative abundance as a dependent variable of the mass to charge ratio and comparing these values to already established values.

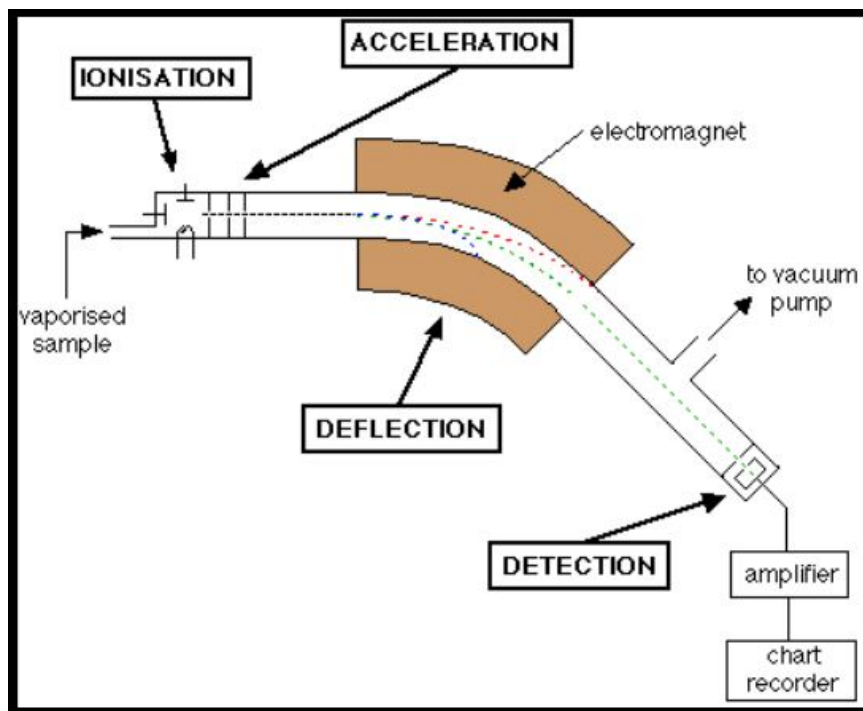


Figure 1-3: Working of a typical mass spectrometry [3]

Chapter 2

Problem Statement

In this chapter, a brief introduction to the overarching problem is visited. It is followed up by the overview of the project and methodology employed to address the problem. All this is tied up with the objectives and targets of the thesis.

2.1 Objective

The primary objective of this project is to create a reliable tracking process that encompasses all the factors involved in retrieving of a part from the field, to best support root cause analysis and parts dispositioning. This can be translated into three sub-categories:

- Develop a logic for the tracking process that triggers response from field engineers based on the information fed to the system
- Retrieve all the required parts and scrap the unwanted ones
- Layout a flow path for the part once the part is in-house

2.2 Motivation

Waters Corporation is an analytical instrument manufacturer of liquid chromatography (LC) and mass spectroscopy systems. Waters makes high premium products and is an industry leader. However, the recent increase in the failure rate of their product is a key concern for the company. Mechanical together with electrical components constitute the majority of the failures. Some typical failures include printed circuit boards (PCB), pumps, leaks, power supplies and needles. Failures in the field directly affect the sales of the company in the long run and may negatively impact market share. The driving force of this project is, first, to identify potential sources of the problem and, then, come up with practical solutions to these existing issues which have a meaningful impact.

2.3 Problem Statement

At present, Waters is experiencing obstacles with regard to the robustness of their product. The failures surrounding Waters are largely one-off, implying difficulty for the quality department to ascertain the problem. In addition to this, the allocation of feasible resources is dependent upon the identification of the problem, and thus, the problem gives rise to two obstacles, simultaneously. The act of interviewing several individuals belonging to varying departments was undertaken in order to obtain the required understanding of the procedures conducted at Waters, and to navigate towards the inherent core of the problem. The preliminary analysis helped in identifying the minor problems that included a dearth of control charts and SPC in Waters inspection area, and reluctance in terms of utilizing all the data available at the machine shop. This data ought to be translated into valuable information. In addition, there exists the need to ensure that the documentation associated with field engineers is more streamlined in nature.

When it comes to the areas of concern, one such area exists in the domain of Standard Operating Procedures (SOPs). This concern can be elaborated by citing that there exists a dearth in the usage of SOPs as a tool for documenting root cause results across the mechanical and electrical departments, respectively. However, the most potent problem that is presently being encountered concerns the broken tracking process which deals with parts that are expected to be returned from the field for either the purpose of root cause analysis, or for scrap. This problem is further aggravated as a result of a dearth of information tracking activity associated with the returned parts (hot parts). In addition, although Waters does possess a tracking system, it still needs to be overhauled. Engineers who have the responsibility for root cause analysis are constantly complaining about the unavailability of parts, or about incorrect parts having been dispatched from the field at the time that the root cause analysis is to be carried out. At the same time, data related to receiving material hints at the notion that a great number of parts are indeed being sent back from the field. Having evaluated that, there needs to be a significant amount of interaction across the processes of different stakeholders but, currently, this interaction is lacking.

2.4 Process Overview

The parts tend to be returned after undergoing a two-step process. The first step to this process is the information tracking for hot parts, whilst the second concerns material tracking. Firstly, the information is extracted from the system, and consequently, the preliminary analysis reaches its conclusion. At the decision making stage, the part may be placed on the list classified as the hot part list. This automatically implies that the part ought to be returned, and that the field is responsible for the dispatch of the part. In turn, this information is fed into the returns and tracking process with the aid of the Waters SAP system. As far as material tracking is concerned, all hot parts alongside the warranty parts are sent back to the Milford facility, where the Returns Department tends to pursue their established protocol when it comes to deciding what ought to be done with the parts under discussion.

Moreover, there exists a great deal of scrap material that is being returned. A high level process overview is shown in the process flow of Figure 2-1.

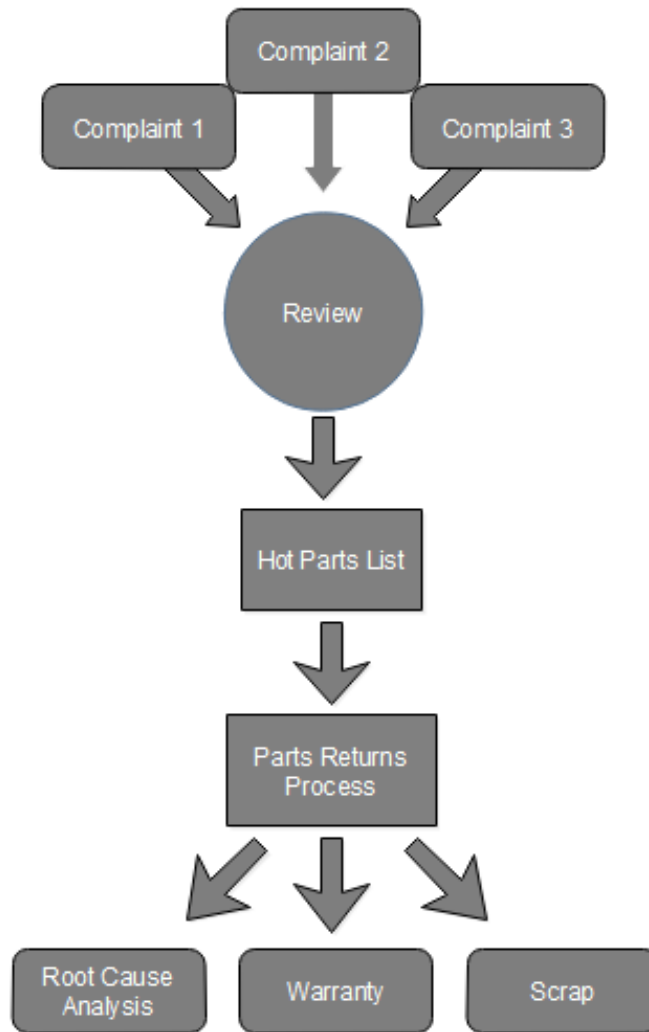


Figure 2-1: High level process overview

2.5 Project Scope and Approach

The scope of the project is narrowed to, first, develop a better information capture metric for the hot part list, and second, optimize the parts tracking process by filling the gap in the current process. Thus, the emphasis of the thesis will be on streamlining

processes and structures that focus on ensuring effective and streamlined interactions between various processes and information transfer at each stage of the process.

A systematic approach is taken to reach the end goal and objectives. It begins with understanding the process thoroughly by interviewing people and collecting information and their recommendations for process change. All of the information is filtered and funneled to get it ready for analysis. Strategies are formed to tackle gaps and issues and finally, a framework is structured to streamline the process. Figure 2-2 captures and depicts the overall approach:



Figure 2-2: Project Approach

2.6 Task Division

Broadly speaking, the focus of the entire project carried out by our three-student team is channeled towards the optimization of customer experience. The objective deals with the conception of an efficient process to pave pathways towards an improved product. The project is divided into three components. While each of these is the focus of an individual thesis, these component projects were carried out with joint and several leadership across all three teams. The three main areas include the Metric System [9], the Tracking System (this thesis), and the Coding System [10], respectively. In spite of the project being divided into three distinct portions, the development of improvements in all three elements simultaneously is crucial as a result of the existence of interrelated elements across the three portions. Therefore, the nature of this project necessitated close correspondence, constant communication, and instant feedback. The relationship between projects is summarized in Figure 2-3.

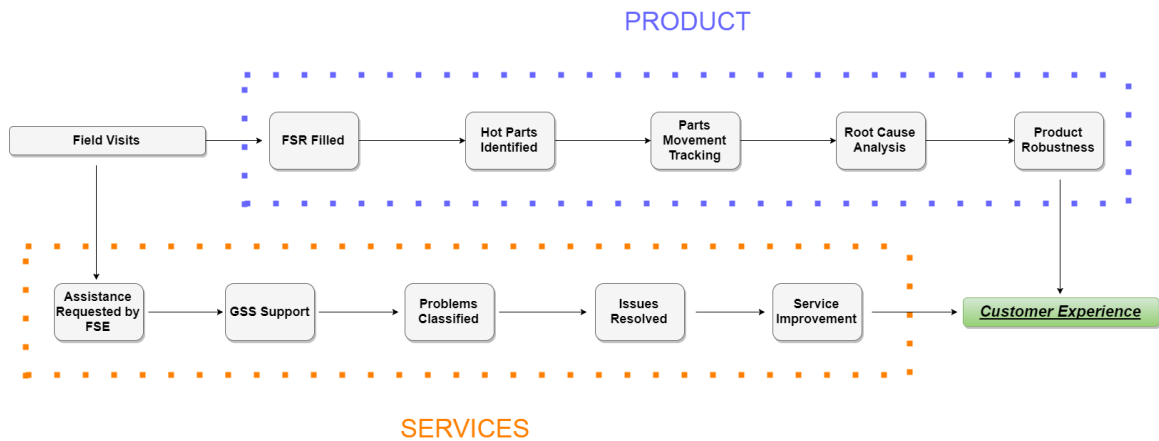


Figure 2-3: Projects Interaction and Relation

Chapter 3

Literature Review

“The traditional, non-integrated, hierarchical life science organizations tend to work in a Commons-like way. The pool of resource is absorbed to further the aims and interests of individual functions rather than ensuring the greatest benefit to the overall organization.” [4]

This description in “Tragedy of the Commons” [5] concisely puts forth the hindrances in the way of the Waters Corporation and other multinationals companies. All of the varied overall operations must be combined and driven towards a shared objective. This chapter elaborates upon this by reviewing the literature on processes and process flows, and then provides an overview of the network of various stakeholders at Waters.

3.1 Process and Process Flow

A process flow is defined as a network of complementary processes that require resources to convert certain inputs into outputs. These outputs are then used in the next phase until a specific objective is completed [6].

The process flow may be set up using a variety of strategies, two of which are noted here. The first strategy is used when the priority is to enhance the process development. First, the current process is evaluated and analyzed. The analysis may be a strict assessment or an informal check to gauge the effectiveness and detail the problems in the current process as well as identify other amendments that can be made. Next, the established problems from the analysis may be corrected and the detailed amendments are carried out. Figure 3-1 shows this technique of process development.

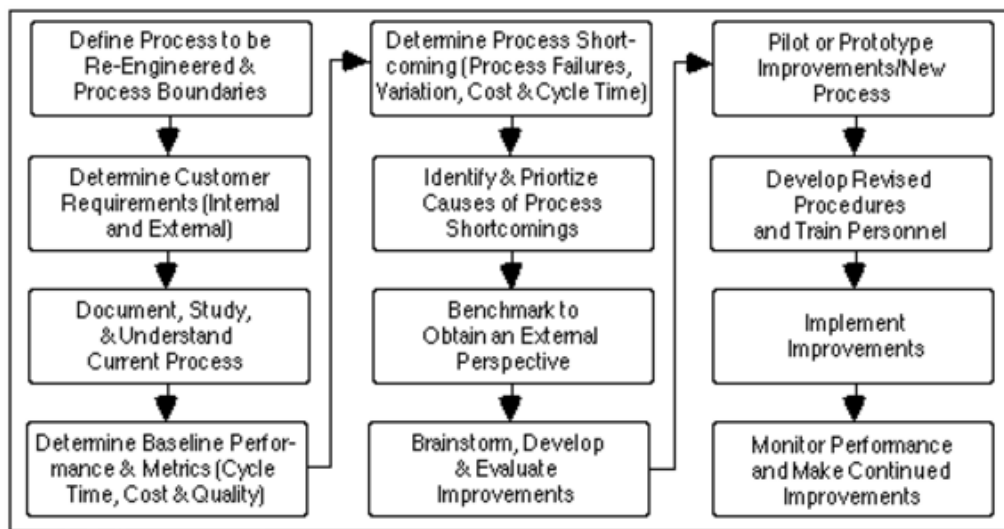


Figure 3-1: General process improvement or process reengineering approach [7]

A second strategy is to set up a workshop to define or refine the process with the main members of the company. The group can detail the various stages of the process and assess them by checking whether each of the stages carries out the appropriate function and the output is efficient. The problems hindering the process can be listed in the workshop so that they may be corrected and the overall process refined. Other recommendations can be made according to similar experiences of other organizations. The workshop can be made more successful by making sure that the group does not unnecessarily restrict itself. It is also necessary for the organizers of the workshop to make sure that ideas flow smoothly by resonating the groups discussion. The organizers may also negotiate and resolve conflict between various

group members. Furthermore, it has to be made sure that any pushback from the company does not negatively affect the efforts made by the workshop.

The philosophy applied to this project is to have a mix of both the approaches, as suited to the company structure and norms. Emphasis was placed on capturing best practices of each of these approaches, and using these to develop the best solution to the product robustness problem.

3.2 Lean Six Sigma: DMAIC

“DMAIC is a data-driven quality strategy used to improve processes. It is an integral part of a Six Sigma initiative, but in general can be implemented as a standalone quality improvement procedure or as part of other process improvement initiatives such as lean” [12]. The basic contention is that any process can be improved by the application of the five major steps towards six sigma, i.e., DMAIC. These five steps are Define, Measure, Analyze, Improve and Control.

3.3 Waters Quality and Field Department

This section identifies the common acronyms and terms used at Waters Corporation. Furthermore, the workings of the two most widely used software systems, within Waters, have been explained, which will establish a basis for the rest of the thesis.

3.3.1 Common Acronyms

An acronym is a word or name formed as an abbreviation from the initial components in a phrase or a word, usually individual letters [11]. As with many other corporations, Waters also has plentiful acronyms. Table 3-1 represents a list of the most common used acronyms at Waters pertaining to this thesis project.

<i>Acronym</i>	<i>Description</i>
SAP	Schedule And Planning
CIT	Customer Information Tracking
RCA	Root Cause Analysis
FSE	Field Service Engineer
FSR	Field Service Report
TPM	Technical Product Manager
LC	Liquid Chromatography
MS	Mass Spectrometry
HHA	Health Hazard Assessment
e-returns	Electronic Returns

Table 3.1: Common acronyms and their description as used at Waters Corporation

3.3.2 Software and Techniques

Multiple tailor-made software systems are used for various different purposes at Waters; due to the complexity and the set objectives of the system, hardly any of the software packages are off the shelf items. The software systems serve varied functions including customer interaction; capturing and analyzing failures; a one-stop location for all the company related documents, past records and database; sharing information and communication within employees, et cetera. Two examples of these tailor-made software packages are CIT and SAP, which are the two most pertinent software systems for this thesis. As the name suggests, Customer Information Tracking is used as a means of communicating customer interactions. It captures all of the interaction that goes on at customer site, and acts as a bridge between the corporation and the end users. As it is used in the downstream, CIT is usually the first to draw attention to any problems in the field. For this reason, it is heavily monitored by Field relating groups and by the Quality Department which provide support and service with an end goal to enhance customer experience. Access to CIT is controlled to eliminate the risk of potential leak of valuable/classified information to third parties.

SAP, on the other hand, is the backbone of Waters internal communication. There are a wide array of documents related to any subject matter, ranging from machining

SOPs to financial transactions, available on SAP. This software can also be linked in some ways to other software to have a better flow of information and stakeholder engagement. Moreover, SAP provides controlled visibility to Waters employees, limiting them to certain sections, depending on their authorization.

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Chapter 4

Evaluation of Existing System

The first step in improving a process or methodology is to gauge the status quo to get an understanding of the work that is already being done in this scope. A detailed analysis is thus needed to point out all the gaps and loopholes that have room for improvement, and consequently incorporating these improvements in the updated framework. Therefore, once the details of the process are understood, a new streamlined process can be introduced and implemented.

4.1 Overview of Current Process

This section characterizes the current system in depth and discusses the merits of it. Potential gaps and opportunities are identified which will be addressed in Chapter 5.

4.1.1 Process Flow of Hot Parts List

Hot parts can best be described as the parts of the product or instrument that exhibit failure or malfunctioning more often. The recurrence of a malfunction for a specific hot part is calculated using statistical inferences based on prior data gathered during experimentation. The preliminary analysis starts by collecting data for Technical Product Managers (TPMs) to review. Once the data is collected, it is organized by the quality department so that they can identify and rectify the problems asso-

ciated with that part via the Root Cause Analysis (RCA) process. The key metric used by the quality department is to normalize the failure rate with the install base to reflect an accurate representation of the failures. For example, if 10 degasser pumps failed while a total of 20 installations were done in the time period, then the failure rate would be 50%. Next, the organized data is handed over to Technical Product Managers (TPMs) for preliminary analysis. Their job is to trend the data and find any anomalies that exist in the data. This task is critical because it forms the basis for the root cause process. Lower or insignificant failure rates in the initial analysis dictate that the root cause process should not be carried out. However, if a negative trend is identified, then further consideration is needed. A presentation is set-up by the TPMs for the engineers to review; the team of engineers, mechanical or electrical (depending on the nature of the malfunction), engage in a discussion with the TPMs to reach mutual agreement either in favor or against performing root cause analysis. Concurrently, if both the stakeholders agree then the malfunctioning part is added to the hot part list. The hot part list is continuously updated and parts are either added, if new failures occur, or removed, if corrective actions have been implemented.

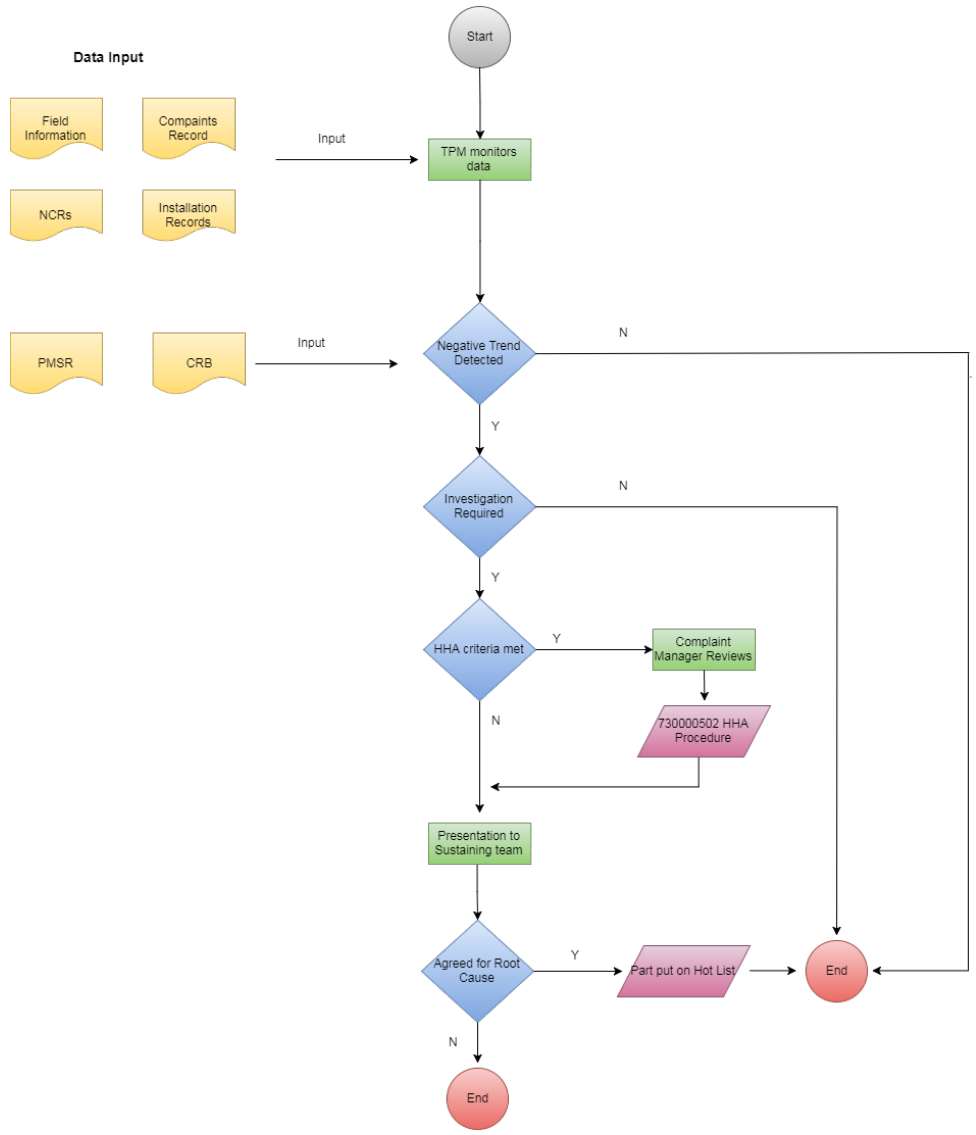


Figure 4-1: Hot part list process flow

The flow chart in Figure 4-1 exhibits the details of the hot part list maintenance process, recognizing the stakeholders and the work done by them. Firstly, data collection is comprised of field information, complaints, and records. Field data is a source of key information, particularly in terms of failure data. Field engineers fill out Field Service Reports (FSRs) during either installation or repair, and that information is used for trending analysis. Secondly, the Complaint Review Board (CRB) is another key stakeholder. As the name suggests, the CRB deals with complaints from the field, and has the required expertise in judging the importance of root cause analysis for the concerned part. Furthermore, the CRB also provides input into the preliminary analysis done by TPMs, based on their visibility regarding the complaints data for each system and part. Finally, once the part is put on the hot part list, formal investigation begins to identify and rectify, where possible, the root cause.

4.1.2 Parts Tracking Mechanism

The Part Tracking Mechanism is crucial to this structure. It is a twofold process, consisting of in-field and in-house components.

The “**in-field**” process is comprised of field service engineers visiting a customer site for a scheduled appointment. This visit could be pertaining to either an install or a repair. In any case, field service engineers are required to fill out field service reports (FSR) after their visit. The first step acts as a filter, to put parts into different categories at the time of filling out the FSR. Here, the field service engineer knows what to do with the part: either send it back or scrap it. Parts that are sent back are routed by their return numbers, and help the receiving operator determine where to send the part in-house. Hot parts, as mentioned earlier, are the parts required by the sustaining engineers to perform root cause analysis. These parts come under a “CIT number”(CIT#). The CIT# is a unique number and is generated at the time when a customer contacts the company to schedule a service visit. A flag goes up as soon as the part number field is populated with a hot part number at the time of filling FSR. At that point, field engineers know that it is a hot part and it needs to

be sent back under a CIT number. Secondly, if the part is under warranty and no claim is generated to get credit or the part is not under warranty, then those parts are sent back under an “RA number” (RA#). The RA number is also a unique identifier generated by the field logistic department on the request of the field engineer in order to send the part back. Since Waters is a global company operating in numerous countries, this presents additional challenges. Another caveat relates to international returns: all international returns are sent back using this same process but with an “RE number”. The only difference between an RA# and an RE# is that a claim is generated on an RE# and hence it can be credited to either a customer or a field service engineer. All international returns have to go through approval before being shipped back to Milford. Lastly, if the part is simply scrap, it is sent with a label identifying it as scrap on it for the material receiver to correctly identify. Returns are handled by FedEx or are sub-contracted to a trucking company to send the part back from across the globe.

<i>Label</i>	<i>Description</i>
CIT #	Hot Part
RE #	electronic returns with claim
RA #	Non electronic returns and usually domestic returns
Scrap	Scrap material

Table 4.1: Labels and their description at Returns Department

The second step is the **in-house** movement of parts. When the returned part arrives at the Milford facility, it is directed towards the returns area by the material handlers. Once the part reaches the returns area, it is sorted based on the return number mentioned earlier and stacked in and about the designated area. All these tasks are done manually by the operator. Special attention is given to the boxes that come under a CIT number because these are the hot parts that are required by the sustaining engineers to perform the root cause analysis. TPMs are notified by the returns department regarding the hot parts received. TPMs then go and search for the “suitable” parts that can be used to perform root cause. A TPM’s criterion for characterizing a “suitable” part includes if the part is not too old, not hazardous, has

the right part number, etc. Hence, not all hot parts sent back are used to perform root cause analysis. TPMs visit the returns area once a week, usually on Fridays. Furthermore, any international returns follow an “e-returns” process where a claim is generated to handle financials, and returns have to go through an approval process. A person working at the Milford facility is responsible, for LC parts, for approving or declining the returns from different countries. This person takes into consideration a number of factors such as the number of parts already received for that part number, and the transportation cost associated with it, and makes a judgment based on their experience. All of the parts coming through this process are subject to approval, even the hot parts if they are coming from a different country.

Even though parts are decommissioned after usage according to their return numbers, most of them are scrapped. Only returned unused parts and some of the hot parts are not scrapped. Unused parts are put back into the inventory and are a part of the supply chain again, while hot parts that are picked up by the TPMs for RCA are not scrapped. The remaining parts are scrapped on a bi-weekly basis in-house through the services provided by a third party.

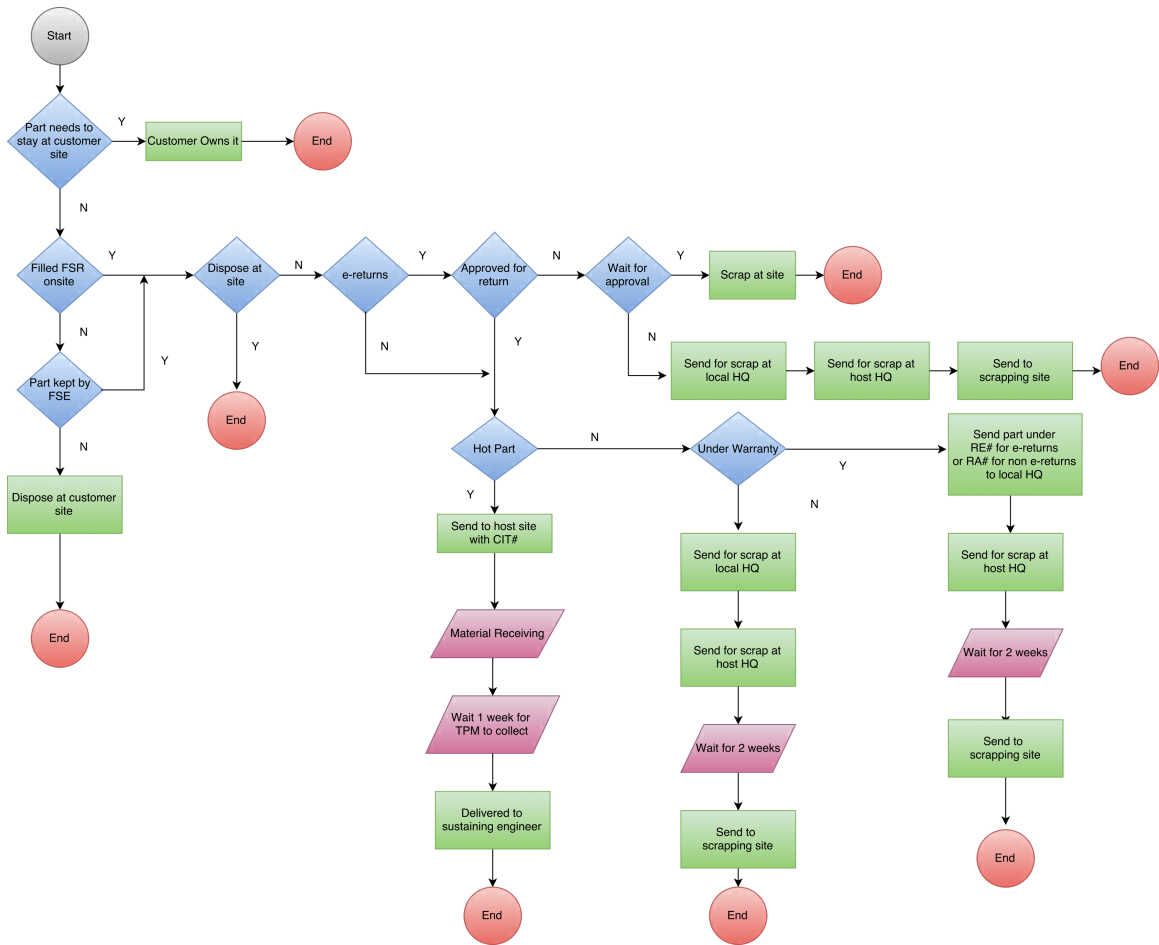


Figure 4-2: Movement of parts from field to in-house

The flowchart in Figure 4-2 details part movements from field to the Waters facility, and then to the relevant personnel or authority. The flowchart further points out that sometimes a part cannot be sent back because it's a billable part and hence, the customer owns it. Other reasons might be that the customer wants to keep it or the part is owned by a third party service contractor who does not want to return the part. Furthermore, once FSEs are done with their visit, they complete FSRs either on site or afterwards. The protocol is to fill FSRs onsite to capture all of the data, failures and other details. However, the majority of the FSEs fill FSRs at a later time, which prompts them to disposition the parts onsite and also results in a superficial assessment of the problem. Hence, valuable information is lost in the process. In contrast, if FSRs are filled on site, the FSR system guides FSEs in regards to what to do with the part. If a claim is generated, the e-return process is followed as discussed earlier in this section. Sometimes the approvals might take over a month, and due to the urgency of the matter, FSEs do not wait for the approval. Hence, the parts are either scrapped onsite or sent back to the local headquarters for scrapping.

Finally, once approval is given (for e-return process) or if the part does not follow the e-returns process, the part undergoes the “follows it” course as stated earlier in this section and shown in the flowchart. Unique identifiable numbers, CIT# and RE# or RA#, are allotted to hot parts and warranty parts, respectively, while scrap comes under a scrap label.

4.2 System Performance

In an earlier section of this thesis, the mechanisms for the hot parts list and for tracking parts in the current system have been discussed. This thesis will now analyze the performance of the current system.

4.2.1 Analysis of Returned Parts

In order to better understand the tracking process, analysis is done to get a distribution of the parts per category spanning over the past three years. This will help us understand the gaps in the current process. Parts are grouped into five different categories. All of these categories have already been described in section 4.1.2, except “FSE Returns”. Here FSE Returns means the number of unused parts sent back from the field which, after inspection, are put back into the supply chain. Another key point to highlight is that these returns are coming in boxes of varying sizes and weights. There is no standard box size and hence one box can carry only one part or can have as many as 200 parts, depending on how many a box can accommodate. Figure 4-3 shows the distribution of parts for the past three years.

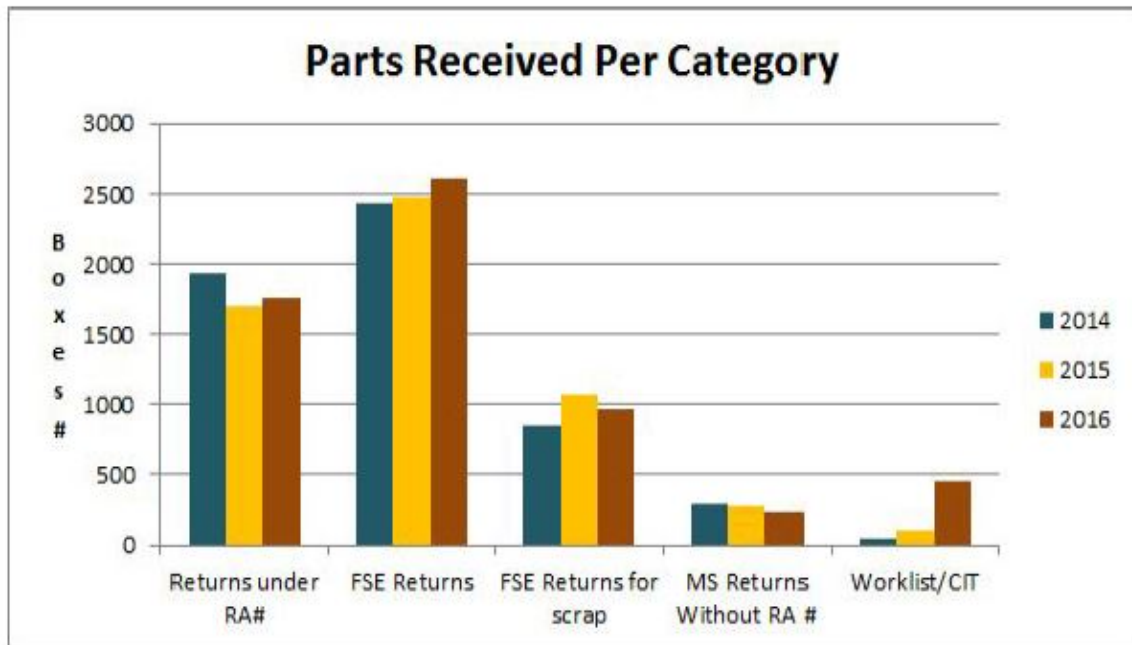


Figure 4-3: Parts returned per category

As shown in Figure 4-3, the majority of the parts that are sent back fall under FSE Returns and Returns under RA. They contribute to up to 75% of the returned parts. The total number of returns in the past three years is 17214 boxes. Another

trend that can be identified from the data is that the number of returns each year is relatively close to that of previous years. This makes planning easier for future predictions. Moreover, another important result is the small number of hot parts (Worklist/CIT) received each year. This explains the concerns shown by the sustaining engineers for not receiving enough parts from the field to effectively execute RCA. The number of boxes received each year from 2014 to 2016 for hot parts are 51, 102 and 452 respectively. This means that hot part returns make up 3.5% of the total. Based on this data, the return of hot parts is an area of concern. Hence, further analysis is done on the data, and a trend is identified in the number of hot part returns spaced on an interval of months, as shown in Figure 4-4. Even though more boxes of hot parts were received in 2016 compared to previous years, the total number of parts is significantly less compared to the total returns. The slow start in the beginning of each year reflects the nature of the business, where sales are attributed more to the end of each quarter rather than the beginning.

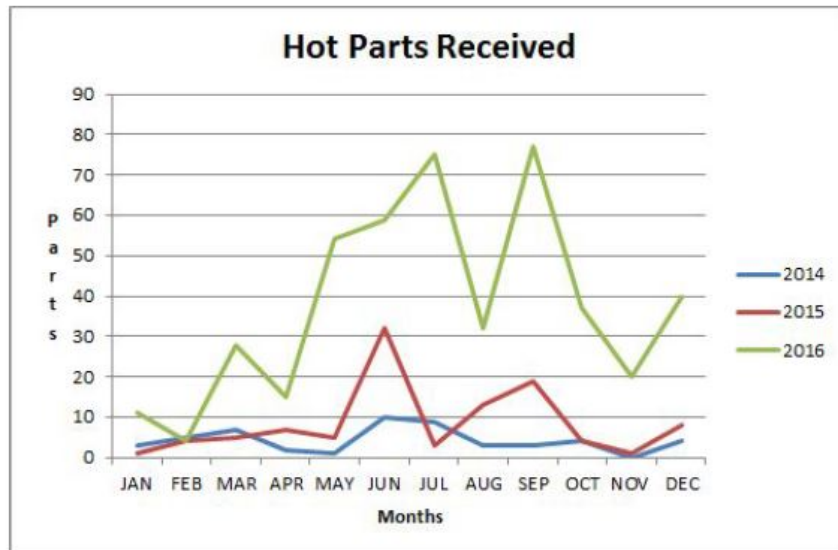


Figure 4-4: Hot parts received per year

4.2.2 Scrap

The second biggest concern in the current tracking system is dealing with the large amount of scrap coming to the local headquarters at Milford. Waters does not dispose of the scrap material at a client’s site for various reasons. Firstly, Waters, as a company, is trying to be environmentally responsible; the Waters environmental policy dictates that the scrap should be processed properly instead of being exposed to the environment. Secondly, in some countries there are stringent environmental regulations that Waters has to adhere to, that require handling at Waters itself. Thirdly, there is always a threat of competitors and a third party who might obtain Waters product and use it to negatively impact the Waters business. Lastly, Waters does not want their product to end up in a grey market where customers or competitors can buy their parts and instruments cheaply, or obtain parts that may very well be defective. The majority of the returned parts are scrap material. Hence, the risk of losing pivotal information justifies the steps taken by Waters to return the scrap back to the headquarters at Milford. Even though only one out of the five categories has a scrap label on it, in reality, there are other categories that contribute to the total scrap. For example, warranty parts end up in scrap because no one is responsible for them; hence, they stay in the returns area for two weeks before they can be disposed of. The same applies to the MS parts. Table 4-2 shows the breakdown of scrap boxes per category for past three years.

<i>Scrap Description</i>	<i>2014 (boxes)</i>	<i>2015 (boxes)</i>	<i>2016 (boxes)</i>
# of Returns (RA’s)	1940	1701	1752
# of FSE Returns for scrap	853	1071	968
MS Returns Without RA #	286	279	234
Worklist/CIT	51	102	452
Total Scrap Returns (Boxes)	3130	3153	3406

Table 4.2: Scrap per category

The number of scrap boxes received each year for the past three years is approximately the same. However, the number of parts within those boxes can be different, but that is not currently monitored by Waters. To better understand the scrap data,

analysis is done on the bi-weekly scrap results; the result for the past five months is summarized in Figure 4-5. The average scrap is approximately 6000 lb bi-weekly.

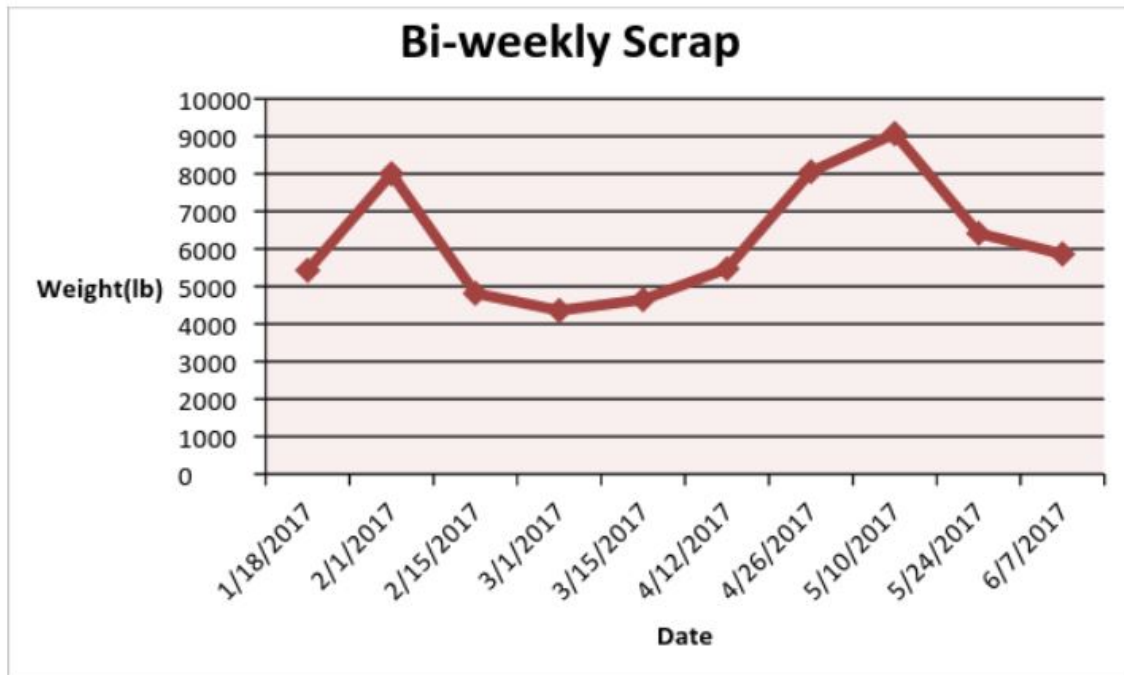


Figure 4-5: Bi-weekly scrap results

4.2.3 Transportation Cost

Based on the scrap analysis, the amount of scrap received by Waters is enormous. When sending parts back, significant cost of transportation is realized. Even though transportation and scrapping are two separate items, the transportation costs can be seen as an indirect cost for scrapping. The mode of transportation also acts as a factor in determining the cost of transportation, and hence the cost of scrapping. The most common method for sending parts back is FedEx. There are subcategories on how to send the parts back, such as overnight delivery, standard, etc. Moreover, other modes of transportation include air and rental trucks which are significantly more expensive than FedEx, but these options are available depending on the need of the business. As previously noted, Waters has a policy of sending parts back to manufacturing headquarters for scrapping. Hence, LC parts from all over the world

are sent back to Milford.

4.2.4 Scrap Inventory Management

Inventory management is one of the more important duties required for the management of parts. Having discussed the scrap processed and the transportation costs, the last analysis involves the inventory managed each year. Keeping inventory of good parts provides a supply buffer but, increases operating costs for the new and unused parts that have been returned from the field. An inventory for scrap parts, on the other hand, results only in additional operating costs without any benefits. Waters has this inventory because all returned parts have to come back to the Milford facility for in-house processings after which they are scrapped in two weeks. The level of inventory can reach high levels depending on the number of returns, and at that point in time, it is hard to manage and differentiate between the returned parts. Figure 4-6 shows the trend of returned parts measured by weight for the past three years. These trends highlight mixed results. On one hand, it is promising to see a decrease in international returns (reduced transportation cost) and that fewer hot parts and scrap are sent back, while on the other hand, the increase in domestic returns indicates the opposite situation. In fairness, the value generated from returned hot parts outweighs the incurred transportation cost. Furthermore, overall hot parts received for all three years remained the same. Due to lack of hot parts monitoring, it is hard to know the distribution between domestic or international hot parts returns.



Figure 4-6: Scrap inventory received by weight at Waters

4.3 Potential Problems in Process Flow

This section will address the gaps and issues in the current system. Information from the previous two sections of this chapter will be analyzed and used to highlight problems with the current system.

4.3.1 Gaps in information collection

Information acquisition and tracking information are two major gaps, and problems arise due to these gaps. However, part tracking is a far greater concern than information acquisition. One of the biggest concerns in the information flow is that there is no set procedure or agreement regarding what the upper limit is when trending the failure data: the failure rate can reach as high as 10% before a part number is put on the hot part list. There is a need to set the upper limit of the failure rate of specific parts to have standardization when analyzing the trend. A conservative

approach needs to be taken when determining these limits to better catch product failures and problems before they can impact the business adversely.

However, at the same time, an excessively conservative approach will be a wasted effort as it would result in redundant outputs. Furthermore, there is a need to divide products into consumable and non-consumable categories, and then analyze accordingly. The upper limit will tend to be slightly higher for consumables due to their shorter lifecycle and intended purpose. Stemming from this, another gap in the current system relates to the age of the part. The primary purpose of the hot part list generation is to conduct RCA on those parts. However, age is not considered at the time of trending analysis and hence TPMs have to manually filter out parts when the parts arrive in-house because a four or a five year old part is not used for RCA. Lastly, cost is another metric that should be factored in when trending the data. Dedicating substantial time for RCA can be costly. Hence, there should be a cutoff point for cost as well, where if the cost of the part is below that threshold, it can be ignored.

4.3.2 Lack of Reliable Part Tracking

The part tracking system poses greater problems in comparison to the information tracking, and has more gaps and hence more opportunities to improve. With the current system, many parts are lost in the process or end up at a different location than originally planned. This begins with FSEs not filling FSRs onsite and hence disposing of the parts onsite rather than sending the parts back to Milford for either scrap or root cause analysis. Potential value is lost due to this. Furthermore, FSEs sometimes do not wait for the approval from the returns department if the part is meant to be sent back via the e-returns process and, end up scrapping the parts onsite. Again potential value is lost in the process. These lost parts can be detrimental in other ways as well. For example, these parts can end up in a grey market, with a third party, or even worse with competitors. If this happens, there is a major threat of key information being leaked in the market. Scrapped parts may also be hazardous in nature and if not properly cleaned can be life-threatening to people in contact with

them. In addition, even when the parts are at Milford, there is a risk of them being lost. This is particularly true for warranty parts because there is no owner of those parts, due to the fact that these parts are written off and have a zero dollar value at that time. Some of the hot parts are also lost because they are not collected by the TPMs on time.

Another gap is the amount of time parts sit in the returns area before any action is taken, i.e., parts collected for RCA or sent for scrap. As far as RCA is concerned, a hot part should be directed towards the responsible sustaining engineer. When the hot part is added to the hot list, sustaining engineers commit to work on that particular part. That same engineer should directly receive a corresponding part once the part is in-house. The sustaining engineer could either be from mechanical or from electrical organizations, depending on the part. Currently, TPMs personally go to the returns area to sort and collect the part and are then responsible for delivering the part. Another problem that arises within the system is the time consumption in dealing with the part. The approval process in the e-returns is one of the major hindrances faced. An approval to send the part back can take as long as one month. It is not due to negligence of the approver; rather the delay is due to the amount and volume of requests that need to be processed. There are approximately 7000 approvals done per year. Due to the lack of personnel, by the time approver gets to the current request, a month has already passed.

Another problematic area is the amount of scrap received by Waters each year. The larger impact is not the scrapping cost, but rather the transportation cost and time. Sending scrap back from Los Angeles to Milford is going to cost more than sending scrap from Boston. The weight of these parts adds to the cost of the shipment. Factoring in international shipments can raise the cost further. Optimization of decisions related to scrap and returns could better account for differences such as these.

Furthermore, a lack of hot parts has been a key concern for sustaining engineers.

Even in the case of returned parts, some are filtered because they are too old or not in the right condition to perform root cause analysis. This filtering and decision step should be done in the field rather than in-house. An automated system should take care of this decision rather than require manual input. Another step not taken into consideration by the current system is to notify FSEs via CIT not to send the hot parts back if the returned hot parts inventory reaches a certain level. After a certain number of hot parts are already available, sending more parts does not add value in the RCA process. In fact, it might be a burden at that point due to the transportation and other handling costs associated with the sending of parts.

Moreover, regulatory conditions in countries (like China, India and Australia) act as a hurdle in sending back the parts. Waters has a large customer base in these countries, and hence it is of immense importance to satisfy their needs. Geographical and environmental differences can play an important role in the failing of a part, and being unable to perform RCA in a setting similar to that at customer's site can be damaging to the Waters reputation. Lastly, there is a need for better returned inventory management. Unused parts are dealt with efficiently as they are used in the supply chain again, but the rest of the returns are not dealt with likewise. Particular areas with marked borders and tags should be set up to better support storage and retrieval of parts. A fishbone diagram shown in Figure 4-7 summarizes the problems with the current system.

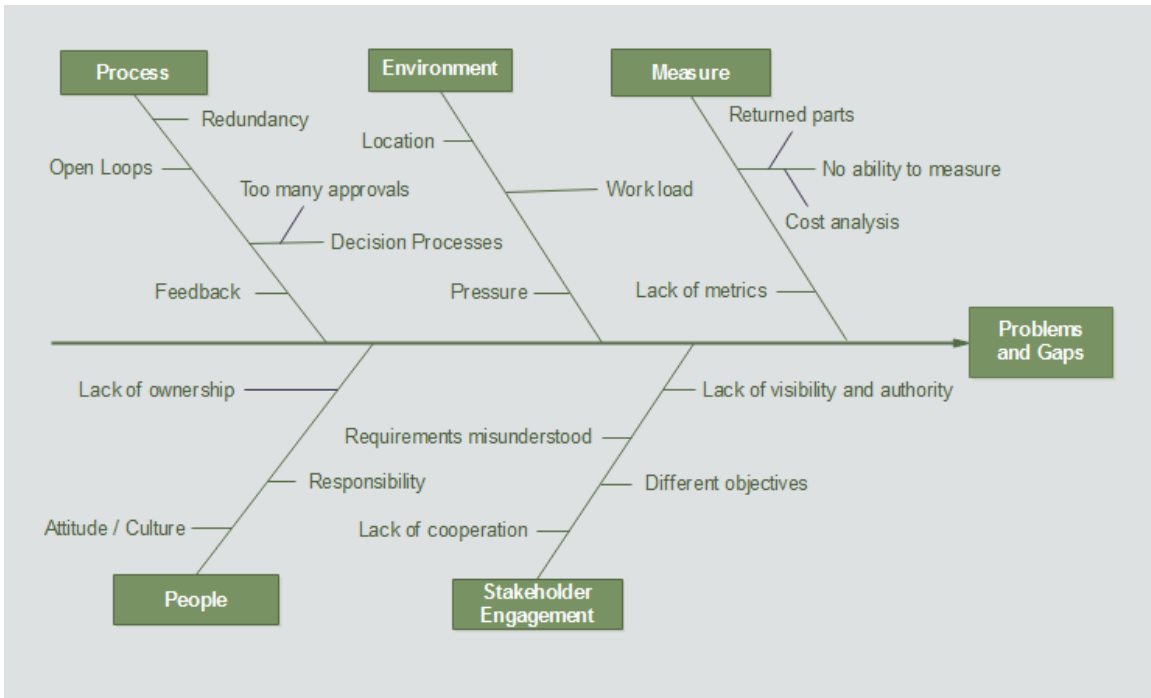


Figure 4-7: Problems and gaps in the parts failure process

Chapter 5

Proposed solution

The current tracking system requires human expertise to a great extent. Hence, the tracking system that is currently in place needs to be upgraded to ensure minimal human intervention. Additionally, the system should not only cater to gathering data, but should also be able to analyze data collected by it. This reduces the response time of the system.

5.1 Metric Addition

Characterization of the current hot part list process has helped surface gaps, redundancies and inefficiencies in the process. Furthermore, by analyzing the system and taking input from the people working on the hot parts list, a number of key new metrics are proposed. These metrics would go in the trending analysis phase. According to the proposed mechanism, the system would pull information from the current sources, as shown in the Figure 4-1, and apply these new metrics to filter the results for TPMs to analyze. By doing this, the cost of manual sorting done by TPMs later in the process would be reduced. The proposed metrics are shown in Figure 5-1.

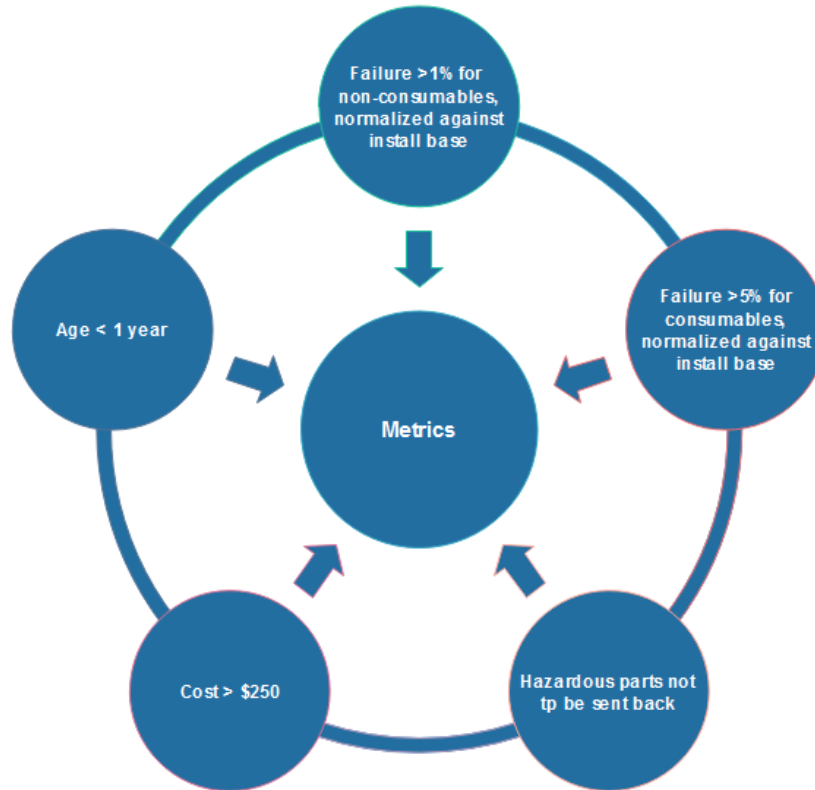


Figure 5-1: Proposed Metrics for hot parts

As seen in Figure 5-1, the five given metrics are correlated and thus need to be considered together. One of the gaps mentioned earlier in chapter 4 was the lack of standardization and clear limits to raise the flag for adding parts to the hot part list. To fill the gap, a metric is proposed where, if the failure rate for the past year is more than 1%, for non-consumables, normalized over the installed base, then the part should be put on the hot parts list. Secondly, a similar criterion applies for consumables, but due to different objectives and applications of such products, the part is flagged if the failure rate, for the past year, is more than 5% normalized, over the installed base. Thirdly, age impacts the relevance of part for RCA, suggesting that the age of the part should not be more than 1 year, which is synonymous to saying that the part is under warranty. Warranty failures are of more concern compared to a ten year old part failure; incorporating this metric will provide a more accurate picture of the current state of failures and will filter unwanted information. The fourth metric

that is proposed as a means of improvement is part cost. As an example, suppose that the part is of a low dollar value (e.g., \$20); then it is not worth the time and effort to investigate the part because, in that scenario, the root cause analysis is not a value added process but, in fact, it is costing the company. Assuming comparable part volumes, a lower limit of \$250 for part manufacturing cost (rather than the retail value) is set. Parts below this value would not show up in the TPM trending analysis. Finally, the fifth and last metric is related to health hazard. If the part is deemed hazardous by TPM or sustaining engineers, it should not be sent back. This metric is in place, but it needs to be proactively monitored rather than reactively.

5.2 Flow Re-Design

An array of problems were identified in section 4.3.2 regarding the current procedure followed by Waters for sending parts back for various different reasons. The process is not streamlined and has a lot of unwanted and nonvaluable steps. Therefore, in order to rectify these problems, the process flow is redesigned as described in this section. The end goal for this flow redesign is for it to be readily adopted, and hence an effort has been made not to deviate from the current arrangement excessively. Best practices from the current process flow are incorporated into the proposed system. Further inspection of the flowchart in Figure 4-2 shows that the parts are sometimes not sent back because the customer or a third party is an owner of that part, and if the part is not under warranty, FSEs cannot send the parts back. Due to the interdependence of this project with related development of an improved Metric System [9], we can confidently assume that with the metric system in place, FSEs will be completing FSRs onsite. Furthermore, once FSEs complete FSRs onsite, they will know, specifically, about the nature of the part and what to do with it. If the part is hazardous, it is disposed of at the customer site. Other updates to the standard operating procedure include the following changes. If it is a hot part and falls under warranty or FSE requests a claim, the claim goes for approval but the part is sent back to Waters for RCA immediately. This reduces the wait time for approvals

to send the part back. Claims can be generated without the part, so this takes a burden off of everyone. If the part is a scrap part then the part is directly sent to the nearest scrapping site. Previously, it was sent to Waters from across the globe just to get scrapped. As can be seen in Figure 4-2, previously, the same part had to go through many different steps and facilities just to get discarded at the end. Lastly, if the part falls under warranty and it costs more than \$250, only then should it go through e-returns process. Even then, the movement of the part is not restricted, i.e., the warranty claim process is separated from the part movement process. With this proposed solution, claims can be requested for these specific warranty parts and the parts can simultaneously be sent for scrap at a nearby contracted scrapping facility.

The problem of receiving parts from countries with stringent regulatory policies is also dealt with in this re-designed process. The parts from such countries as China, India, and Australia, will now be sent to a local designated depot where an experienced FSE will put the failed hot part in an existing running system, and try to test it in a replicated environment (an environment meant to emulate the customer setup or other standard environment). The FSE will do a preliminary RCA and fill out forms detailing his/her findings, which will then be sent to design engineers at Milford to study and analyze. Even though the part will not be sent back, the purpose of sending the part will still be achieved, in terms of adding information to identify and address root cause problems. This is a step towards helping the entire customer base, by enabling continuous improvement.

Finally, in this new process flow, the part routing is independent of the claim generation. FSEs will not be waiting for approvals to send the parts back. Instead, parts will flow to the specified location, and human interaction on intervention is minimized once the process is initiated. Overall, as seen in the flowchart of Figure 5-2, it is evident that there are fewer branching or decision points, while also focusing more directly on achieving the objectives set at the beginning of the project.

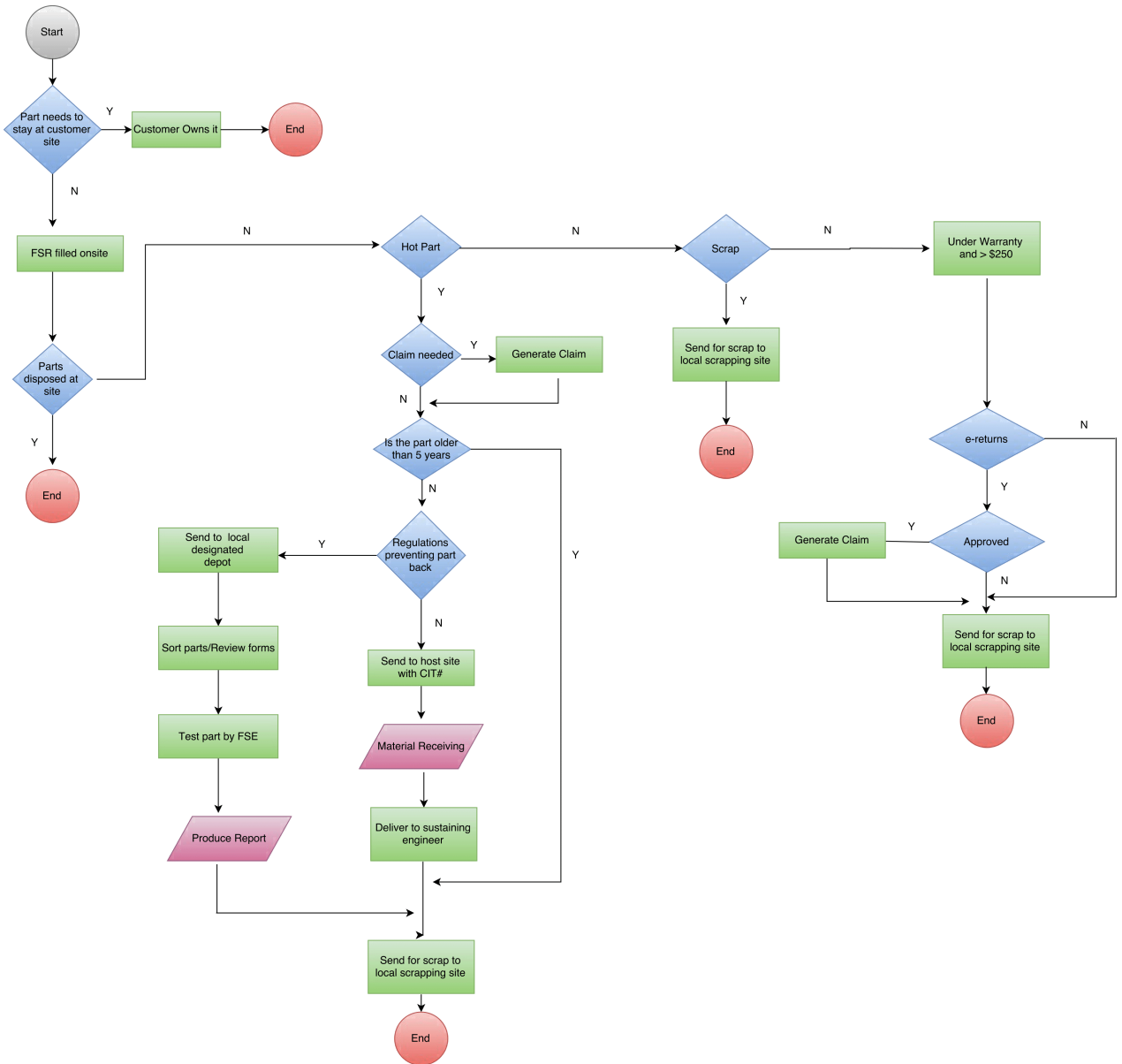


Figure 5-2: Proposed process flow for movement of failure and return parts

5.3 Impact and Discussion

This section analyzes the process flow proposed earlier in the chapter. The main objective of this section is to scrutinize the flow redesign to ensure it attends to the gaps and opportunities specified in Chapter 4.

5.3.1 Aid Root Cause Analysis

One of the biggest concerns for this project was the shortage of failed parts to the sustaining engineer; hence, a primary objective of this thesis project has been to aid the root cause analysis(RCA) process. The solution proposed in this thesis addresses that problem. Previously, FSEs were sometimes waiting for the approvals from the returns department, if they had to generate a claim on the part. To avoid waiting for the response, which could take almost a month to come, FSEs were disposing of the part at the customer site, or sending the part back to Waters as scrap. This decision was at the FSE's discretion. These specific parts are of immense value, because claims are generated mostly for warranty parts, and those are most sought after by sustaining engineers for RCA. The proposed solution differentiates and clearly draws a distinction between parts return and claim processes. With the proposed solution, parts can be sent back while approval for the claim is still pending. This will not only result in more parts being received by sustaining engineers, but the time frame will also decrease considerably due to elimination of the wait time for approvals. Additionally, another selling point for this proposed solution is that redundancies are removed from the system. TPMs will no longer have to go to the returns area to sort the parts, to see whether the parts are not old or hazardous. The addition of the new metrics to the hot part flowchart automatically does that sorting beforehand. This also helps in sending hot parts back which are actually meant to be scrap, but are very much needed as far as RCA is concerned. These metrics are set by sustaining engineers themselves and hence all the parts collected will be valuable.

Moreover, setting up an upper limit on the failure rate for consumables and non-

consumables, of 5% and 1% respectively, to trigger putting parts on the hot list, will impact the overall working of TPMs. Currently, the process is subjective and based on experience, in deciding whether to put the part on the hot list or not. With limits in place, TPM's procedures will be more definitive and clear. This also ensures standardization in work, which will be beneficial when a new person is assigned to this task. Another value added proposition associated with this system, is that the parts are now directed to the final destination, e.g., to a sustaining engineer, once the part arrives at Milford. This means that when sustaining engineers agree to put the part on the hot list, they become the owner of that part and hence are responsible for the part. TPMs will no longer need to sort or deliver parts; they will only be responsible for the trending analysis. This will reduce the number of exchanges a part makes in the process, and also reduce the overall time of part flow; currently, the part sits in the returns area for one week, on average, waiting to be picked up by TPMs, and this wait time is now eliminated. Lastly, no part will be lost in the new process. Currently, many parts are either not sent back (that should be) or lost in-house. By making the sustaining engineer the owner/responsible for the part once it is on the hot parts list, lost parts can be avoided. Hence, the part will not be sitting in the returns or somewhere in receiving area, just waiting to ultimately be thrown away as scrap.

5.3.2 Cost Saving Alternative

A large amount of scrap parts are processed at Milford, and thus many inefficient steps are involved. As pointed out, currently all the scrap comes to Milford for LC instruments, and to Wimslow for MS components. A third party, Fortune Metals, has been contracted for scrapping. They visit Milford biweekly, collect the scrap parts, and provide a Certificate of Destruction (COD) for regulatory purposes. The proposed solution approaches this in a different way, and with a new solution for scrapping. Instead of trucking or sending parts by FedEx to Milford, only for the parts to await weekly collection by Fortune, scrap should be directly sent to a nearby Fortune Metals facility, of which there are numerous sites in the US. Markers in Figure

5-3 indicate such Fortune Metals facilities in the US.

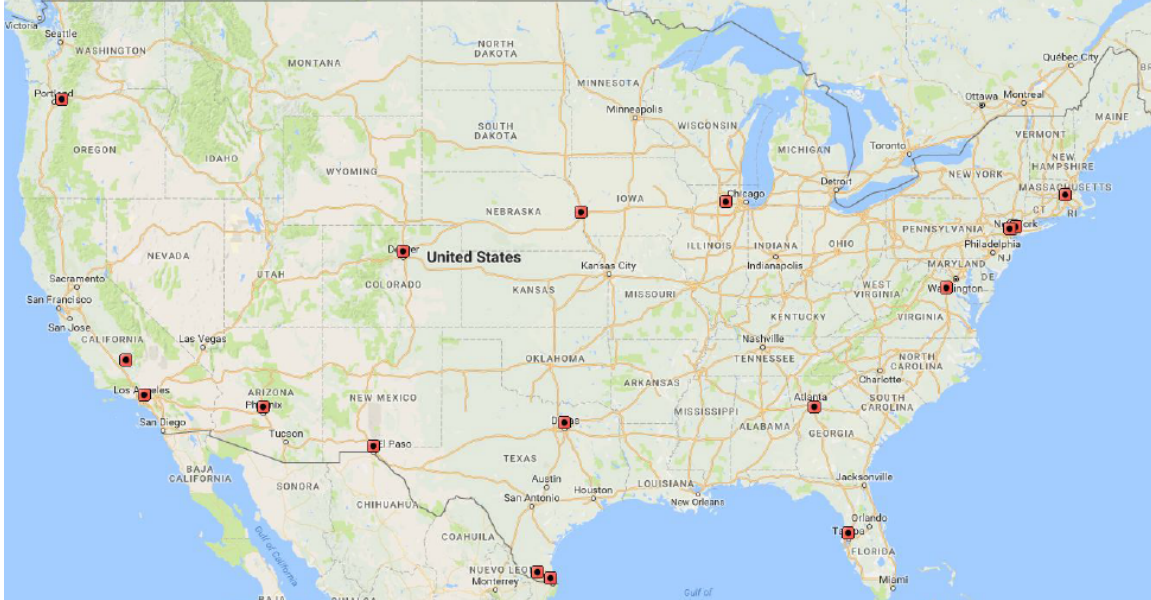


Figure 5-3: Fortune Metals facilities map [8]

Scrapping locally at these sites has numerous advantages. Firstly, it reduces the cost of sending the scrap back. Intuitively, the cost of sending a part from Los Angeles to Milford is higher than sending it to a nearby city. The process remains the same with minor changes, including FSE decommissions, coordinate palletizing, wrap in plastic, label with RA number and shipping processes. Thirdly, Sum-of-squared-differences(SSD) tracking ensures coordination with Fortune Metals and provides the address for the local facility. Fourthly, the local service coordinates with Waters Traffic to arrange trucking/FedEx as usual, but simply provides a different delivery address. Fortune Metals can then provide the Certificate of Destruction (COD). Another cost saving impact this rerouting of scrap would bring is the reduction in the amount of scrap received and processed at Milford. This would reduce the inventory cost associated with the scrap. It will also impact the labor cost associated with handling and monitoring of all the scrap in-house. Even though the primary objective of the project is to aid RCA, the cost component is a welcome offshoot of that effort.

5.3.3 Streamlined Process

The scope of this project is to streamline the processes and methods related to parts return and root cause analysis, in order to channel efforts in an optimal manner. Therefore, key redundancies have been eliminated from both the information flow and the parts tracking processes. No replica of work would be performed in the revised process. Most of this redundancy removal is due to more clearly specified roles, responsibilities and ownership at each stage. Another contributing factor to the increased efficiency is the enhanced visibility to everyone. Moreover, the proposal removes numerous approvals that were previously waiting in the pipeline and bottlenecking the system. This reduces the cycle time of the e-returns approval process, and will increase throughput. Parts will be directed to specified locations right away, eliminating the wait time.

Updates made in the system will yield reduced stress and pressure on employees. Unnecessary waiting time is a key source of frustration. FSE, TPMs and the returns department, who are waiting, duplicating or clearing the backlog, are the direct beneficiary of these changes. This will increase workers uptime and, hence, efficiency. Additionally, this process promotes stakeholder interaction in a more automated but useful manner. Lack of coordination and information flow leads to wasted efforts and even major mistakes. Lack of engagement is mostly due to different objectives, in which individuals put their department's objectives first rather than that of overall company. With flow redesign, and with a unified corporate-level objective, the returns and root cause analysis approach presented in this thesis provides an enhanced and efficient system.

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Chapter 6

Future Work

The new framework for streamlined processes in both the information and part tracking activity has been outlined in Chapter 5. The proposal is ready for implementation after the major stakeholders have approved it. Furthermore, implementation is the final step when it comes to strategic decision making. Even if strategy analysis and strategy formulation is highly effective in nature, and carefully sought, implementation retains its significance as a crucial and imperative stage, determining the quality of final outcomes that ensue.

Findings obtained from the preliminary analysis at Waters identifies important opportunities related to the introduction of new software, titled “Cloud 4 Service” (C4S). This software is expected to play an integral role in terms of providing a catalyst towards support of the new process proposed. For this reason, analyzing the software is essential in terms of determining whether it would be able to live up to its expected prospects or not. Software is not the only element of concern when it comes to the findings and needs identified from the preliminary stage; the stakeholders involved also impact the efficiency associated with the tracking and processing activity. Interestingly, the major stakeholders have stake in information and part tracking. These stakeholders are well aware of the changing pace of technology and the need for the incorporation of this technology into complex ventures such as the parts tracking process. This leads one to believe that efforts directed towards implementation of

the revised tracking process will be well thought out, well executed, fine tuned, and very much in alignment with the end goal. It is likely that the C4S software possesses the capability to replace the current software, CIT. When it comes to providing our framework with an implementation platform, the C4S software is expected to play a substantial role. Awareness of the pending C4S software changes enabled a great degree of freedom when it came to defining the new parts routing framework.

The new C4S software ought to be ready and will set in the forthcoming period of 8-12 months. The significance of this duration is that it will allow enough time to provide a channel for the proposed parts routing and information framework to be effectively implemented. In this regard, C4S will be instrumental in deploying the proposed framework. Once the system undergoes initial implementation, a quarterly evaluation of the newly conceived system should be generated, and the evaluation should be utilized to further analyze the difference between the existing and proposed parts routing and RCA results. This provides a solid ground for future improvement in the efficiency and evolution of the framework proposed in this thesis.

Chapter 7

Conclusion and Recommendations

This chapter will give a final conclusion for the entire project as well for this thesis. The deliverable requested at the beginning of the project was to streamline the current process flow by creating a framework around the tracking of information and parts which will aid root cause analysis. Final recommendations are recapitulated in this chapter.

7.1 Conclusion

The crux of this seven-month long project has been to define improved business and operational processes that are advantageous for the business in not only the short run, but also the long run. The MIT team (consisting of the author, Basma [9], and Gokce [10]) addressed potential challenges by conducting a detailed characterization activity with respect to the current parts tracking, returns, and root cause analysis system, and identified gaps and opportunities, together. Based on this, a new framework was proposed for the purpose of changing and improving the process. This step was taken with all the stakeholders possessing knowledge of the activity and procedure under discussion. This was imperative in order to carry out the overall improvement process, and all elements, including the stakeholders, the members of the team responsible for the project, and the facilitators and technical experts played a substantial role propelling the project in the right direction.

A framework and demonstration has been created for the purpose of explicating the new process that the team has proposed for the field engineers [9]. This demo illustrates the method by which the FSRs ought to be engaged and interact with the new proposed process. Moreover, the demo also identifies the content that ought to be extracted and documented after a field visit. Subsequently, key information should be fed into the system, elements of which are used to complete the RCA process. After this, the results of the RCA are delivered to the authorized personnel who are assigned the task of closing the process loop. This process reflow project and demonstration substantiates the feasibility of the technology and the associated methods with respect to Waters environment.

Overall, the team has successfully generated propositions that were directly linked with activities and opportunities for improvement. A new framework for information and parts tracking has been proposed. The importance of an effective process flow has been highlighted, and the benefits summarized in terms of improved efficiency, speed, and cost in parts and returns tracking.

As future work, potential additional precautions should be considered. The company ought to consider and introduce continuous monitoring by using a method that ascertains that the part and information tracking systems, respectively, are operating together in a way that is symbiotic in nature. This would ensure that everything falls into place and that the new processes flow in a manner that is smooth, directional and in line with the strategic plan proposed at the inception of the project. Lastly, any potential risks should be addressed preemptively such that these risks and mistakes are addressed and reduced. This would ensure a long-term environment for not just the project and associated process flow, but also for the stakeholders involved in making sure that everything is rightly done, and accurately executed.

7.2 Recommendation

According to the results of the study carried out, multiple suggestions can be made. An analysis and evaluation mechanism should be set up after project implementation, to ensure the long-term growth and advancement of the newly proposed process. These reports will also serve to regulate and standardize reliable methods throughout the organization. Well-defined teams, that are engaged throughout the whole development process, should be set up. Another step that would be helpful to take would be to carry out project planning to make certain that the people carrying out certain parts of the new framework are aware of the connection between their own responsibilities and the rest of the process. Moreover, the efficiency of the new parts tracking process should be assessed by checking the resources utilized by personnel and endeavors. This will also help gauge whether the proposed parts tracking changes has been successful or not and identify further opportunities to evolve and optimize the parts return and root cause analysis system.

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