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Reclamation Process in the field of Medical Devices

DEGREE PROGRAMME IN INTERNATIONAL BUSINESS
2020

Author(s): Rukanen, Emmi	Type of Publication: Bachelor's thesis	Date September, 2020
	Number of pages: 34	Language of publication: English
Reclamation process in the field of medical devices		
International Business		
<p data-bbox="312 701 424 730">Abstract</p> <p data-bbox="312 775 1444 987">This thesis was made for a case company to study their reclamation procedures and to create guidance for clients to file a reclamation for faulty products. This thesis aims to make it easier for customers to deal with the beginning of the reclamation process and at the same save time for both the customer and case company. Well-handled reclamation cases are important for the clients, subcontractors, and the case company as it adds trust, communication and can generate new ideas for technological advancements.</p> <p data-bbox="312 1032 1444 1173">For this thesis I researched the topic from available literature, Finnish Law on products liability, the European Medical Device Directive, ISO-standards and conducted interviews using Qualitative method. The thesis includes a wide explanation on warehouse management, quality control and enterprise resource planning.</p> <p data-bbox="312 1218 1444 1503">From my research I found out how the case company utilizes their newly acquired warehouse management system, how their client- and subcontractor process in currently handled and how differently workers form different department understand the current process. I made a ready-to-use template for the clients to use in case of a reclamation. I found out how important it is that correct people know how the processes work and how important it is to get all the necessary information to the right people as fast as possible to give the customers an agreeable reclamation experience. Suggested changes and alternatives can be found in the conclusion chapter.</p>		
reclamation, enterprise resource planning systems, warehousing spaces, management, ISO standards, legislation		

CONTENTS

1 INTRODUCTION	4
1.1 Objectives and research questions	5
1.2 Boundaries of the project.....	6
1.3 Ethical issues of the project	6
1.4 Conceptual framework	6
1.5 Theoretical background.....	7
2 CASE COMPANY	8
3 QUALITY MANAGEMENT.....	9
3.1 Quality Management theory	9
3.2 Reclamation process theory.....	10
3.3 PDCA-cycle.....	11
3.4 Data collection process.....	12
3.5 Relation to the thesis	12
4 MANAGEMENT SYSTEMS	12
4.1 Supply Chain Management.....	13
4.2 Warehouse Management System	13
4.3 Enterprise Resource Planning.....	14
5 STARTING POINT	15
5.1 Legislation	15
5.2 Product Liability Act.....	17
5.3 State-of-the-art	17
6 INTERVIEWS.....	19
6.1 Qualitative interviews.....	19
6.2 Interviews	20
7 SUGGESTIONS AND JUSTIFICATION.....	22
8 READY TEMPLATE	23
9 GUIDANCE FOR INTERNAL PRACTICES.....	24
9.1 Three cases.....	25
9.2 Guidance for export coordinator.....	27
10 FURTHER STUDIES	28
11 CONCLUSION.....	28
REFERENCES	
APPENDICES	

1 INTRODUCTION

This thesis is done to develop and showcase the student's abilities to use and adapt the knowledge she has acquired during their studies in Satakunta University of Applied Sciences and work in various internships and practical training positions. A thesis is a requirement in order to get a bachelor's degree and it may help to provide information for the case-company.

The thesis benefits its writer as it shows what she has learned and how well she can use the information and tools that she has been given. Thesis will also benefit the case-company where it has been made as it will give them possible solutions and ideas to improve their processes. Satakunta University of Applied Sciences also benefits from the thesis as they will get another finished thesis and perhaps, they can see what skills were needed and adjust their teaching methods or what they emphasise to future students as important knowledge and skills.

My connection to the case-company and topic come from my practical training period and summer job from April to August 2019. I worked as an export coordinator in the case-company, got to know the company quite well and now I have a good comprehension of a few changes that could be done to improve their operations, make work there run smoother and ease the process which I am tackling in this thesis.

Well-handled reclamation cases are important for the clients, subcontractors and the case company as it adds trust, communication and can generate new ideas for technological advancements.

1.1 Objectives and research questions

This thesis aims to make it easier for the case company's clients to start a reclamation case, to make the whole process faster for all parties related to the case and to clarify the usage and possibilities of the company's new warehouse management system and enterprise resource planning. Clear instructions for subcontractors and customers save time for those who handle the warranty cases and the department which handles sending and receiving goods.

The main objective is to provide the case-company with an evaluation-/estimation-system for the case company's reclamation expenses. To do this the question of **how reclamations are handled currently, how much of the case company's time it takes currently to handle the cases, how the sub-contractors and clients currently handle reclamations and what kind of improvements they would appreciate**. Other questions that need an answer are: **How are the reclamation cases noted down in the company's ERP-system? And if they are not, how they should be effectively moved and noted to the ERP?**

The questions regarding communication between those who make a reclamation and the one who receives the claim/warranty will help in the making of the instructions given to the clients and subcontractors. With clear understanding and knowledge about what kind of information the case company needs from every claim/warranty case the cases can be solved faster and with less miscommunication.

Later in this thesis I will be telling about qualitative research and I conducted interviews and used a qualitative approach in them. I chose that because it suits my thesis research as qualitative interviews are concerned with *how people think and act*, it also looks at *situations and settings as a whole concept where all is linked together*. Qualitative interviews are about *understanding patterns* rather than just collecting data and they reveal the meaning and links that interviewees attach to their work. It *helps to understand how people see things*. (Taylor, Bogdan & de Vault. 2016., p. 18-20).

1.2 Boundaries of the project

The thesis will not cover issues that are not mentioned here. Issues close to my thesis are for example other written or spoken instructions given to the case company's employees which they would in turn give to the customers and sub-contractors. I will also not be covering the full extension of the enterprise resource planning (ERP) and how it should be used effectively as it is too wide of a subject for a bachelor's thesis. Also, the thesis will not place significant weight on the monetary side of the warranty claims or stock value in bookkeeping point of view.

1.3 Ethical issues of the project

There should not be any ethical issues related to my thesis work. I follow guidelines set to me by the commissioning case company and Satakunta University of Applied Sciences.

1.4 Conceptual framework

From the conceptual framework (figure 1.) can be seen that the case company needs some specifications and clarification to their reclamation procedures. Solving each case takes time and with easy to understand guidance, the process can be hurried along. As a part of this thesis I will provide clear and simple instruction for the company's customers regarding how to act in a situation of a claim and what information the customer should give the case company in order to make the reclamation process faster and reduce the amount of emailing back and forth. In the end I will recommend the company to do some changes in how they utilize their current resource planning platform.

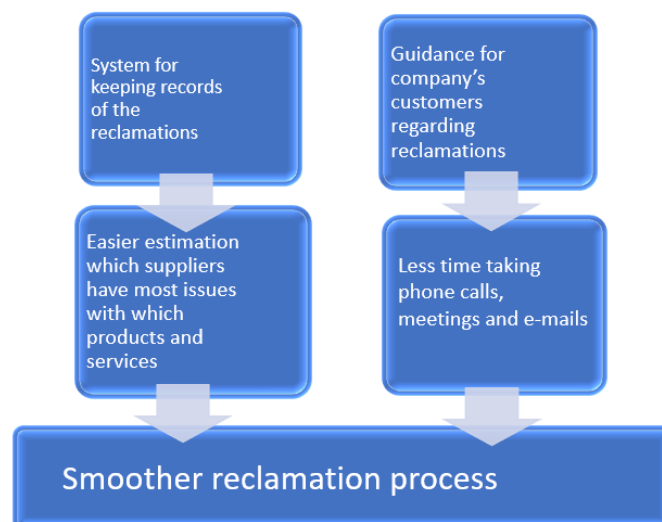


Figure 1. Framework (Rukanen. 2020.)

The thesis study is divided into two parts: theoretic and empirical. The empirical part consist of interviews and study of procedure models and current ways of how the company operates in reclamation cases. The theoretical part explains reclamation- and quality management theory.

1.5 Theoretical background

This thesis is a Project based thesis which means that it aims to create a certain type of product and describe the creation process. Project based thesis's product is often a guidebook, training material, marketing plan or a process description. (Pirkanaho. 2019). In this thesis I will be making a instruction for the company's customers and a suggestion to create a system for estimating and keeping records of both customer- and sub-contractor reclamations. The product is an integral part of this thesis. One of the problematic aspects of this thesis work was the limited amount physical literacy sources due to both public and university libraries being closed for a considerable portion of time because of the COVID-19 restrictions. Big part of physical books about the research were not yet transferred into e-books, but I tried to replace them with reliable and current internet sources.

2 CASE COMPANY

The client company who commissioned this thesis is in the medical field. It employs 150 people. Most of these employees are located in Finland, Sweden and Russia. Sixty percent of their revenue comes from exporting and their products and services are currently being used in 115 countries. The case company has the highest credit rating (AAA) from Bisnode and they are kiwa-certified. They are the largest manufacturer of medical furniture in Scandinavia as well as the largest employer in the field in Finland. In addition to the 180 employees already mentioned, the company employs many more people through subcontracts around the world. With all of these people combined, the company employs 180 people. Most of the company's revenue comes from Scandinavia, central Europe, Russia and Middle East. Annual turnover is over 30 million euros and they have made considerable new investments in their business, so I predict further growth for them. (Case company's website. 2020.)

The case company produces surgical operating tables and accessories, high-quality physiotherapy products, examination tables, senior care essentials, hospital beds, delivery beds, antimicrobial hospital equipment and massage tables. These products can also be leased from the company as many senior care homes do. Basically all the steel parts used in their products are made in the factory using Finnish raw material and some components like, motors and gas springs come from western-Europe. The products they make are cut by computer-controller lasers, robots and automated painting. (Case company's website. 2020.)

Medical industry is very tightly governed by laws and regulations. In the field people's health and wellbeing is the most important factor. For these reasons it is imperative that all the laws and standards are followed to a tee. These laws come from European Union and different countries around the world have high standards of their own. Quality control and active follow up of the product development are key. All the products need to be designed to perform flawlessly for years and be the best quality to stand daily use in demanding conditions. The case company takes feedback from their customers very seriously and any warranty- and reclamation cases need to be solved

efficiently and in a way that leaves all parties compensated. (Case company's website. 2020.)

3 QUALITY MANAGEMENT

3.1 Quality Management theory

With Quality Management, an organization aims to emphasize their quality and to keep it consistent. In Quality Management the main emphasis is on small and continuous improvements in order to eliminate mistakes from the process and to embed the quality to the process and products from the very start. Quality is assessed in audits. These are independent and can be either internal or external. (Logistiikan maailma. n.d.)

One of the most well-known measures of quality is the International Organization for Standardization (ISO). (Ng. 2012). ISO 9001 standard is based on many quality management principles and helps organizations to deliver good quality and consistent value. (International Organization for Standardization. n.d.) For a long time, different quality initiatives have been a key part in businesses strategy. These kinds of more traditional initiatives such as ISO series, zero defects policy, statistical quality control and quality assurance are and have been a major way for businesses to stand out and endure in the turmoil of globalization and the challenges it brings. What sometimes overwhelms organizations is the question of which quality initiative to choose and stick to. (Pereira. 2019.)

One significant standard that is used in the case company is the ISO 13485. The standard specifies the requirements for a quality management system that is used in companies which manufacture and provide medical devices and -services. (International Organization for Standardization. 2016.) According to Det Norske Veritas (DNVGL), ISO 13585 is used by companies who develop, design, produce, store, distribute, install medical devices and provide services and maintenance for the

devices. This sector and field are highly regulated all around the world, so the ISO 13485 standards most important function is to ease the harmonization of the laws and regulations of the quality management of medical devices. (Det Norske Veritas-website. n.d.)

Newest version on the ISO 13485 has been published the first of May 2016. The changes made then, were about expanding the standard to apply to subcontractors and all the companies involved in the design, production, storage and maintenance. Other new requirements in the ISO 13485:2016 are validating the existing software tools, analyzing the care- and maintenance information and the verification in case there are changes or faults in the subcontractor-bought parts. (Det Norske Veritas-website. n.d.)

3.2 Reclamation process theory

The case company mostly does B2B instead of B2C. The reclamation cases and regulations are still basically the same. Reclamation means a notification from the buyer to the seller about a flaw or a defect in the sold product(s). (Luottomiehet. 2001, 2). (According to the Consumer Protection Act 20.1.2978/38, 15 a §, amendments up to 29/2005 included, consumer has the right to file for a claim and the seller has to comply to that in the way stated in the products warranty agreement. The act protects the consumer and sets guidelines on how to proceed when there is a flaw in the product(s). (Act on Consumer Protection 38/1978, section 15.)

The law does not state how the reclamation should be done, weather in a letter, e-mail or a phone call. Written form is the most used as it offers better protections. The reclamation should be done in a “timely manner” depending on the nature of the product in question. One of the most common causes of reclamation is a mistake in the invoice. This is usually solved by giving the customer a credit note. (Luottomiehet. 2001, 2). In this thesis, I will be focusing on claims relating to products, not services or invoices.

All reclamation cases should be handled quickly and professionally. This way the customer feels like their needs are met and will more likely order products again in the

future. Ill-handled cases have a habit of causing the client to tell their peers about how they have not been treated right, which can lead to the company losing potential clients. (Luottomiehet. 2001, 2).

3.3 PDCA-cycle

The Plan, Do, Check, Act-model (PDCA) is useful when examining why reclamation and customer surveys are important. The model can help to gain information on how the company has succeeded in its actions compared to their intentions and plans. It points out the fails but also the opportunities and places where change is still needed. Before using PDCA-method, the manufacturer shall analyze the root cause of the problem by using Ishikawa-fishbone root cause analysis method and the 5 times why. After the root cause has been identified, the PDCA-method is being used. Firstly, the company must plan what they will do in order to make a change, define the corrective actions and then the plans needs to be implemented. After these check points are finished, the results are checked, and, in this stage, the company sees if the changes worked or not. In the final part of the model, the company needs to improve in order to meet the goal set in the first phase. (Drewitt. 2013.)

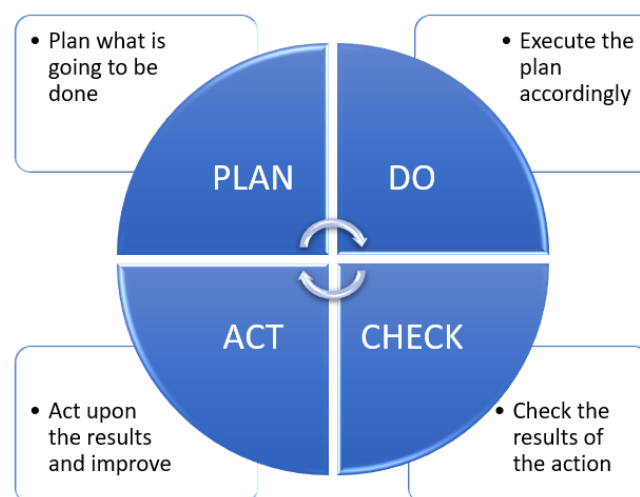


Figure 2. PDCA (Rukanen. 2020.)

PDCA-cycle can be repeated as many times as needed and each time it is done, the company gains more information on itself and customers. A company could make it a

habit to use the PDCA-cycle once a year for their customer service to be able to see the long-term effects of different changes. (Drewitt. 2013.)

3.4 Data collection process

The Research Approach that is used in this thesis is the Inductive Approach which is based on observations and acquiring data set, then identifying certain patterns and habits and lastly defining a general theory about the facts that were learned from the facts and figures. (Fronz. 2012, p. 40.) For acquiring information about the reclamation process I interviewed four people who work in the case company and deal with these issues regularly. The focus will be on quality of the answers, not so much on the quantity. Other data will be collected from the case company's archives, their intra, guidebooks, EU-law and ISO-standards, which they follow.

3.5 Relation to the thesis

Quality Management and reclamation relate closely together as with effective quality management, the amount and severity of reclamation cases should lessen. With the help of this thesis I hope to ease the reclamation process for all the parties related to them.

4 MANAGEMENT SYSTEMS

The case company uses few different systems to control and oversee the actions happening in the company from sales to warehouse situation and much more. They are a part of an encompassing supply chain and I will be briefly explaining the main systems and what supply chain management means.

4.1 Supply Chain Management

In a supply chain all the stages or nodes of production, marketing, sales, finance, distribution, product development customer service etc. are directly or indirectly involved in filling a customer's request. It also includes manufacturers, suppliers, transporters, warehouses, retailers and customers who are an integral part of the supply chain. All the stages may not be present in all supply chains. Supply chain management (SCM) builds upon this framework and seeks to achieve linkage and coordinator between the links and entities of the supply chain and sometimes the organization itself. Optimizing the chain cuts costs, makes the chain more efficient and provides the customer with value. The objective of a supply chain is to maximize the overall value generated. In order to stay competitive, the supply chains need to adapt to the global changes in technology and meet the customers' expectations over and over again. (el Ouasghiri. 2019). If the SCM is done properly and the whole chain works as it should, there should not be any reason for the customer to file a reclamation. If it would happen anyhow, the customer service part of the supply chain handles the claim until the customer is satisfied.

4.2 Warehouse Management System

In supply chains, warehousing plays a key role because it links the material flows between supplier and end-user or customer. "Warehouse management system (WMS) mainly aims to control the movement and storage of material within a warehouse and process the associated transactions, including shipping, receiving, put-away and picking" (Ramaa, Subramanya & Rangaswamy. 2012). WMS can make the facility work faster, more accurate, at better quality and safer for the workers. It can also lengthen the shelf-life of many items such as fresh produce. Companies such as Cimcorp Group offer robotic material handling solutions to achieve better warehouse management for food handling which is still largely done by manual operations and is a growing industry around the world. (Cimcorp. 2020).

Big part of warehousing in the world is still done manually and in those warehouses, humans are essential for making sure the supply chains and deliveries will not stop.

Lately we have seen the impact of global pandemics on warehouses. During crisis, it is essential to have a working warehouse and to get products moving such as medical items and consumables. If a pandemic strikes the workers in a warehouse and they all need to stay home, the warehouse stops working, products do not move and company loses revenue. This scenario shows how important is to use automation in intralogistics which does not require manual labor. It has even been suggested that automated intralogistics is key to ensure fast deliveries during crisis time and indispensable method for companies' risk management. (Henttinen. 2020, p. 7).

As one of the main points of WMS is to provide information about the processes, whereabouts of products and material flows, it benefit quality management and reclamation cases to know and have real time data of the actions taking place at the warehouse. If there is fault in a product, WMS eases the process of finding our if the fault happened in the warehouse, how it happened and how to fix the issue from ever happening again. Optimized WMS can also help to reduce the area needed for the warehouse and that saves costs in land or rent. (Ramaa, Subramanya & Rangaswamy. 2012.)

4.3 Enterprise Resource Planning

Enterprise resource planning (ERP) systems are softwares that consist of different modules and categories such as sales, finance, production planning, human re-sources, exporting and product explanations. ERP's are often highly customizable to serve the purpose of each company that uses it. (Kumar, Esteves & Bendoly. 2011., p. 2).

It is typical for an ERP that is integrated in a sense that it is the base and core of the company and to the ERP there are connections from other parts of the company such as warehousing system, payroll, invoicing, purchasing etc. ERP makes the whole company more transparent when several departments get the same, up to date information from the same platform. For this reason, it is important that whatever "base-information" that is put to the ERP must be correct because every else department will base their actions to that. ERP feeds of all the instances that are put into it and gives the information forward in a form which each department benefits the

most. The main goal of all ERP's is to up the productivity through eliminating overlapping work, monitoring stock levels, utilizing full capacity of the factory, alarming if something is going wrong and much more. All of this is customizable to the needs of the company using the ERP. (Logistiikan maailma. n.d.)

The case company uses a Finnish enterprise resource planning system called Digia. Nearly all their actions are linked to Digia which helps the information flow from one department to another. The company's WMS is connected to the ERP which enables that for example information on what and how many spare parts are in stock and can be sold to customers. All new orders are written to Digia by the sales coordinators and from there the sales department and coordinators can see how quickly products can be dispatched to customers. After an item is sold, it is taken away from the warehouse and finally when the product has left, the customer is billed, and billing happens in Digia as well.

Basically, anything you want to check regarding the situation at the warehouse or sales, can be found in the ERP which brings the whole company together. If there is a case of reclamation, the person in charge can check when the product was sold, when it left the company, from which manufacturer it came from or if it was made in the case company or if the same or similar product would be available to send to the customer as compensation.

5 STARTING POINT

5.1 Legislation

Field of medical equipment and devices is highly controlled by the law in European Union. Currently in the effect is the European Medical Device Directive (MDD) which is meant to unify and integrate the laws relating to medical devices (Council Directive 93/42/EEC). In the EU there are new European Medical Device Regulations (MDR) to which necessary sectors will move by the end of May 2021. (European

Commission. 2020). The transition timeline has been moved from the original schedule “to prevent shortages or delays in getting key medical devices on the market” (Haahr. 2020). The postponement has to do with the global pandemic, COVID-19, and making sure that hospital and medical professional will not run out of necessary medical devices in time of crisis. The European Parliament supports the delay in order to prioritize funds and manufacturing capacity. (Haahr. 2020.) New regulations are meant to ensure that there is a better protection of public health and patient safety. (Council Directive 90/385/EEC, 93/42/EEC, 98/79/EC.)

According to the European Commission the regulations will strengthen the medical device industry and make it more reliable. The MDR also aims to ease the people’s access to the medical devices and make sure that they are safe and efficient. New and more comprehensive regulations will take force in May 2020. (Website of the European Commission 2020). In the preparation of this new regulation, the European commission has heard statements and statistics for various member countries, representatives of the industry and standardization organizations. (Konkarikoski. 2020)

Below you can see the original timeline, which was planned, but due to COVID-19 was postponed.

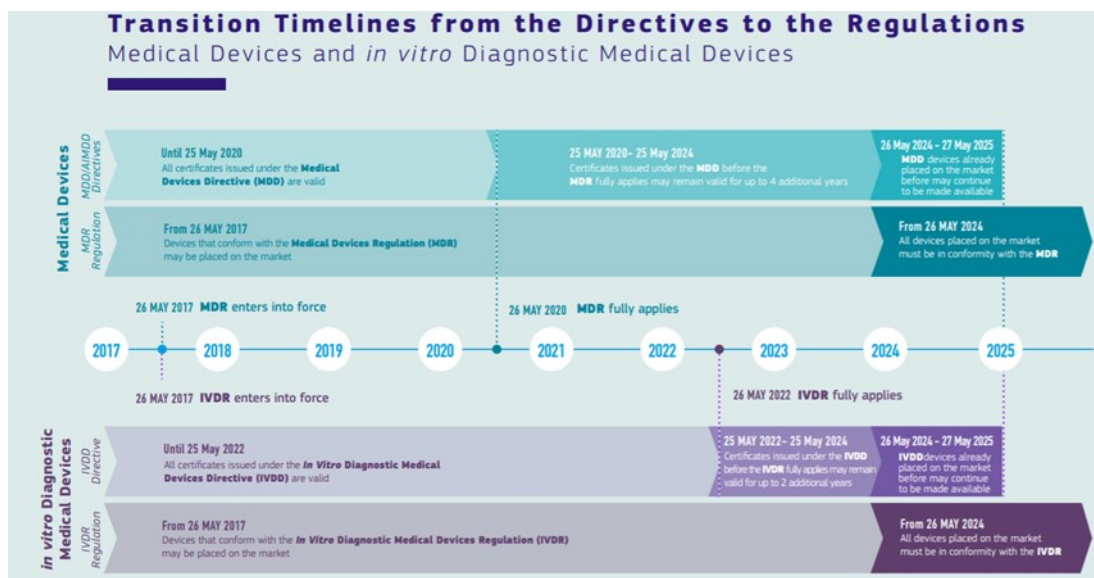


Figure 3. Transition timelines from the directives to the regulations. (European Commission. 2020.)

The MDR requires that the manufacturer of the sold medical devices also keeps a record of the post-market information regarding the products. This means that every hazard-situation, customer feedback and reclamation cases must be written now to a system for possible later inspections. (Website of the European Commission 2020).

5.2 Product Liability Act

The Finnish Product liability Act applies to the compensation for damage caused by a movable product or component used in manufacturing of a product. The injured party has to prove the damage and fault in the product. Agreed compensation needs to be paid if the product has not been as safe as was told and expected. Things like, marketing, safety instructions and the foreseeable use are all factors when considering the case and suitable compensation. According to the Act, the case company is liable to compensate their clients for possible faulty products and damages caused by them. (Act on Product Liability 694/1990, sections 1-4a.)

5.3 State-of-the-art

Currently the client reclamation process starts with the client contacting the case company either via e-mail, by calling or by leaving a service-request through the company's website. From the reclamation forms a "ticket" and each reclamation and warranty case has its own ticket number. The service coordinator responsible for the geographical area takes the ticket, starts to handle the issue by claiming it either a warranty/claim case or if it is a spare part order. All conversation, photo-evidence and other documents are stored in the case company's claim handling re-reporting system. The same system is also notified if a delivery error happens or if there is deviation in the services.

Next step is to determine if there was an incident related to the case- If yes, then the ticket moves to the Regulations manager who then takes the coordination

responsibility. If there was no immediate danger in the case, no one got hurt or the reclamation message did not contain words such as 'incident', 'danger' or 'close call', service coordinator will continue to work with the customer claim by investigating the root cause of the technical error in questions.

Next is determined if there was a technical defect or fault in the delivery of the product(s). If yes, the client is sent a replacing product(s) or agree on another form of compensation. Depending on the case, the Production manager and Dispatch department are also notified on the case. The Service coordinator asks the client for more information and usually the client sends a photo of the faulty product where the coordinator can then determine what caused the fault and what would be the best way to fix the situation. If it is a case of a minor technical issue, replacing spare part is sent to the client and the client is asked to send the faulty component back to the case company. Returned component is analyzed by service coordinator, and if needed the component is returned to subcontractor for further investigation.

This is mostly the case with electrical components. In this case the faulty component is placed in the dedicated storage place for that certain subcontractor where the component came from and the information about the case is written in the corresponding Excel-file. If necessary, in order to get the product fixed, a repair service personnel is/are sent to the client to make sure the product is properly fixed and will not cause further reclamations. You can see Appendix 1. for how the case is currently handled. If there is a case that involves damages caused by the freight company, those cases are dealt with the coordinator who booked the freight.

The case company has recently also started to write down the purchase reclamations according to the supplier, into a basic Microsoft Excel document. In the Excel they write the supplier, name of the part in question, the case company's code, the purchase order's number, the serial code and date of the component, a short description of the fault, who made the report, who was in charge of the purchase, when the supplier has been notified about the reclamation, the compensation given to the case company and the date when the reclamation case has been finalized and closed.

Once every month a compilation of the reclamation cases is drawn up and shared with the departments of sales, -production, -acquisitions, -product design and the management so that everybody knows what is going on and in which areas there is room for improvement. The aforementioned department heads can then hold discussions with their subordinates about advancements and possible changes.

6 INTERVIEWS

6.1 Qualitative interviews

Qualitative interviewing has its foundation in conversation that has the emphasis on the interviewer asking questions and listening. This interview style differs from others in a sense that in this case the participants are viewed as “meaning makers” and not as passive by-standers from whom the interviewer merely drains information. Gubrium & Holstein. (2002). Level of standardization I chose for these interviews is semi-structured, meaning that the interviews are non-standardized and start with a predetermined list of questions and themes which will guide the interview, but they are not set in stone and all the respondents will not be answering the exact same questions. There is variation between interviews and what kind of discussion will develop in each interview depending on the interviewee and their expertise. (Saunders, Lewis & Thornhill. 2019, p. 438.)

For the purpose of making this thesis and acquiring the information from the interviews I felt like the semi-structured interview was the best choice for that it gives the guiding questions so all the participants know the theme and what the general discussion is about, but leaves room for more in-depth questions and finding out about relating topics that I did not know were related to the topic of the interview, like warehouse management and end-user reclamations.

Interviews were done in order for me to get a better understanding/picture of how supplier reclamation/claim-cases work in reality at the moment, who are a part of it

and how the different systems are used in it. I conducted the qualitative interviews in four parts, by interviewing people from four different positions inside the case company.

The four people whom I interviewed at week 18 all had slightly different perspective on the topic and different answers, even though I asked some of them the same questions. This shows that different people in the company have a different understanding of how certain things should be done and how warehouse management and reclamation cases should be handled. The interviews were held over the phone. The original idea was to conduct the interviews face-to-face, but due to the circumstance relating to COVID-19, I was not able to physically visit the company.

I e-mailed the interviewees and asked if they would be willing to be interviewed and suggested them a timetable. During the interviews I wrote down notes of their answers. I had seven predetermined questions, but as this was a qualitative interview and I was fairly informed about the topic and the interviewees also knew the subject well, I was able to broaden the questions and to get more information that I had previously forecasted. I emphasized the quality of the questions and answers over the quantity.

6.2 Interviews

For the interviews I chose to interview Logistics Engineer, After Sales Engineer, Purchase Manager and Team leader of physio- and service-intralogsitics. My questions to the Logistic Engineer were mostly about the WMS, components bought from subcontractors and ERP. The Logistic Engineer had the broadest answers regarding the WMS, because he was the one mostly in charge of it and was involved in the project when the new WMS was taken to use in March 2020. The After Sales Engineer had a lot of answers regarding the reclamation cases and he told me about the case company's different procedures regarding a few of their big suppliers.

Firstly I asked about the WMS, who makes changes there, how fast the changes can be seen and if there is a technical delay in how fast the changes appear in the WMS. All the interviewees answered similarly, but the Logistic Engineer had the broadest

answers. He told me that they are using Leanware as their WMS and they have the basic model at use. Perhaps in the future they will connect it to Unifaun.

The warehouse employees have tablets and when new products arrive, they look for the delivery note, see that the correct products have arrived in full and good condition and that they match to the ERP's purchase order form. Then they mark it to the WMS and it updates to WMS and ERP within 1 to 5 minutes. When checking for the upholstery purchase orders, the warehouse workers use a scanner to read the barcodes in the products. This has greatly helped in identifying the right upholstery orders. Others whom I interviewed did not know as much about the new WMS system, but they seemed to have the same basic idea.

The case company manufactures a big portion of their product components by themselves. These parts have many stages in their production from forming the shapes of the item from metal, to welding items together, to painting and so on. Because there are so many steps in the production, the 'black parts' are not marked to the WMS and it would not make sense to move them there either, since they are always made to order. I got a detailed explanation about this from the Purchase Manager and Logistic Engineer. The interviewee who worked in intralogistics told me that if there is a reclamation regarding the 'black parts' those are very rarely inspected or otherwise marked down anywhere. The faulty metal parts have just been thrown away.

All the people who I interviewed told me approximately the same thing when I asked that who takes care of the freight of the faulty products back to the supplier. Everyone answered that in case the supplier is not Finnish, the case company's export coordinator handles the transport. Purchase Manager told me that if there is need for reclamation, the reclamation is done and the faulty products gets send back. The item(s) are taken out of the warehouse and if the products had a serial code, all the other products that had the same part where the fault has occurred may be checked if there is a reason to believe that there are faults in the other products that have already been sent to customers.

Most cases if the supplier is foreign, they get information about the case, they sent the export coordinator the freight information and needed papers and book the freight for

the faulty items. The suppliers handle and pay the return of the items from Finland to wherever. Logistic Engineer told me the same things about the returns. He also told me that in the WMS there is possibility to change the status for the items in the WMS from 'non-marketable' to 'available'. This is something that perhaps was not clear to the Purchase Manager.

My final interview was with the After Sales Engineer. He had the most knowledge regarding contact with the company's own clients and end-users, whereas the others were mostly experts in suppliers and communication with subcontractors. He told me the chain of events in case a customer notices a fault.

First the customer calls the company or sends an e-mail. This claim forms a 'ticket' to the system and then the company and customers agree on how the faulty product is returned or if repair people will go to the customer and inspect the issue there. After Sales Engineer handles the reclamation of spare parts for the end customers. The After Sales Engineer told me an example about a fairly large company that supplies the case company with spare parts. Over a month all the faulty parts from this supplier are collected in a carton box and written in Excel about what each product is, why it has caused a reclamation and some codes from where the supplier can identify the products. Once the month is up, the supplier sends back a reclamation transport code and the box is sent to the supplier.

7 SUGGESTIONS AND JUSTIFICATION

Currently the case company keeps a Microsoft Excel about the purchasing reclamations. It has a place for basic information such as purchase number, code, descriptions of fault, serial number of the component, responsible person, date when the case is closed and refund/compensation. I suggest the whole Excel file should be moved to Digia (ERP-system) for easier access to certain persons. The company does not currently use this feature in Digia, but they could pay for the demo-version of it

and possibly realize that that would free them from too many Excels and they would central more information to the ERP.

Currently not all customers use any template such as the one in appendix 2 to report damages. Until they do so, the coordinator could start keeping records of them and storing pictures of proof the damages and clients e-mails. Once the customers start using the template, a dedicated employee could perhaps once a month round up all the reclamation reports and transfer them into an Excel-type chart in the ERP in order to the case company to see in one look that which customers most often get damaged products, which products and if they are freight damages, which freight company was in question.

Send the template in Appendix 2 to every customers in the contact list or give the list to the distributors and Export Sales Managers, Product Manager and Export Coordinators who can then give the template to the customers/regions whom they are in charge for.

I also suggest that the Logistic Engineer could keep a short presentation or a meeting with few key people regarding how the WMS functions and what is possible to do with it and what is not. This is not something that every person in the company needs to know, but it would help if the correct people knew how the management system works. I would suggest a twenty-minute meeting to go over the basics.

8 READY TEMPLATE

According to Philip Hodgson (2007) there are a few characteristics that can be found in all good manuals and guides. These are 'avoiding lengthy paragraphs', 'include only the necessary information', 'provide lots of white space' and 'has clean and readable font'. Hodgson explains that users of ready templates and guides get easily frustrated if the outlook is messy, information is scattered, and the users are unclear of what they

are expected to do. Increasing amount of businesses are re-thinking their ready-made guides and templates that they give to their customers. (Hodgson. 2007.)

In this thesis I wanted to provide the case company a template which they could give their customers in case the customer would have to file for a reclamation. The template asks the customer to fill in only the necessary information needed to effectively start the reclamation process. If all the information is filled in to the report, the department which handles the cases can get to the point quicker and will not need to bother the customer with “small” questions such as ‘what is the serial number on the faulty item’ or ‘what were the item codes’. All of this information will already be on the report filled by the customer. It speeds up the process and lessens the number of mistakes and misunderstandings. The report template can be found in Appendix no. 2.

The report is made to be clean looking and simple to use to minimize the customers effort. It includes places to write the reclamation date, PO number, client name & company name, case company’s contact persons information, number of items, product code, items name, the date when fault was noticed and serial number id applicable. The customer can also choose if the reason for this claim is either freight damage, deficient packing, wrong products delivered to them or wrong amount of items delivered, delayed delivery from what was agreed or a manufacturing fault. There is plenty of white space for describing the problem, possible questions for the case company, a place to specify how the customer would like to be contacted regarding this and space for other comments or remarks. In the bottom of the report there are case company’s contact information such as address, phone number and fax, e-mail address and web address.

9 GUIDANCE FOR INTERNAL PRACTICES

There are multiple ways that reclamation from the case company to the original supplier can be handled. Each have benefits and require different amount of effort from each party.

9.1 Three cases

I have laid out three different cases regarding supplier reclamations and how they should be handled inside the case company. This guidance can be used to tell how each different case could be handled. In the first case the faulty item that case the client to file a reclamation, the case company returns the faulty item to the supplier to be fixed.

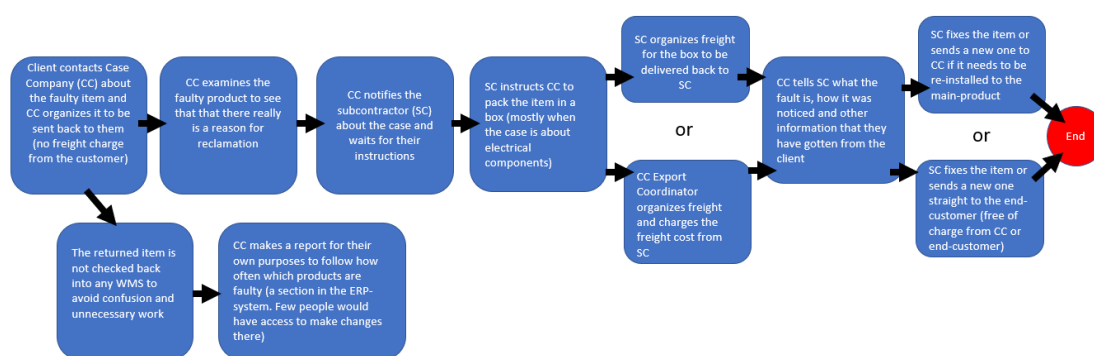


Figure 4. Case 1. (Rukanen. 2020.)

When the end customer has sent the item back, it is not checked back into the WMS even if there would be “non-marketable” section where to put it in order to avoid confusion in the stock balance. All the items sent back to the case company should be registered into a section in the ERP, so I do not see a reason to check them back to the system. Next step is to examine that the product indeed is faulty and then notify the supplier about the case. Once the supplier asks the item to be sent back to them it is agreed who pays for the freight. Mostly the suppliers are Finnish, so the costs are not excessively high, but for foreign suppliers, larger item or bigger amount of faulty items rises the freight costs. In case that the freight cost would be considerable, I would advise to use the Incoterm Ex Works in which the supplier organizes and pays the freight.

Once the faulty item has reached the supplier, they can either fix it or send a brand new one back. If it is a separate product it could be sent straight to the end customer

to save time and stops along the freight. However if the new item is a component in a bigger piece of medical equipment, it should be sent back to the case company who can then re-install it back to the medical equipment and then sent to the end customer.

In the second possible case, the faulty item gets discarded completely. Below you can see a chart (figure 5.) to illustrate the process. Once the item is sent back to the case company and they have examined it to truly not be in the required condition and have written all the information down to the new section in ERP. The returned item should not be checked back to the stock balance.

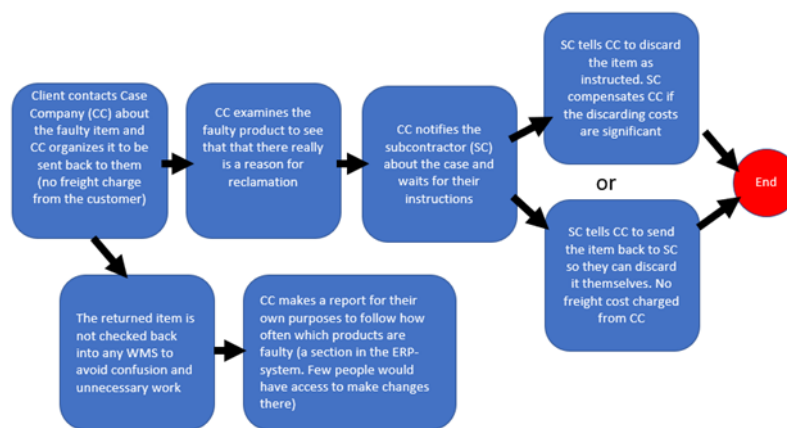


Figure 5. Case 2. (Rukanen. 2020.)

Next step is to notify the original supplier about the situation. Either they instruct the case company to send the faulty item back to them to be discarded (freight costs on the supplier) or they ask the case company to discard the item. As a big part of the items are metal, the case company actually receives money from the discard, because scrap metal is valuable. On the other side, if the discarded item is an electrical component or there are many of those, it will cost the case company money to safely and environmentally friendly discard them. This cost should be compensated by the original supplier. Once the item(s) is safely discarded and the end customer is compensated the case will be closed.

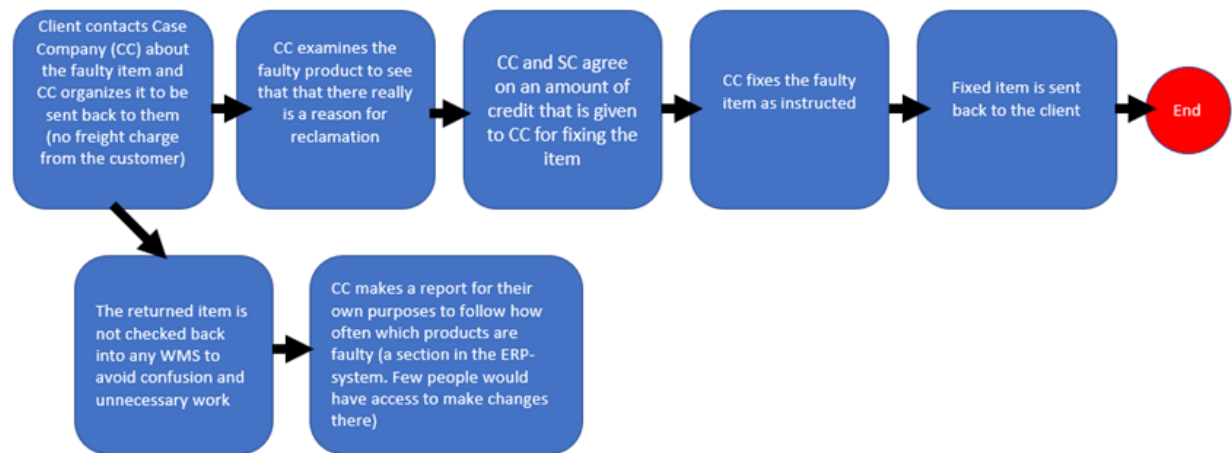


Figure 6. Case 3. (Rukanen. 2020.)

The third possible supplier reclamation case (figure 6.) is about the possibility of the case company fixing the broken item and the supplier compensating them for it. This method saves time, since the item does not need to be sent back to the supplier which can be far away and it saves the environment as well. The case company has agreed with certain suppliers that they charge by an hourly rate or per machine hour, for the work they do repairing the faulty item that caused the end client to start a reclamation. Once the fault in the item is verified, information is saved to the ERP, supplier is contacted and is agreed that case company will repair the item and charge the supplier for it, the item is fixed and sent back to the end customer.

9.2 Guidance for export coordinator

From working experience I know that some of the case company's customers prefer to reach out to the export coordinator, with whom they are in contact a lot. The export coordinator then has to forward the client reclamation inquiry to the After Sales Engineer or his assistant, who will then run the suggested process of warranty cases. I suggest that a small manual should be written to the export coordinator about these cases, so that she/he knows what to do or if there is a substitute for holiday season, they could easily check what needs to be done.

A good manual for the export coordinator has clear structure and when followed properly, it reduces the number of mistakes and quickens the process. There should be

too much unimportant information is the manual because it may hide the key-points of the message and make it harder for the coordinator to find the right part of the information. This is especially dangerous if the coordinator is new at her/his job or is only a part-time substitute whom the coordinator has not have enough time to explain everything. New ERP and new products only add to the possibility of confusion. According to Korpela if there is a possibility for a misunderstanding, it will happen. (Korpela. 2019.)

10 FURTHER STUDIES

Based on my research at the case company I would suggest that another bachelor thesis student could do research on the finance-side of the company. Specially on the value of warehouse or stock and how it is affected by changes in the warehouse. For example what are the effects of keeping the stock of products very low in order to make the value of stock look a certain way on the financial statement? and how this affects the availability of certain products and especially those that are often needed quickly by customers but not so quickly available because they are not kept in stock?

11 CONCLUSION

Research questions have been answered and I have concluded that properly handled reclamations are essential for the case company. This applies to client reclamations and supplier reclamations. If a situation happens where a client is not entirely happy about their purchase or there has been a situation where any harm has been caused to the client it must be handled like the law requires and in a way where the client is not left feeling betrayed or like their opinion did not matter. That will most likely lead to the customer not purchasing anything from the company again and telling others not to do so either. This naturally hurts the company's reputation and sales.

For the case company in this thesis it is important to have their management systems up to date and communicating with each other so all the necessary workers can quickly check the needed information to perform their duties. This means that the ERP and WMS need to be connected. Effective quality management ensures that the company keeps their high standards and avoid reclamations as far as possible.

I have suggested that inside the company a group of selected workers would have a short but informative session where they would explain how the newly installed warehouse management system works and what new possibilities it brings. I justify this because from my interviews I noticed that not everybody knows how the systems work and it would help their actions regarding reclamations if those key people knew the system, especially because reclamations are not only a customer support matter, but instead they are connected to warehouse management, bookkeeping and accounts, quality management and product developing and relations with third party instances like logistic companies and expenses regarding all of those. I would also like to conclude that possibilities with more automation could be looked into in the factory floor.

During the thesis process it became clear how much the case company wants to develop further and become even better supplier for their clients and to make it easier for them to contact the company in case of reclamation. Also noticeable was their effort to keep records of various cases and to know which products most often cause concern and reclamations. With the positive attitude of those whom I have worked with I am sure that the case company will reach their next goals and stay leading the industry of medical devices.

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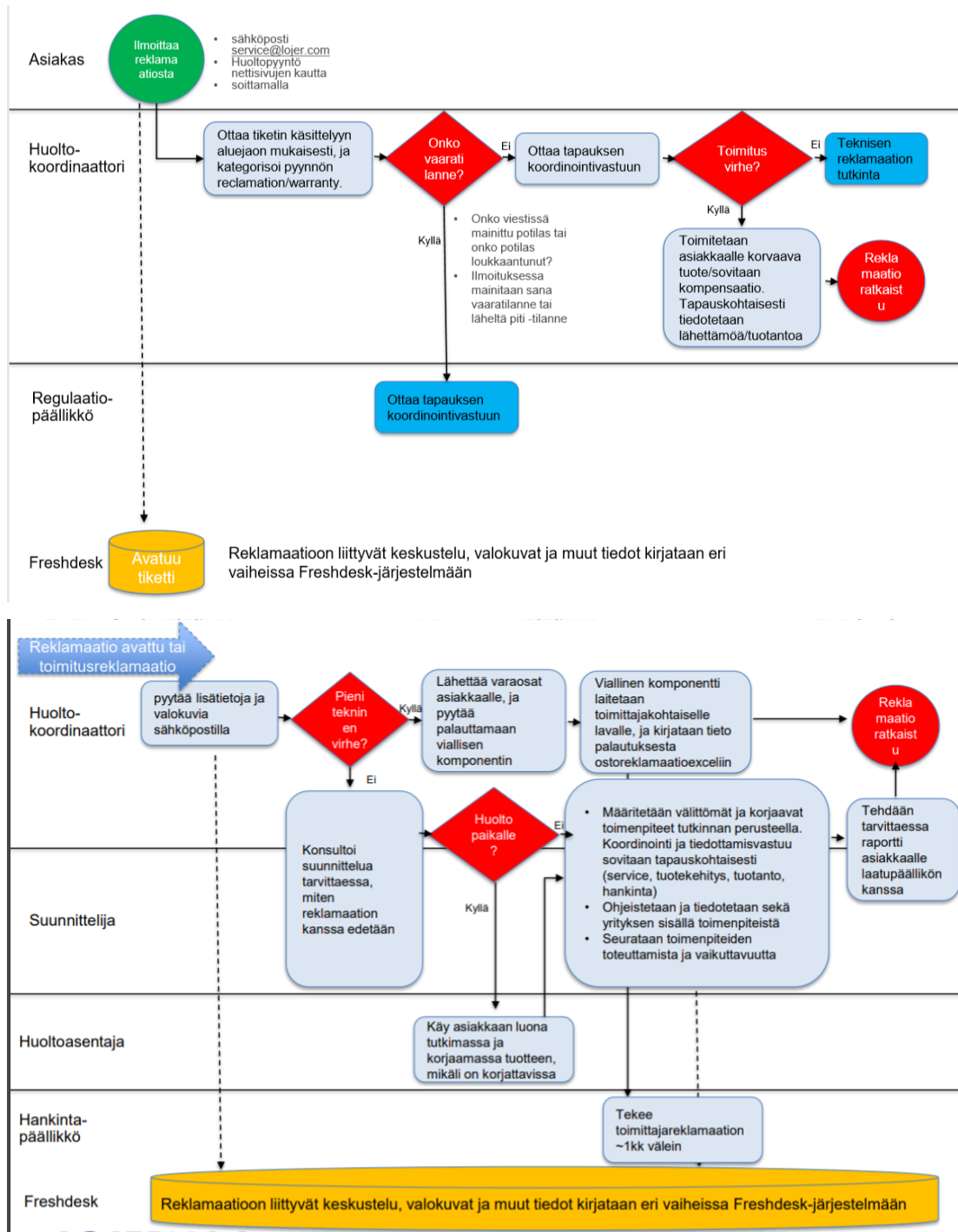
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APPENDIX 1



CLIENT RECLAMATION REPORT

RECLAMATION DATE:	PURCHASE ORDER NO:	CLIENT NAME & COMPANY NAME:	CONTACT PERSON:	
NUMBER OF ITEMS [PCS]:	PRODUCT CODE:	ITEM NAME(S):	FAULT NOTICED DATE:	SERIAL NUMBER IF APPLICABLE:
1 CAUSE OF RECLAMATION/DESCRIPTION OF FAULTY ITEM				
Reason for reclamation:				
<input type="checkbox"/> FREIGHT DAMAGE <input type="checkbox"/> DEFICIENT PACKING <input type="checkbox"/> WRONG PRODUCT DELIVERED <input type="checkbox"/> WRONG AMOUNT DELIVERED <input type="checkbox"/> DELAYED DELIVERY <input type="checkbox"/> MANUFACTURING FAULT				
2 DESCRIPTION OF PROBLEM				
3 POSSIBLE QUESTIONS				
4 HOW WOULD YOU LIKE TO BE CONTACTED?				
5 OTHER REMARKS				