

Improving Quality Assurance of Radiology Equipment Using Process Modelling and Multi-actor System Analysis

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Abstract

With the introduction of RIS and PACS technologies in clinical radiology, the field has become increasingly technology dependent. The quality assurance in radiology have however yet to catch on. With many quality assurance programs mainly focusing on the clinical side of radiology whilst little attention is paid to the technical aspects. This thesis serves to change that, by investigating quality assurance of radiology equipment in the workflow of hospital physicists and biomedical engineers at Södersjukhuset emergency hospital.

To improve said workflows, process modelling and multi-actor system analysis was utilized in combination with the on-site inventory system Medusa. In order to model the workflows, the process modelling technique flowchart was used. To add additional information into the flowcharts, multi-actor system analysis was employed. This was done for the workflow of both scheduled and unscheduled maintenance of radiology equipment. Initially resulting in a pair of pre-study models which modelled the after the existing workflows.

From said pair of pre-study models, both redundancies and main objectives for improvement were deduced. This in combination with an extensive semi-structured literature review, led to a list of requirements. Two pairs of improved models were then created with the list of requirements in mind.

All the models were then evaluated, including the pair of pre-study models, in workshops held with hospital physicists, biomedical engineers and respective leadership staff. These workshops contained both an open discussion and a questionnaire, asking the participants to rate the alignment of the models with the different requirements in the list. Based on the results from the workshops, one of the proposed pairs of improved models were then chosen as the final solution of an improved workflow.

A workflow in which redundancies were reduced, traceability capabilities added in form of digital storage, and alignment with legislative demands from SSM assured. A step in the digitalization of Södersjukhuset. Utilizing digital technology to improve quality assurance in the workflow of radiology equipment.

Keywords

Healthcare Informatics, Quality Assurance, Process Modelling, Radiology, Multi-actor System Analysis, System Analysis

Sammanfattning

I samband med introduktionen av RIS och PACS teknologi i klinisk radiologi, så har fältet blivit mer teknikdrivet. Kvalitetledning av radiologisk utrustning har däremot inte förändrats. Då de flesta kvalitetslednings program har primärt fokus på den kliniska sidan av radiologi och förbiser de tekniska aspekterna. Detta examensarbete försöker bemöta detta, genom att utreda kvalitetsledningen av radiologisk utrustning hos arbetsflödena av sjukhusfysiker och medicintekniska ingenjörer på Södersjukhuset.

För att förbättra arbetsflödena, så användes processmodellering och analys av multi-aktörsystem i kombination med det lokala inventariesystemet Medusa. För att skapa en modell av arbetsflödet så användes processmodelleringstekniken flowchart. För att lägga till ytterligare information i flödena så utfördes en multi-aktörsystem analys. Detta utfördes för både förebyggande- och avhjälpande underhåll av radiologisk utrustning. Vilket resulterade i ett par av förstudiemodeller som modellerade det nuvarande arbetsflödet.

Baserat på detta par av förstudiemodeller, så kunde både överflödigheter och huvudsakliga förbättringsmål härledas. Detta i kombination med en semistrukturerad litteraturundersökning, ledde till en lista med krav på modellerna. Sedan så skapades två par av modeller som förslag till förbättrat arbetsflöde, baserat på listan med krav.

För att utvärdera alla modeller, inklusive förstudiemodellerna, så hölls workshops med sjukhusfysiker, medicintekniska ingenjörer och respektive chefspersonal. Dessa workshops innehöll både en öppen diskussion och ett formulär, som bad deltagarna att utvärdera de olika paren av modeller gentemot de olika kraven som hade formulerats i listan. Baserat på resultaten från dessa workshops, så valdes en av de två förslagna paren av modeller för förbättrat arbetsflöde, som en slutgiltig lösning.

Ett arbetsflöde där överflödigheter har motarbetats, spårbarhet förbättrats med hjälp av digital lagring, och sammanställning med regulatoriska krav från SSM har säkerställts. Ett steg i digitaliseringen av Södersjukhuset, genom att utnyttja digital teknik för att förbättra kvalitetledningen av radiologisk utrustning.

Nyckelord

Hälsoinformatik, Kvalitetledning, Processmodellering, System Analys, Radiologi, Multi-aktör System Analys

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List of acronyms and abbreviations

ALARA As Low As Reasonably Achievable

BPMN Business Process Model and Notation

ISO International Organization for Standardization

NVA Non-Value-Added

OMG Object Management Group

PACS Picture Archiving and Communication System

RIS Radiology Information System

SSL Radiation Safety Act (Strålskyddslagen)

SSM Swedish Radiation Safety Authority (Strålskyddsmyndigheten)

VA Value-Added

Chapter 1

Introduction

Quality assurance in the workflow of biomedical engineers and hospital physicists at radiology departments is a relatively unexplored topic. Therefore, this master's thesis is aiming at exploring the use of process modelling and multi-actor system analysis to improve quality assurance of radiology equipment. Utilizing both methodologies and an existing software solution in the form of an inventory system to improve said workflow. With the overarching goal of improving the overall quality assurance of radiology equipment at Södersjukhuset emergency hospital.

The chapter will include the background of the thesis, research questions posed, and the delimitations of the project as a whole. It serves to give the reader a thorough understanding of the origin of the thesis, the key questions which are being investigated and in which confines the project had to stay within.

IT in radiology is an expanding field. With the introduction of [Picture Archiving and Communication System \(PACS\)](#) and [Radiology Information System \(RIS\)](#), meaning a move from analog film to digitalized image storage, the discipline has been steadily growing. Giving radiologists access to digital tools to aid in diagnosis, connecting clinicians across hospitals efficiently to improve knowledge sharing, and allowing for higher volumes of patients to be examined in a clinical production setting [1].

However, even though the benefits of digitalization have been proven in radiology [2]. The same cannot be said of the workflow of biomedical engineers and hospital physicists at radiology departments. Especially, when it comes the documentation of functional controls of radiology equipment, so-called quality assurance documentation. If parts of the quality assurance workflow could be digitalized, then benefits such as automation and traceability

could potentially be harnessed [1][2]. To the potential benefit of clinicians, engineers, physicist, and patients alike.

It is essential to have well thought out approach in order to gain the most out a digitalization process. Otherwise, one might fall into the same pitfalls as other similar digitalization projects. Or worse, one might not gain anything at all from the digitalization process. Only contributing to more administration and increased equipment downtimes, which is not unheard of in this setting. Taking this into consideration, inspiration on how to approach this properly can be drawn from other quality assurance programs in clinical radiology, other disciplines in healthcare and other business sectors [3].

1.1 Quality assurance programs in radiology

Quality assurance in radiology is not a new phenomenon by any means of the imagination. A lot of work has been done in the field, with positive results [4][5]. However, much of the literature focuses on the caregiving processes and clinicians. Whilst little attention has been placed on the technical aspect of radiology. A discipline, that in its essence, is heavily technology driven.

That is not to say that technical aspects have been completely overlooked. Some quality assurance programs have briefly glanced at the technical aspects, which shows that there is a certain awareness of the need of a holistic viewpoint [5]. However, one needs to fully address both the clinical and the technical aspects of radiology, in order to achieve a proper holistic approach to quality assurance in radiology. Thus, what is lacking, is the bridge between the two aspects.

A bridge which would be a merging of quality assurance programs in radiology, of both technical- and process-oriented standpoints. Investigating what the product would from these two combined. Which is both sound in principle and needed in practice, based on the increased technical dependency caused by digitalization of healthcare.

1.2 Legislative demands

A central principle that governs all radiology, which is very well established, is the *As Low As Reasonably Achievable (ALARA)* - principle. It dictates that radiation dosages should be kept at a minimum when performing medical imaging, whilst still maintaining a good image quality. This is due to the cancerogenic nature of radiation and is a principle which is applied to all

aspects of radiology [6]. Of course, Swedish radiology legislation is no exception and is in essence built around this principle. Thus, Swedish radiology departments are obliged to adhere to the regulations of the [Swedish Radiation Safety Authority \(Strålskyddsmyndigheten\) \(SSM\)](#) [7]. The regulations put out in [Radiation Safety Act \(Strålskyddslagen\) \(SSL\)](#) in 2018, regarding the clinical practice of radiology, states the following:

- Functionality- and performance checks on medical ionizing equipment needs to be performed at regular time intervals, ensuring that the equipment is functioning correctly.
- Furthermore, if any service is performed that might change the properties of said equipment, then functionality- and performance checks needs to be performed.
- Lastly, each equipment needs to have a person or a function that clears the equipment for clinical use after service.

If the workflows of a radiology department adhere to these regulations, then said workflows follows both the legislative demands and by extension, the [ALARA](#) - principle.

In the event of an inspection from [SSM](#), said radiology department would not receive any demerits. Which is in the interest of any stakeholder within the radiology department. Especially, hospital physicists who are tasked with ensuring adherence to the regulations.

1.3 Research questions

The two main research questions that were posed in this thesis were the following:

1. What can multi-perspective process modelling reveal about redundancies in a complicated sociotechnical system, such as a radiology department?
2. What kind of workflow and software solution is suitable to address the redundancies found?

1.4 Södersjukhuset and SoftPro Medical

The thesis was written in collaboration with hospital physicists and biomedical engineers at the radiology department of Södersjukhuset. An emergency

hospital located in Stockholm, Sweden. The hospital garners a workforce of 4892 employees, in a wide variety of clinical disciplines and specialties [8].

The workload of the hospital is high. For example, in 2019, the hospital had a total of 111 039 emergency visits and 516 727 planned visits. Of which, 24 335 were surgeries and 7 831 were deliveries. It also performed 147 486 image diagnostic exams and 74 193 mammography screenings at the hospital and in satellite clinics. Thus, making it one of the largest emergency hospitals in the entirety of Nordic. With a very high volume of radiology related examinations [8].

In order to keep track of all the equipment used at the hospital to support such a workload, the biomedical engineers utilize an inventory system called Medusa. Medusa is developed by SoftPro Medical Solutions, which is a medical IT supplier based in Sweden [9]. They served as the external supervisors for this thesis. Lending a helping hand with key insights into system development in the medical industry. All proposed solutions were also centered around the inventory system Medusa, in one way or another. Thus, making their cooperation key for a successful thesis.

1.5 Delimitations

The thesis serves to propose a solution that address the redundancies found, using process modelling and multi-actor system analysis, in quality assurance of radiology equipment. However, only a selection of all the redundancies found were eliminated/reduced. Ensuring that the scope of the thesis did not get too large and that the thesis could be performed within the allotted timeframe. Thus, the redundancies chosen were those which were deemed to be of the largest impact on the system as a whole.

Furthermore, modelling and proposing a solution is one thing, whilst implementing a solution is another. No implementation plan was proposed for the solution models. That is a task closely tied to the management of the work units, being the hospital physicist team and the biomedical engineering team at the radiology department. However, to an extent this fact was elaborated upon, but no actual plan of implementation was proposed.

Lastly, this thesis was performed during an ongoing pandemic caused by the covid-19 virus. This resulted in a somewhat limited number of resources available at the hospital, as the hospital implemented guidelines that limited the available resources for development project. Focusing on the core task of providing healthcare instead. It did not affect the project in a crippling manner, but the above delimitations were taken as in part an effect of these restrictions.

Chapter 2

Background

In this chapter, a review of the relevant theory will be presented. It will serve to give the reader an increased understanding of the theory behind the topic at hand. The theory review will center around process modelling, which is the core topic of this thesis. Multi-actor system analysis will then be elaborated upon, to further the understanding of the methodologies used. Furthermore, a review of lean principles will be presented, with focus on healthcare specific application of lean. Finally, an introduction to process mining will be given to show the potential of process modelling when applied to a system, being quality assurance of radiology equipment in this case. Thus, giving a full overview of the current state of the field of process modelling.

2.1 Process Modelling

Process modelling is the systemic mapping of the activities and interactions in a system making up a workflow, in order to gain a holistic understanding of said system. It views a system as a set of steps, interlinked, to form a complete end-to-end chain which is visualized in a step-relationship diagram [10]. The end-to-end system is what is called a process and the act of visually modelling the entire system is called process modelling [11].

What separates process modelling from other system mapping techniques, is the way the steps are formulated. In process modelling, the steps are not strictly defined, but rather confined within pre-set boundaries. Thus, a step within the methodology of process modelling, is an activity of which the input and the desirable output are predefined [10][11][12]. Whilst the activity itself is left to the stakeholder, someone who is performing the tasks within the activity, to decide the approach upon.

The interlinking factor, the relationships between said steps, is described with the help of arrows. The arrows between the steps indicates to the beholder, from which step an output is being directed as an input into another step. Thus, forming the step-relationship diagram in the model and ultimately, a complete visualization of the end-to-end system to the beholder of the model [10][13].

Much different from checklist approach, the specifics of performing a step in a process models are inherently variable. Allowing the stakeholder, which is driving the process within the step, to operate within his/her own discrepancy. It is also what fundamentally separates process-oriented workflows from administrative-oriented workflows, like the checklist approach. Where the different activities within a step are strictly defined. As opposed to the variable nature of the activities in process modelling [12][14].

The process modelling framework gives one a methodology in which to models the behavior of the system without micro-managing every detail of the process. Which is a viewpoint that has been established as a reasonable one when handling complicated systems [12]. Especially in systems that are heavily dependent on humans interacting with them i.e., systems within healthcare.

Process modelling is a well-established methodology, which in itself garners a wide variety of techniques due to its extensive usage in different business sectors. One of the most common techniques is [Business Process Model and Notation \(BPMN\)](#), which in itself has multiple extensions [15].

When performing process modelling, it is vital that the right technique is utilized. Therefore, the modelling technique is something that should be determined early on when modelling a system. Ensuring that the maximum amount of information is extracted from the system, so that informed decisions on improvements can be made. But also, to ensure that the beholders of the finished process model easily can draw conclusions from the resulting models [16]. If the beholders cannot draw conclusions from a model, then the model is not very useful for system design purposes [17].

A flowchart, which is used in this thesis, uses a series of geometrical objects in order to define the steps within a process. Utilizing the above-described arrows to interlink the objects, the steps, in order to create a flow of information in between them [14]. The arrows both enable an interlinking pattern between steps and indicate in which direction the information is flowing. Ultimately, forming the end-to-end system. The geometrical objects, or in other words shapes, come in an array of pre-set configurations. Thus, ensuring that there is a harmonized understanding of what a shape in itself carries for meaning. The shapes in themselves can furthermore be color-coded

to carry additional information. It is however not necessary in order to utilize the method. To a novice user, this is the method to be preferred.

What the **BPMN** technique does, is that it adds additional information into the model. This is done by increasing the arsenal of shapes available to the user and adding symbols which are used in-between steps, in connection to the usage of arrows. These symbols serve to add information such as, which information is being delivered between steps, or if there are any time-delays present [15]. However, this type of modeling has a higher barrier-to-entry. As the annotation is more extensive. Which can be seen as a disadvantage when introducing process modelling through the means of **BPMN** to new users. Especially, when one is trying to model a complicated system, that a wide variety of stakeholder need to comprehend in order to adhere to [18].

There are also several process modelling techniques which are under development. This is an effect of the extended use of process modelling in an increasing amount of business sectors. To be noted, is that new process modelling techniques are being maintained and developed by the **Object Management Group (OMG)** [19]. It is a standards consortium that works to ensure harmonization of process modeling techniques. They ensure that there are market standards for process modelling that professionals can utilize. Thus, making sure that process modelling is being continually developed in a harmonized fashion as new areas of implementation are emerging.

Unfortunately, in healthcare, relatively little work has been done regarding process modelling. That is not to say that the area is completely unexplored in healthcare. Only that it is not as established as in contrasts to other sectors. And in the cases that process modelling has been performed in healthcare, the predominant technique used has been flowchart. Probably due to it being one of the oldest techniques on the market [14]. This is unfortunate, as there is probably a lot to be gained from exploring and improving process modelling of a complicated system, such as healthcare workflows.

2.2 Multi-Actor System Analysis

At the core of process modelling is the idea that a system is fundamentally based upon human-computer interactions. A so-called sociotechnical system. It represents the idea that technical solutions are not standalone entities. But rather, that the technical solutions are an integrated part of the user workflow [20]. The idea being that together the users and technologies build up a system. Therefore, the system should be treated as such.

Sociotechnical systems are quite well-established in modern design theory.

What it tries to emphasize is that one should and must take the human aspects, such as interaction with the system, into consideration when designing and depicting a system [21]. Otherwise, there is a risk of ending up with an unrealistic view of the actual system and its dynamics. A model which would be an incorrect projection of reality. Thus, disabling any opportunity to enforce improvements grounded in reality. An inherently ineffective and risk negligent approach.

When mapping out the flow of a process model, it is highly beneficial to consider the actors that interact with the system, following the reasoning above. In order to achieve this, multi-actor system analysis is employed. Multi-actor system analysis allows someone who is modelling a system to gain an understanding the specific connections between the actors and the system [22][23]. Analyzing the role, responsibilities and needs of the different actors throughout the model. Thus, enriching the model. However, it should be made clear that multi-actor system analysis is not dependent on process modelling techniques. It is a methodology all of itself.

Multi-actor system analysis is a powerful methodology when modeling a complicated sociotechnical system, such as a healthcare workflow. Where there are a wide variety of different actors, all of which need to be considered in the analysis. It can be done for simpler workflows and yield beneficial results, but it is in complicated systems that the methodology is truly excels [24].

An actor is a person or organization who directly or indirectly has an effect on the system which is being modelled. In system design theory, actors are considered stakeholders of the systems [25]. The terms stakeholder and actor often go hand-in-hand. By analyzing the needs of multiple actors in regard to a chosen system, one can deduce suitable requirements on the system. Which is a potent tool when aiming at creating a holistic solution.

However, the profiles and requirements of the actors is not the only thing that can be leveraged from multi-actor analysis. If the multi-actor system analysis information is integrated into a process model, then the process model becomes enriched with useful information from a design perspective. And when this happens, redundancies and system architecture become clearer. As the true disposition of resources reveals itself. Enabling the beholder to make informed decisions on improvements from a resource management standpoint. This is a highly desirable characteristic in healthcare. Where resources often are scarce, and the workload often is high [26].

The main benefit of multi-actor system analysis coupled with process modelling techniques, is that these methodologies together have the ability to create a highly detailed model of the observed system. A model which is

not only based on the system at hand, but also the actors who interact with it. Which then can be improved upon with the resources at hand. The idea being, firstly, create a process model with an appropriate technique in order to get the step-relationships visualized correctly. And then add on the actors influences on the systems in a visual manner. Based on both the actors' characteristics and responsibilities. Resulting in a highlighting of the different stakeholders visually and overall holistic view of the system.

2.3 Lean Principles

The lean principles are in essence a process improvement framework and the ideology which builds up lean has its origins in Toyota manufacturing during the 1980's. Lean centers around creating value for the customer whilst minimizing resource waste in the form of redundancies. Effectively producing more value for the customer with less resources [27]. Thus, ensuring efficient use of both individual and organization resources in the production chain [28].

In lean, value is defined by the needs of the customer. Activities that add value to the customer, are called **Value-Added (VA)** activities [27]. In the case of this thesis, since it is set in a hospital setting, the customer of the hospitals production is the patient. Thusly, lean is seeking to improve processes in order to generate value for the patients of the hospital. This implies that the clinic should be aligned with the goal of creating value for the patient.

However, it has become apparent that lean projects need to incorporate a holistic view in order to be effective in healthcare organizations [28]. Analyzing the needs of multiple stakeholders in the production chain, much like what is mentioned in section 2.2., in order to avoid having a too narrow viewpoint during implementation of lean principles. Especially, if the process improvement is concerning the use of new technology [28].

Waste in lean, is defined as anything that is not adding value the customer, the patient. It defines seven categories of waste, namely: *Excess Transport*, *Excess Inventory*, *Excess Motion*, *Waiting*, *Overproduction*, *Overprocessing* and *Defects* [27]. All of which are to be considered during process improvement. Steps in the process which incorporate these forms of waste are called **Non-Value-Added (NVA)** activities. In order to employ lean in a production chain, **NVA** activities must be identified and eliminated [29].

There exist multiple ways of employing lean in a hospital organization and one of the most commonly used tools is *value stream mapping* [30][31]. It utilizes process modelling techniques to outline all the steps in the production chain, including both **VA**- and **NVA** activities. Creating a visual map for the

project team which includes all the operations which are performed in order to achieve the end-product. This process model, the value stream map, is then used to isolate all redundant **NVA** activities which are to be eliminated in the improved model. The process of eliminating these **NVA** activities are referred to as *creating flow* in lean theory [27].

Furthermore, lean applies a *pull* principle in order to minimize waste in the system. Making sure that each step in the improved process is based on the demand from the subsequent one. Thusly, the production chain is based on the end-customer demand. Eliminating the cost of having staffing & inventory in standby. Also, reducing the risk of overproduction since the entirety of the improved chain is grounded in end-customer demand, thus creating pull [27].

Finally, lean emphasizes the mindset of continually seeking of perfection in the organization. This is done by implementing a constant improvement plan [32]. Thus, ensuring that the hospital is continually improving. Having this sort of plan is seen as the defining barrier for successful lean implementation in any organization and is referred to as *Kaizen* in the original Toyota Production System [30][33].

2.4 Process Mining

A field that has been getting a lot of attention lately is process mining. Process mining is tightly connected to process modelling. It is a method of providing an improved model once a system has been modelled using process modelling. Relying on quantitative computational methods and software infrastructure to achieve said goal [34][35].

It is done by analyzing the data that is flowing through the modelled system with the help of mathematical algorithms. The data itself is stored in different databases at checkpoints in the system. With this data, process mining deploys algorithms to optimize the process. Process mining is truly the frontier of informatics and if utilized correctly, can be an extremely powerful tool for making informed decisions [36]. Illuminating improvements which would otherwise be overseen by only using process modelling and qualitative methods.

The power of process mining resides in the fact that it utilizes numerical methods in order to find improvements. As compared to qualitative methods, which are often used when visually analyzing process models. It gives a quantitative measurement of which improvements should be made to a system, which in many cases can be seen as strong advantage [37]. As one of the purposes of performing process modelling is to enable one to improve systems

without relying solely on qualitative methods.

Process mining does however require that the systems are primed for this type of optimization. That means that the system in itself needs to be digitalized to a certain degree. With checkpoints for databases along the data pipeline, allowing for data to be stored. When this is setup properly and the data has been allowed to accumulate over a period of time reaching a sufficient amount. One can begin datamining and in turn, process mining [36][37].

Datamining is like the name implies the act of collecting data and then extracting useful information from the databases where the data is stored. Thus, the prerequisite for process mining that there exist back-end software solutions that accommodates for the databases that are needed. Setting up such software infrastructure is not necessarily a complicated task. However, it should be noted that a lot of systems in modern society still remain analog or partially analog. Thus, process mining is adding to the incentives and benefits of driving digitalization in healthcare [38].

Process mining is similarly to process modelling, more widespread in other business sectors than healthcare. This does not mean that process mining is unheard of in healthcare, only that it is not as common. The consensus being that, if possible, it should be accommodated for when attempting to improve process models. Process mining is on the rise and there are a lot of studies being done using process mining within healthcare [35][38].

The benefit of utilizing quantitative methods is an attractive feature. However, the prerequisite demands databases. If no databases are present, then the method is nullified. Implying that healthcare providers need both to have their processes modelled and their software infrastructure setup before being able to reap the benefits of process mining.

Chapter 3

Methodology

In this chapter the methodology of thesis will be explained in detail. Giving the reader insight into the data collections techniques employed and the sequence in which the different parts of the thesis was performed. It will start off with a map of the methodology, which visualizes all steps taken during the thesis. Followed by in-detail explanations of all different steps in said map in an order corresponding to the map. Thus, giving an overall description of the methodology of the thesis with the same flow as the thesis was performed.

3.1 Methodology Map

Below, in Figure 3.1, is a map of methodology for the thesis. The map serves to give a visualization of the sequence in which the different steps of the thesis was performed. All different parts are color-coded as to help the reader understand what parts belong together. Sequentially, the map flows from left to right, with beginning and end being coded with a red color. The literature and pre-study blocks are further broken down into sub-sections within their parent block, as to better illustrate that they are iterative sequences producing outputs which were forwarded to later stages. The parent blocks are the two larger color-coded blocks in parallel to each other.

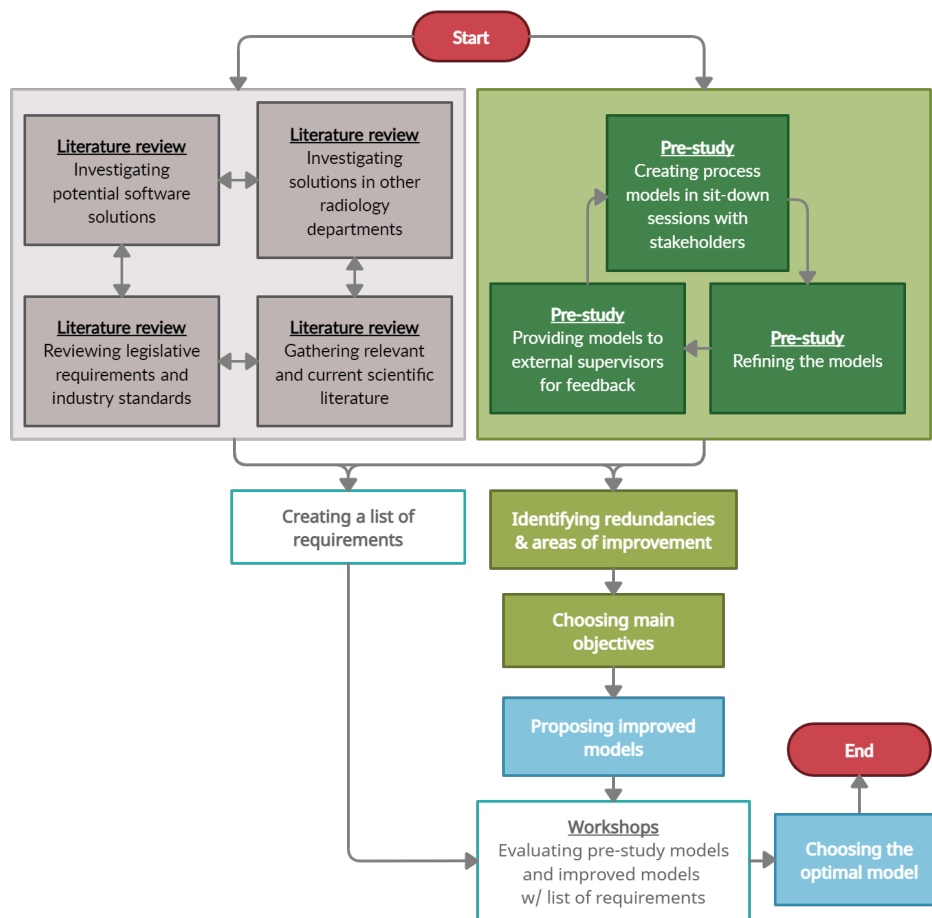


Figure 3.1: Map illustrating the methodology employed in the thesis.

3.2 Pre-Study

A pre-study was performed in order to create a pair of process models depicting the current workflow of radiology equipment. This pair laid out the basis of which the proposed solutions were modelled after. The pairs consisted of one model for the workflow of scheduled maintenance, and one for the workflow of unscheduled maintenance. The modelling was done using the diagram tool Creatley in sit down sessions with biomedical engineers, hospital physicists and their respective leadership staff. After each session, the generated model from the session was evaluated, refined, and finally sent to SoftPro Medical Solutions for feedback. This cycle was then repeated a total

of 11 times, until all parties agreed that the process model gave an accurate depiction of the current workflow.

The category of stakeholders present during the different sit-down sessions varied from each session. Ensuring that the sessions were continually generating new perspectives on the current workflow. Individuals was also varied within each stakeholder groups. Thus, ensuring that the stakeholder groups were properly represented and not biased towards any certain individual.

The process modelling technique used was the flowchart technique, with some modifications. This means that all the shapes and operators used, along with the interlinking arrows in between them, was based of the flowchart method. In order to build in additional information about actors, symbols for stakeholders were added into the process model. This can be seen in Figure 3.3 where all shapes, with the exception of shapes depicting information flow, have a stakeholder symbol at their top right corner. This indicates to the beholder which stakeholder is responsible at each step. The steps themselves indicate what activity is being performed within each step, by the means of color-coding and geometrical shapes. Furthermore, a descriptive text can be found in the steps of the process models. Describing what is happening within that step. Lastly, if information is being passed in between two stakeholders, then this information is displayed by a white shape that has a grey outline. Similarly, the information passed is described in plain text within the shape.

What all symbols means precisely, can be found in Figure 3.2. Additionally, there are logical operators function to create logical arguments when two arrows are connecting into one shape. The operators available are an AND operator, which tells the beholder that both information pathways are active, and an OR operator, which indicate that only one pathway is active. Finally, the arrows are interlinking different steps in order to create a flow through the process model.

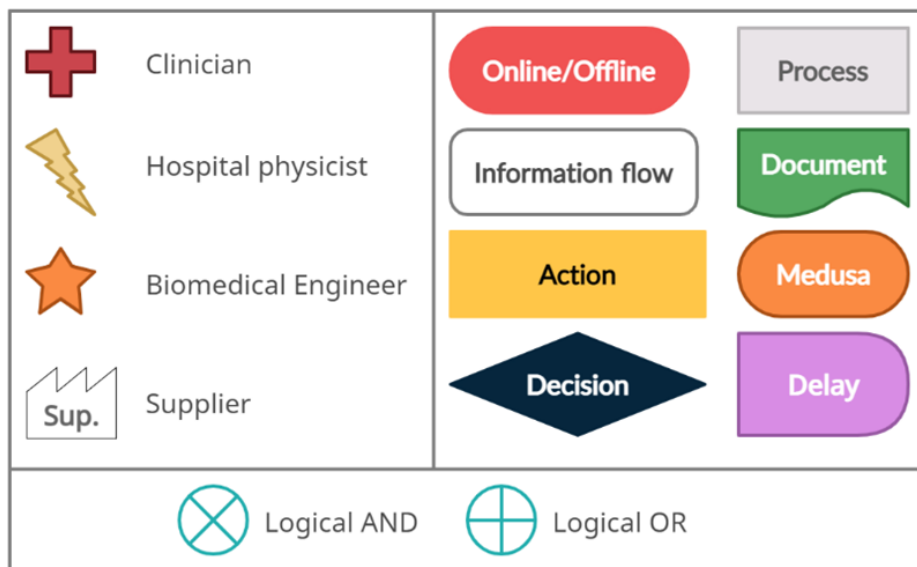


Figure 3.2: Explanation of the different symbols employed in the flowcharts.

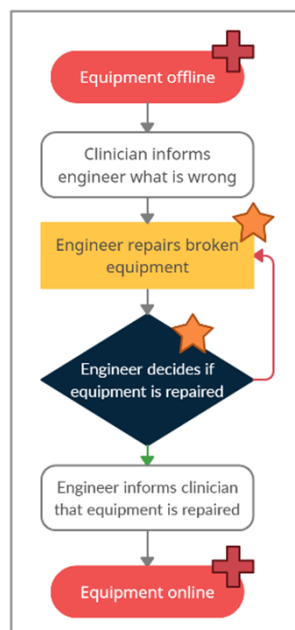


Figure 3.3: Example of a flowchart with actor information added.

3.3 Performing a semi-structured Literature Review

An extensive semi-structured literature review was performed in parallel with the pre-study. This was done in order to establish a strong scientific basis for the thesis and a better understanding state-of-the-art research of the topic at hand. The following standpoints were considered:

- Process modelling techniques.
- Quality assurance programs at radiology departments.
- Legislative demands put on radiology equipment.
- Market standards for quality assurance systems.
- Design principles in software engineering.
- Data collection techniques in scientific research.

3.3.1 Review of Databases and Keywords

The databases used were PubMed, DIVA, Primo, Scopus and Web of Science. The purpose of this database search was to gather a broad scope of modern scientific literature. Thus, proving a deep understanding of the topic at hand. The following keywords were then used during the database search: *Healthcare Informatics, Quality Assurance, Healthcare Information Systems, Standards, System Analysis, Radiology, Business Process Models*.

Finally, a database search in ScienceDirect was performed, in order to gain insight into different methodologies of data collection. This was done with the aim of establish a rigid methodology for creating forms, selecting collection techniques, and performing interviews. The following keywords were then used: *Data collection techniques, Questionnaire Design, Interviews, Focus Groups*.

3.3.2 Review of Presentation by Region Västerbotten

A presentation was held by hospital physicists and biomedical engineers from Region Västerbotten, Umeå, where they presented their solution to the problem of quality assurance of radiology equipment. This served as inspiration for the proposed solutions and during the presentation questions were asked in an unstructured manner.

3.3.3 Review of Industry Standards and Legislative Demands

An assortment of industry standards were selected. These were then used as the basis of the requirements posed on the process models. Any standards that were encountered and deemed relevant were noted. These standards were then cross-referenced with standards found in other scientific literature and the standards mentioned in the interview with Umeå. Thus, validating the them for usage in the thesis.

Furthermore, legislative demands were identified and interpreted. In order to interpret these correctly, the help of hospital physicists was enlisted after an initial interpretation was done. As it is essential that whatever solutions proposed can abide to these demands. Ensuring that the radiology department avoids demerits in the event of an inspection of the hospital.

3.4 Identifying Redundancies and Areas of Improvement

Once the pair of pre-study models were completed, an independent review of the models was performed. The purpose of this review was to identify the redundancies and areas of improvements of said model pair. Maximizing value and minimizing waste, in accordance with the lean principles. It was done by adopting two viewpoints. The first one was a step-by-step approach, walking through the workflow of both models sequentially and evaluating each step independently. The second one was an overview approach, where the entirety of the models were analyzed. Thus, adopting two perspectives in order to gather as many redundancies and areas of improvement as possible.

3.5 Creating a List of Requirements

To get a basis for a quantitative measurement of improvement, a list of requirements was created. This list was based on both the pair of process models created in the pre-study, and the results from the literature review performed in parallel. The list was split into three sections. These three sections being software functionality requirements, general requirements, and legal requirements.

To generate the list of requirements the pair of process models from the pre-study underwent a step-by-step walkthrough. However, different from section

3.4, each step was instead evaluated from the standpoint of which requirement it could possibly generate. Then, the pre-study models underwent another walkthrough, but with a holistic standpoint adopted. The idea being to gather as many requirements as possible to create an extensive preliminary list of requirements.

Then, based on the literature review, interview, and subsequent selection of standards, said list of requirements was updated. Removing any requirements which were not aligned with recommendations by literature and updating any requirements that were poorly described. Ensuring that the list contained relevant requirements aligned with the state-of-the-art literature and had strong connections to legislative requirements.

3.6 Choosing the Main Objectives

In order for the project to stay on track with the allotted timeframe, three main objectives were chosen. These were decided to be the most important redundancies to eliminate, and areas to improve on. Indications from scientific literature were used in order to motivate which of the objectives were the most important. The list of requirements, subsequently, also gave solid indications of which objectives were appropriate to choose.

3.7 Proposing Solutions

Two solutions were then modelled with the objectives to minimize and eliminate the three selected redundancies found from the pair of pre-study models. Each solution consisted of a pair of models, corresponding to the models of the pre-study. Thus, 2 pairs of models were created consisting of a workflow for scheduled maintenance and a workflow for unscheduled maintenance respectively. These pairs of models were then evaluated in subsequent workshops.

3.8 Performing Workshops to Review Pre-study and Improved Models

In order to get a measurement of improvement, three workshops with three separate groups were setup. Utilizing a mixed-method approach of focus groups and questionnaires. The approach of only using a questionnaire without

a workshop was considered. However, this was disregarded as the task of determining optimal solution is by nature a complicated task. Thus, benefiting greatly from the added workshops [39].

The three groups were setup in order to be as homogenous as possible [40]. With one group consisting of hospital physicists, one group consisting of biomedical engineers and the last group being their respective leadership. Each respective group consisting of two members.

The groups were called to a one-hour long workshop each. Before the meeting, one week in advance, they were given the pair of pre-study models and a form which was to be filled in during the workshop. This was done so that they could prepare for the workshop, thus ensuring that the workshops were time efficient.

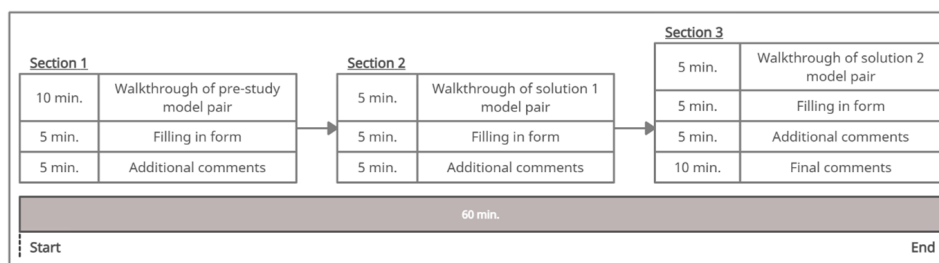


Figure 3.4: Timeline and layout for the workshops.

The workshops started with each member receiving a link to a digital form consisting of 3 sections. One section for the pair of pre-study models, one section for the first solution and one for the second solution. Each section contained a list of requirements, one for each pair of models that was about to be presented. Each requirement in the lists were followed by a scale which the participants were to fill in, ranging from 1-5, rating the compliance of the model to said requirement, and rating of 1 being the model does not comply to requirement, and rating of 5 being the model strongly complies with requirement. The form contained all requirements that the models were to be evaluated against. In total the form contained 15 requirements, the last 3 being an extension of requirement number 12. The list of requirements can be found in section 4.4 and the corresponding sub-sections.

Firstly, the pair of pre-study models were presented for 10 minutes by the facilitator. Walking through both models in a stepwise fashion. The participants were then given 5 minutes to fill in the first section of the form. Another 5 minutes were then spent allowing the participants to express additional comments about the pair of pre-study models.

The process of asking for additional comments was done in a structured way. With the following question shown below being asked, in the numbered order, after showing each pair of process models. In the interest of time, since there was only 5 minutes for asking additional comments, emphasis was put on the first question. The second and third question was only posed if there was enough time left to keep on schedule with the workshop.

1. Which requirement did you feel most/least complies?
2. Is there anything that is missing in the models?
3. Is there anything that is redundant in the models?

Then, 5 minutes was spent with the facilitator explaining the pair of models for first solution. In the same fashion as explained in the paragraph above. Again, 5 minutes was given to fill in the second section containing another list of requirements. Lastly, 5 minutes were given for additional comments from the participants.

Finally, the last solution underwent the same procedure with 5 minutes of explanation, 5 minutes of filling the list of requirements and 5 minutes for additional comments.

The last 10 minutes of the hour-long workshop was spent on a discussion where the two following questions, in the numbered order, were posed. They were stated in a general sense, giving the participants an option to comment on any of the given pairs of process models. This served to fill in the gaps from the previous segments of the workshop. Finally, the last solution underwent the same procedure with 5 minutes of explanation, 5 minutes of filling the last section of the list of requirements and 5 minutes for additional comments.

1. Is there anything that is missing in the models?
2. Is there anything that is redundant in the models?

3.9 Choosing the Optimal Solution

The optimal solution was chosen based on the fairing of three factors from the results of the workshops. These three factors, weighted and combined, was the basis for the choice of solution model to be proposed for implementation.

The first factor was the overall scoring on the questions from the workshops. These scores can be found in section 4.7.4 and served to give an

idea if the participants of the workshop believed an actual improvement had been made. The overall scoring was indicative of which solution model was most appropriate to implement in the clinical workflow. Furthermore, it served to show that there was an actual improvement from the pre-study workflow to the proposed models, as it is key that this it was not assumed.

The second factor was the feedback received from the discussions during the workshops. Thus, the feedback received during the workshops from the different stakeholders was analyzed and reflect upon. This ensured that different stakeholder opinions were amply considered, since there can be intragroup discrepancy depending on the work roles.

The third and final factor was the conclusions drawn from an in-depth analysis of the scoring from the questions in the questionnaire. This also being displayed in section 4.7.4. The diagrams of the scoring for the solutions models were analyzed on a question-to-question basis. In order to identify the different reactions to certain requirements and to draw conclusions accordingly. Furthermore, these conclusions were also cross-referenced with the open formatted information given from the different stakeholders.

The weighting of the different factors was the following. Highest weighting was put on the feedback from the workshops which is describe by the second factor. Analysis of the scoring from questions was second priority and was described in the third factor. Lastly, with the lowest weighting, was the overall scoring from the workshops which was described by the first factor.

Chapter 4

Results

This chapter serves to present the reader with the results and outcomes of the various data collection steps in the thesis. Furthermore, the pairs of process models will be presented visually.

Firstly, the pair of pre-study models will be presented. Then, the results of the semi-structured literature review will be presented, along with redundancies and improvements deduced from the pre-study model pair. Next, the generated list of requirements will be shown along with the main objectives of improvement. Then, the two pairs of proposed solutions will be presented. Finally, the evaluation results from the workshop along with the chosen solution will be presented. Thus, giving the reader a complete account of the results of the thesis.

4.1 Pre-study

The results from the pre-study were a pair of process models that illustrated the current workflow of radiology equipment at Södersjukhuset. The first process model refers to the workflow of troubleshooting radiology equipment that had unexpectedly been taken offline. So-called unscheduled maintenance. The second process model refers to the workflow of scheduled maintenance. Either initiated by the supplier of the equipment or the biomedical engineering staff at the department. Both process models were in the form of flowcharts and were used to identify redundancies and suggest improved process models.

Below in Figure 4.1, is the flowchart of scheduled maintenance for the pre-study models. It is initiated through a booking process with clinical staff, scheduling the equipment for maintenance at a specific date. The clinical staff is composed of nurses that are working specifically with booking patients to

different examination rooms and therefore have an production overview of all the radiology labs at the department.

After the maintenance is booked, the equipment is taken offline on the scheduled day and maintenance is either performed by the supplier of the equipment or a biomedical engineer. This in turn leads to two branches of workflows. One workflow, seen on the left-hand side of Figure 4.1, that is supplier driven. And one workflow, seen on the right-hand side of Figure 4.1, that is engineer driven. However, due to the need of hospital physicist to perform function controls after maintenance, the supplier workflow has a feedback loop into the engineer workflow. Meaning that even if the supplier is performing the maintenance, it will nonetheless feedback into the latter part of the workflow of the engineer.

It shall be noted that if equipment goes through the supplier workflow in the flowchart, then a total of 3 documents will be generated. A service report containing the quality assurance controls of the supplier. A written note to the physicists and engineers from the supplier specifying what maintenance has been performed. And finally, checklists from the quality assurance controls performed by the physicists. If the equipment goes through the workflow on the engineer driven side, only one document is produced. Which is the checklist from the quality assurance controls produced by the hospital physicists.

In the end of the workflow, the engineer documents what is done in the inventory system Medusa by the use of work orders. If service reports are generated, then these are attached to the workorder when they arrive to the engineer's function e-mail, of which there often is a delay. However, the written note from the supplier (if the supplier has been involved in the workflow) and the protocols from the quality assurance checks of the physicists, are stored separately. The former is stored in a physical folder at the department and the latter is stored in a separate digital filesystem. In reality, much of these two documents are rarely stored at their assigned locations.

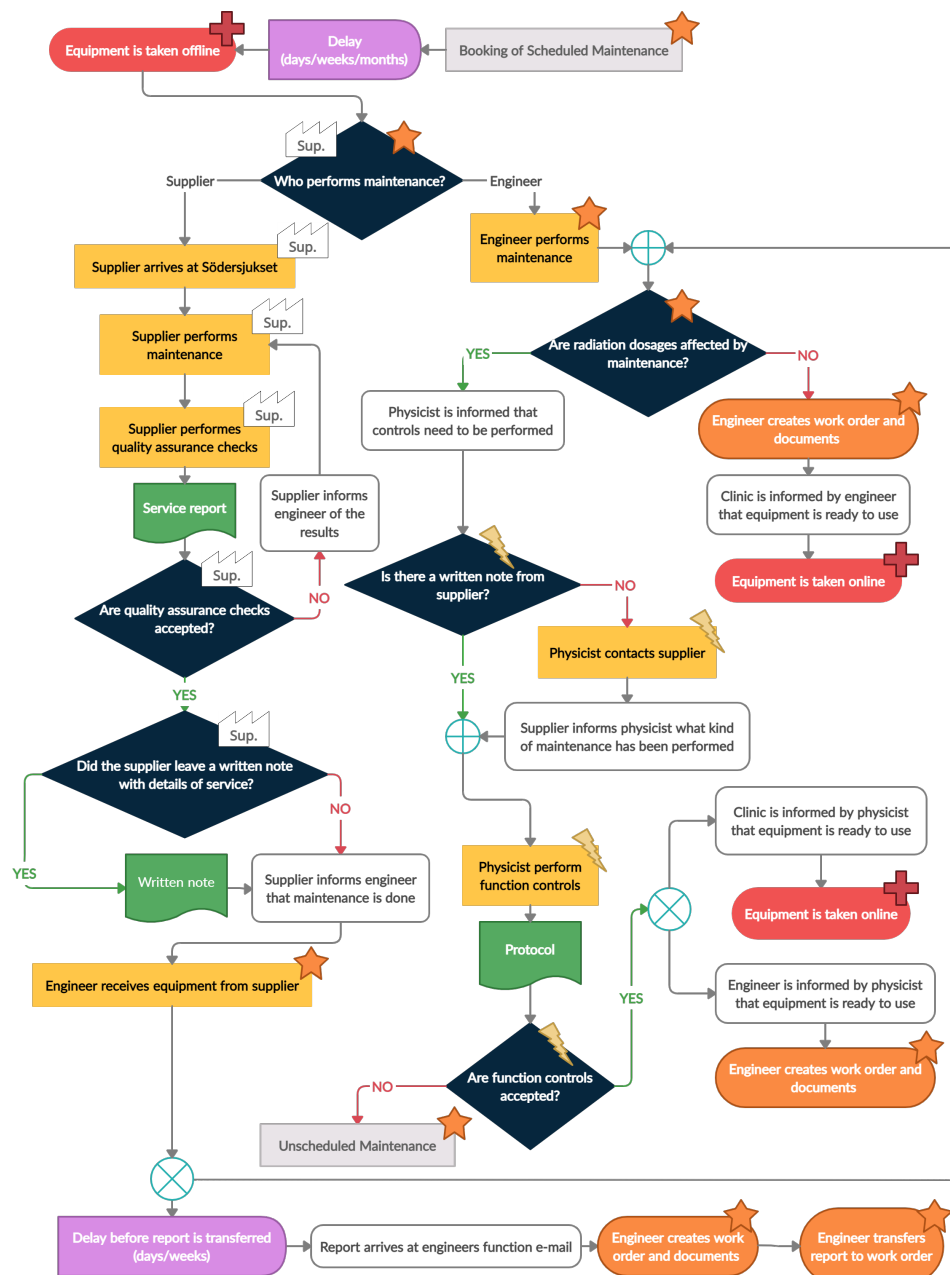


Figure 4.1: The pre-study process model of scheduled maintenance.

Below in Figure 4.2, is the flowchart of unscheduled maintenance for the current workflow. In contrast to the scheduled maintenance in Figure 4.1, this workflow is initiated differently. Either the equipment unexpectedly is taken offline due to malfunction, or a scheduled maintenance turn into an unscheduled maintenance due to unexpected complications when performing the maintenance. Other than that, the workflow is similar to that of a scheduled maintenance. The left-hand side of Figure 4.2 is the supplier driven side, and the right-hand side of Figure 4.2 is the engineer driven side. If the quality assurance controls performed by physicists would yield unacceptable results, then the supplier would be contacted again, as in contrast to scheduled maintenance of Figure 4.1, where this same scenario would lead to a scheduled maintenance turning into an unscheduled maintenance.

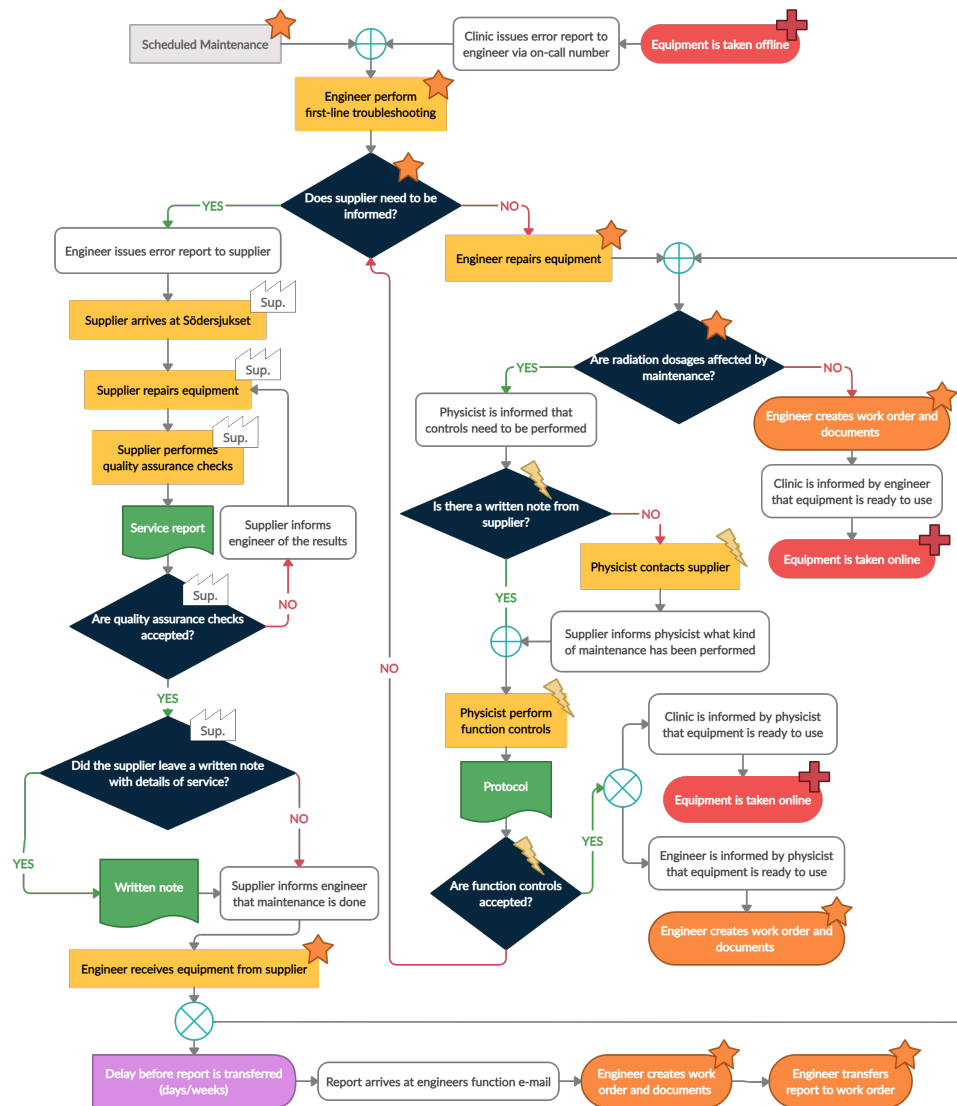


Figure 4.2: The pre-study process model of unscheduled maintenance.

4.2 Semi-structured Literature Review

The findings in the semi-structured literature review gave a strong confirmation that there is a need for quality assurance focused on the technical aspect of radiology. Quality assurance in radiology was not found to be new concept in itself. However, viewing it from a technical standpoint appeared to be. This fact combined with the fact that the literature indicated radiology is becoming more technology dependent, reinforced the idea that one should look it to the technical aspects. Thus, validating the need for the thesis.

When it came to multi-actor system analysis and process modelling, a lot had been done sectors such as agriculture and energy. This was however not the case in radiology, especially quality assurance in radiology, or in healthcare overall for that matter. What little work had been done was focused on the clinical workflows of radiology. With attention often been put on overarching programs to improve quality assurance, instead of focusing on modelling the processes in themselves. In the cases where the processes had been modelled, flowchart was the predominant technique. Mainly due to it being well established as one of the first process modelling techniques.

An interesting discovery was the field of process mining. It serves to give quantitative measurements and suggestions on improvement, in the field of process modelling. Where much of the work is inherently qualitative. It also aligns with the digitalization of the workflow, as databases are a prerequisite for utilizing process mining.

There was a plethora of industry standards to choose from. However, some of them are rather vague in nature in order to be moldable to different projects. What they actually entailed was also somewhat opaque. Both of these facts probably being a resultant of the business models the standards organizations choose to deploy. As an effect, the interpretations of said standards may have been convoluted. Logically, they aligned with improvements proposed from the pre-study.

In contrast, legislative demands were very clear in formulation. Probably due to the self-interest of SSM to have as low a variation as possible when it comes to interpretations by different clinics in Sweden. **Thus, the legislative demands proved to be very useful in giving the thesis clear directions of which to follow.**

4.3 Redundancies & Areas of Improvement

The following areas of improvement and redundancies were found from reviewing the pre-study process models of scheduled and unscheduled maintenance:

Removing feedback loops leading from supplier branch to the engineer branch of the workflow, caused by the need of hospital physicists to perform function controls. Meaning that firstly, the suppliers performed function controls. Then, the hospital physicists performed function controls and finally handing over the equipment to the clinic. Creating a double set of controls made, in a situation where one set of controls would have been sufficient.

Reducing the intermediate steps in the workflow by removing hospital physicists from it. As the hospital physicists perform functional controls on radiology equipment, they are de-facto introducing intermediate steps in the workflow. Steps where information needs to be passed to and from them, in order for the workflow to propagate. These steps, results in an increased downtime of the equipment, which can be reduced.

Eliminating the demand from hospital physicists that the supplier leaves a written confirmation that equipment is cleared for use. The purpose of this written confirmation is two-fold. Firstly, it serves to give an explicit statement of which the supplier takes responsibility for the service performed. A confirmation of which, unsurprisingly, many of current supplier are unkeen to write out explicitly on a note. And secondly, it passes information to the hospital physicists of which parts of the radiology equipment the service has been performed on. Which affects the types of controls that the hospital physicists perform. If the written confirmation is not left to the hospital physicists, said physicists have to contact the supplier and ask for the information.

Ensuring information is not being lost due to the fact that all documentation is being backloaded. Any documentation being done in the inventory system Medusa, is always done after all service is performed. At the very end of the workflow. Which means that information may be lost along the workflow. Especially information that is passed in the initial stages of troubleshooting. In example, information that the clinician gives about what is wrong with the equipment.

Introducing the ability to do real-time tracking of equipment. Another issue that occurs as a consequence of the backloading, is that there exists no ability to do tracking of equipment digitally. All information of the status of

equipment is being held by the stakeholders. And if the case is that a supplier needs to go to the hospital to perform maintenance, then there is no way of tracking the arrival of the supplier. That information is also being held by the stakeholders, which at times even are unaware that the supplier is on-site performing maintenance.

Making it explicit which stakeholder is clearing the equipment for use. The written confirmation by supplier is an attempt of making this more explicit. But in essence, it is rather vague who is responsible for clearing the equipment for clinical use. Which would serve to be a problem in the event of an inspection from [SSM](#), as it will lead to a demerit.

4.4 List of Requirements

The list of requirements was produced from a walkthrough of the pair of pre-study models and then refined to align with both legislative requirements and industry standards. The industry standards, legislative demands, and respective requirements can be found in the Table 4.1 below.

In general, the requirements were split up into three separate categories: Software functionality requirements, general requirements, and legislative requirements. All models, both pre-study and solutions, were evaluated against these requirements.

A third of the requirements and the latter part of Table 4.1, are requirements that stem from the regulations put forth by [SSM](#). This is an important part to note because it is crucial that the system can adhere to these as they are legislative demands. If not, the department is at risk of receiving a demerit in the case of an inspection by [SSM](#). The last three of these, noted with requirement 13-15 in section 4.4.3, are a breakdown of the implicit constituents of requirement 12.

Furthermore, the requirements rely heavily on two [International Organization for Standardization \(ISO\)](#) standards. [ISO 9001:2015](#) [41] that governs quality management systems, which is relevant since the workflow is essentially a quality management system. [ISO 13485:2016](#) [42], which is also relevant since it governs quality management systems, but is specifically tuned towards medical devices. Thus, giving a good encompassment of what is needed to build a quality management system in both a general and industry specific sense.

Finally, the [ALARA](#) – principle is also taken into consideration as it is one of the fundamental guidelines of clinical radiology, which is both ethically and clinically motivated in literature.

Table 4.1: Table showing the requirements and their respective sources.

<u>Requirement</u>	<u>Source</u>
1. Any documentation this is produced during controls is storable and findable in a single place.	ISO 13485
2. The system facilitates tracking of cases from start to finish.	ISO 13485
3. Facilitates minimization of potential radiation dose in regard to malfunction or incorrect settings.	ALARA
4. Allows for a resource-effective workflow.	ISO 9001
5. The workflow is setup in a process-oriented manner.	ISO 9001
6. Facilitates low operational down-time of radiology equipment.	ISO 13485
7. The workflow is easy for the stakeholders to adhere to.	ISO 9001
8. The workflow is easy the stakeholders to learn.	ISO 9001
9. The system explicitly tells users which stakeholder is responsible at any given point of time.	ISO 9001
10. Facilitates that all radiology equipment in the hospital can be checked at an appropriate time-interval.	SSL 2018:5
11. Facilitates that all radiology equipment is checked after a service is performed on the equipment.	SSL 2018:5
12. Rigid enough to serve as a function that decides if the equipment can be put in clinical use.	SSL 2018:5
13. The system ensures that the risk of operator error is minimized.	SSL 2018:5
14. System facilitates alignment with other decision-making functions.	SSL 2018:5
15. System has a technical framework that allows it to accommodate a decision-making function.	SSL 2018:5

4.4.1 Software Functionality Requirements

The following requirements are those put on the functionality of the software, which is the inventory system Medusa. Important to note is that these are the requirements put on the software specifically, not the workflow as a whole.

- 1. Any documentation this is produced during controls, is storable and findable in a single place.** Is all documentation that may arise during the workflow stored in the same place? Thus, ensuring traceability of the equipment, in the case of an incident or inspection from [SSM](#). In other words, how easy is it to find all documentation?

2. **The system facilitates tracking of cases from start to finish.** Is all the information gathered being documented? Not only information from protocols, but also information generated by stakeholders at different steps along the workflow.

4.4.2 General Requirements

These are general requirements put on the workflow as a whole and are hence label as general. The requirements listed in this section are from industry standards and principles depicted in Table 1.

3. **Facilitates minimization of potential radiation dose, in regard to malfunction or incorrect settings.** Is the system setup in such way that equipment cannot deliver excessive radiation dosages? The system must follow the [ALARA](#) - principle.
4. **Allows for a resource-effective workflow.** Is the time and energy of stakeholders being utilized in an efficient manner? In other words, are redundancies managed in the workflow? Since one of the aims of the workflow is to utilize resources a manner effective manner. Thus, driving down cost.
5. **The workflow is setup in a process-oriented manner.** Is the workflow described in processes? Or is work being done in an administrative, checklist manner? If the former is true, then the workflow is process oriented. If the latter is true, then the workflow is not process oriented.
6. **Facilitates low operational down-time of radiology equipment.** Is the downtime of radiology equipment being minimized? Thus, allowing for more patients to be examined, as down-time means a stop in production.
7. **The workflow is easy for stakeholders to adhere to.** Are stakeholders able to follow the process workflow in their day-to-day routines? The process model must be rooted in a workflow that is realistic. Otherwise, the models will encourage ad hoc solutions, which should be avoided.
8. **The workflow is easy for the stakeholders to learn.** Is the workflow formulated in a simple manner? It is important that the barrier-to-entry is low, such that expenditures on education remains low.
9. **The system explicitly tells users which stakeholder is responsible at any given point of time.** Does there exists ambiguity in the workflow?

Or is it clear which stakeholder performs different tasks? If not, there is a risk of the same work being done twice. Thus, promoting inefficiency in the workflow.

4.4.3 Legislative Requirements

These are the specific legal demands which can be found in [SSL](#) and are enforced on the workflow as a whole. They serve to evaluate adherence to current Swedish radiology regulation.

3. **Facilitates that all radiology equipment in the hospital, can be checked at an appropriate time-interval.** Is every single piece of radiology equipment, in the hospital, being checked? Even though no service has been performed on the equipment. The requirement serves to ensure that all equipment is being checked.
4. **Facilitates that radiology equipment is checked, after a service is performed on the equipment.** Specifically, after service, is the equipment being checked? This is put in place to mitigate the risk of service changing the radiation dosages and provide traceability if such an event were to occur.
5. **Rigid enough to serve as a function that decides if the equipment can be put in clinical use.** Is the workflow rigid enough to serve as a decision-making function? Meaning, that if the entire workflow has been followed, the equipment is clear to put in use again. Thus, not needing any secondary approval. This promotes efficient use of managerial resources. It serves as an overall requirement, which is also analyzed in several sub-requirements below.

The following requirements are an extension of the decision-making requirement. They serve to encapsulate aspects that need to be considered in the decision-making function.

3. **The system ensures that the risk of operator error is minimized.** Is there an inherent risk that stakeholders might generate errors when operating in the processes? Or is human error taken into consideration sufficiently? Thus, can one truly rely on the fact that the output of the system does not contain human-induced errors?

4. **System facilitates alignment with other decision-making functions.**
Are there any conflicts with existing decision-making functions? The point being, there should not be any conflicting decision-making functions in the system.
5. **System has a technical framework, that allows it to accommodate a decision-making function.** Is the system technically sophisticated enough, that one can trust it to serve as a decision-making function? Or does further technical solutions need to be implemented, in order to facilitate such a function?

4.5 Choosing Main Objectives

The objectives of the solutions were three-fold. The first two objectives were chosen based on the legislative requirements put forth by [SSM](#). This is to ensure that the quality assurance systems hold up in the event of an inspection. The last objective is purely out of a system optimization standpoint. With the aim of reducing operational down-time. Thus, driving value out of a patient-centric and economic standpoint in accordance to lean. These objectives were seen as the main redundancies and areas of improvement of the pre-study model and thus chosen.

The first objective is to ensure that any documentation that is generated in association to checks on radiology equipment, is stored digitally in a database.

The second objective is that the solution needs to be rigid enough to serve as a decision-making function that puts radiology equipment into clinical use after service. This means moving away from suppliers leaving written approvals, to the system itself working as an approval mechanism.

The last objective is that the solutions should aid in resource optimization of staff within the radiology department. Ensuring that at no point in time, controls on the same equipment are being made twice.

4.6 Proposed Solutions

In the following sub-sections, one will find the proposed solutions and their corresponding models for scheduled and unscheduled maintenance. Two solutions were proposed and they had the following similarities:

Feedback loops were eliminated. There are no longer any feedback loops from the supplier branch to the engineer branch. Thus, if the suppliers have

performed function controls on equipment after service, then these controls are considered sufficient. This leads to a drastic decrease in the amounts of steps in the workflow, especially if the supplier branch is taken. Reducing the risk of operator error along the workflow from both an individual perspective and a miscommunication standpoint. Also, from an economic standpoint this is favorable, as it reduces the number of hours spent by different stakeholders in the workflow.

Hospital physicists no longer perform function controls. In order to eliminate the same work being done twice, hospital physicist is no longer performing function controls on radiology equipment after service. Instead, this done work is being done by either suppliers or biomedical engineers. Thus, lowering the downtime of radiology equipment during service.

Medusa schedules maintenance on equipment that has not been checked. In order to ensure that all equipment is being controlled, the inventory system Medusa needs to schedule maintenance on equipment of which there has been no service for a considerable amount of time. This is a part of the legislative requirements on the system, but the timeframe is at the discrepancy of the clinic. As long as all equipment is being checked, everything is in alignment with the legislative demands.

The main and only difference between the two solutions was the use of work orders in the beginning of the workflow of solution 2. This can be seen in Figure 4.5 and Figure 4.6. The main idea by this being, once an equipment is received by the engineers, then documentation is started immediately. Ensuring that no information is lost due to backloading of documentation. This would reinforce the function of the inventory system as a logbook and not solely as an inventory management system.

4.6.1 Solution 1

Below in Figure 4.3 is the first solution model for scheduled maintenance of radiology equipment. It can be seen in this model that the number of steps is decreased compared to the pre-study model counterpart. There is also a clear distinction between the engineer driven branch and the supplier driven branch, effectively removing the feedback loop. The feedback loop is removed due to the fact that there is no need for hospital physicists to perform functions controls in the solution. This can also be acknowledged in the model, since there are no stakeholder symbols corresponding to hospital physicists present. Initiation of the workflow is done through the means of Medusa. Thus, engineers will automatically be informed when it is time for maintenance.

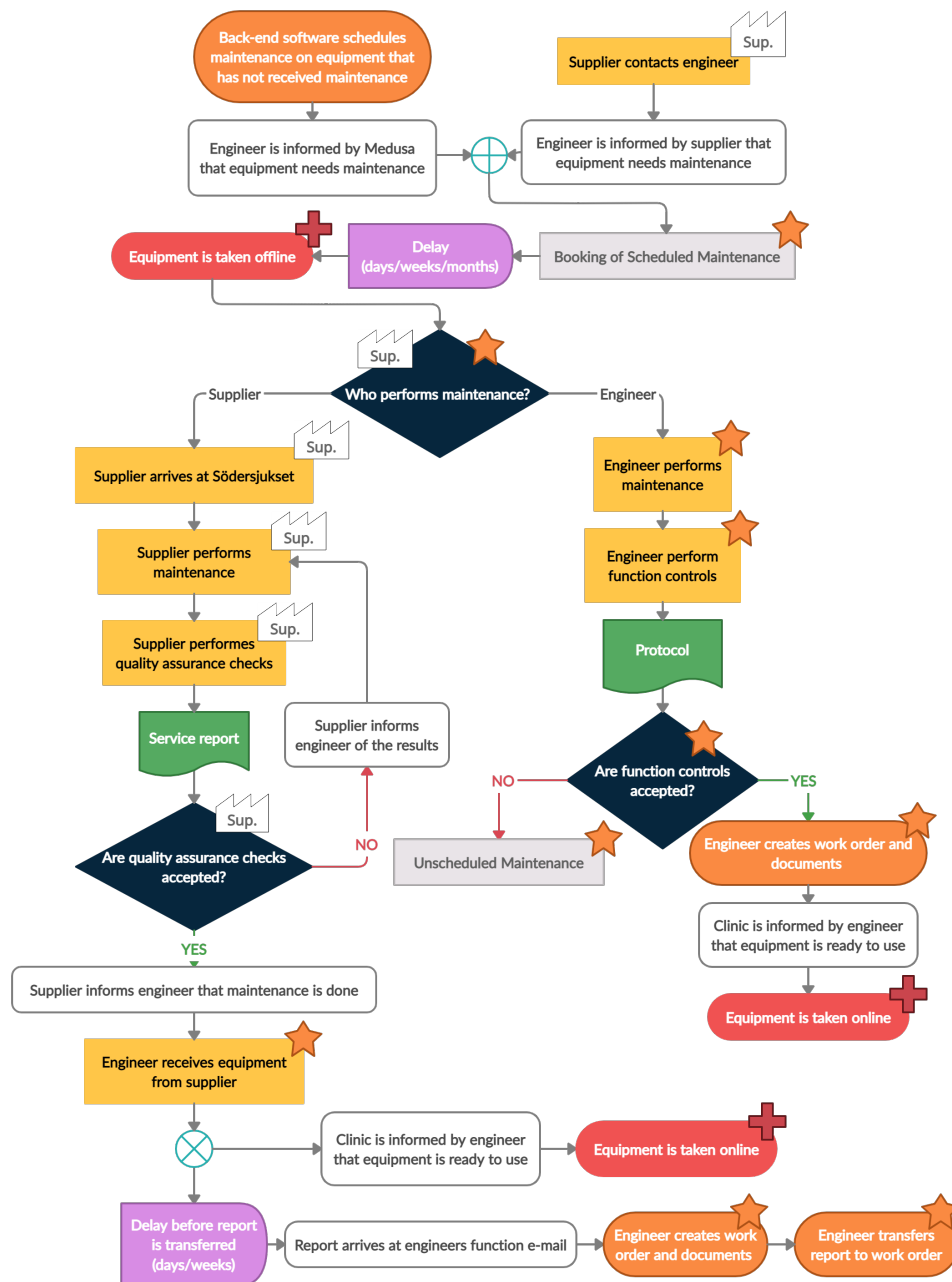


Figure 4.3: The model for scheduled maintenance in solution 1.

Below in Figure 4.4 is the first solution model for unscheduled maintenance of radiology equipment. The model is similar to the model for scheduled maintenance in Figure 4.3. However, it does differ in the initiation of the model. As an unscheduled maintenance is either initiated by a scheduled maintenance turning into an unscheduled maintenance, or the equipment breaking down in the clinic.

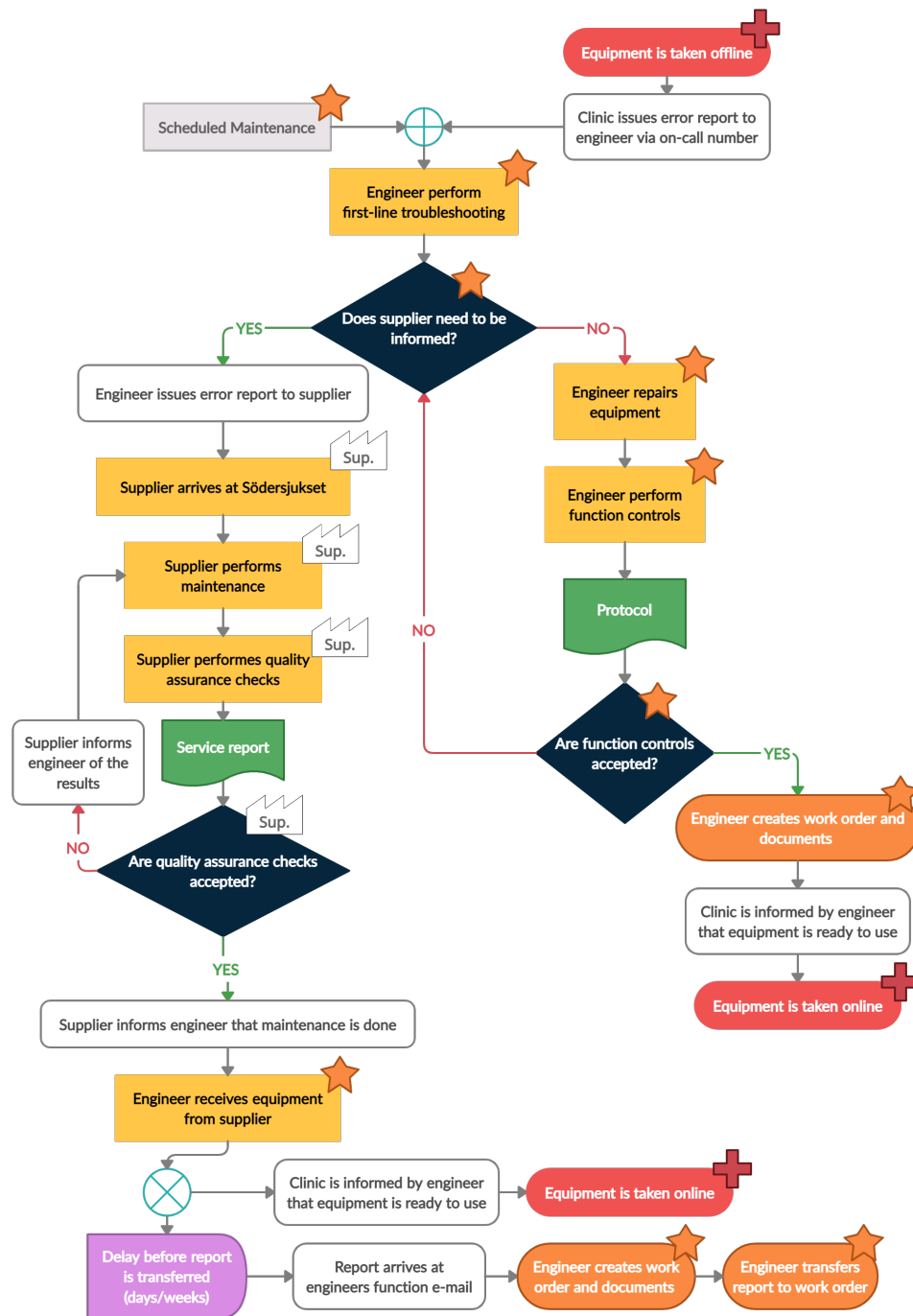


Figure 4.4: The model for unscheduled maintenance in solution 1.

4.6.2 Solution 2

Below in Figure 4.5 is the second solution model for scheduled maintenance of radiology equipment. The similarities to Figure 4.3, is that the model garners the back-end scheduling of maintenance, the elimination of feedback loops, and a removal of hospital physicists in the workflow. The difference in this model, is that a work order is initiated when the equipment is taken offline. Thus, facilitating the possibility of real-time tracking of radiology equipment and ensuring that proper documentation is performed.

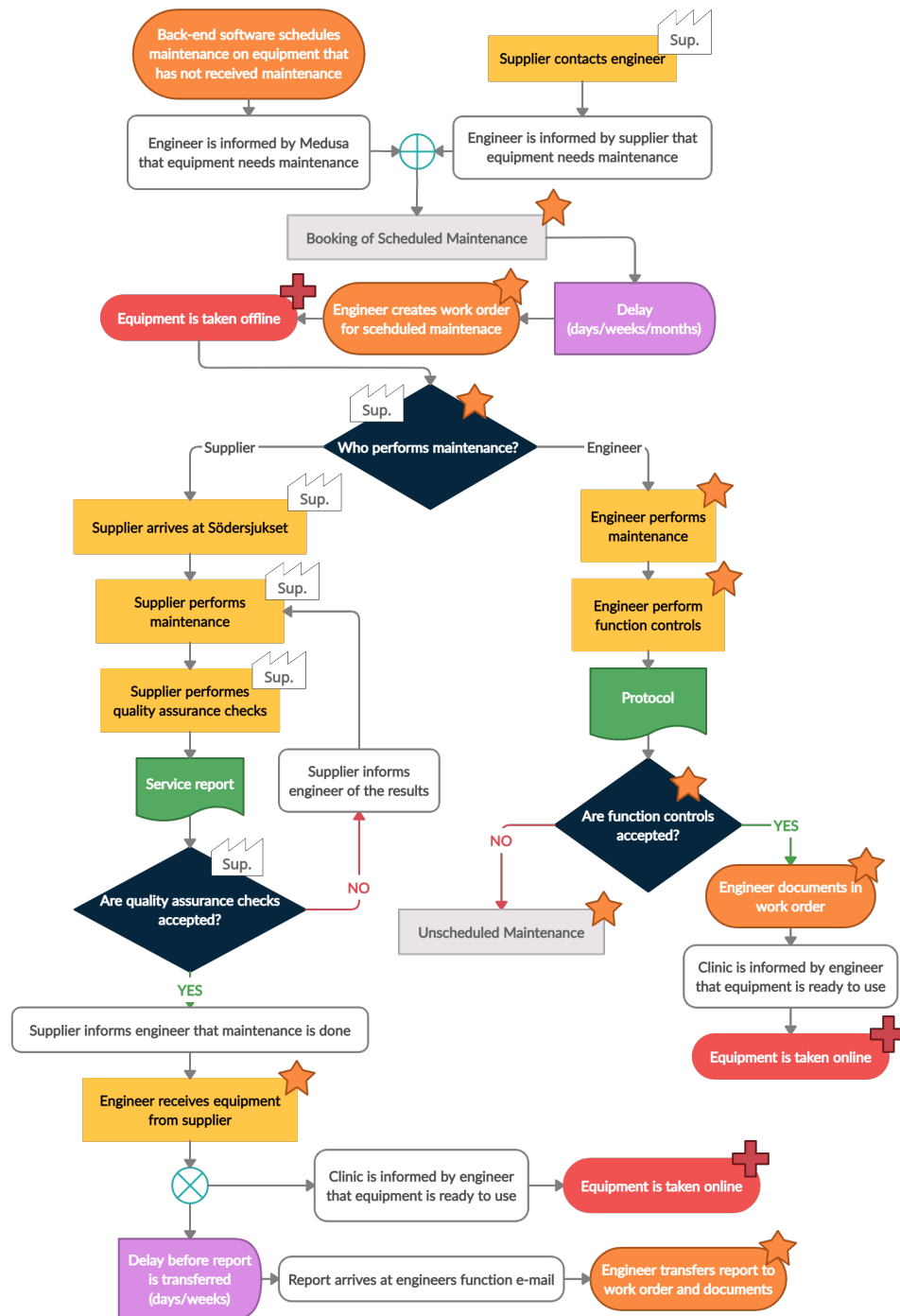


Figure 4.5: The model for scheduled maintenance in solution 2.

Below in Figure 4.6 is the second solution model for unscheduled maintenance. The model remains mainly similar to the previously presented models with the exception of the creation of a work order before first-line troubleshooting is initiated. This is of even greater benefit from a documentation standpoint than the initiation of a work order in Figure 4.5. Mainly due to the fact that the information received from the clinic is noted immediately and not forgot. Thus, ensuring that documentation is complete when reviewing the case in a later point of time.

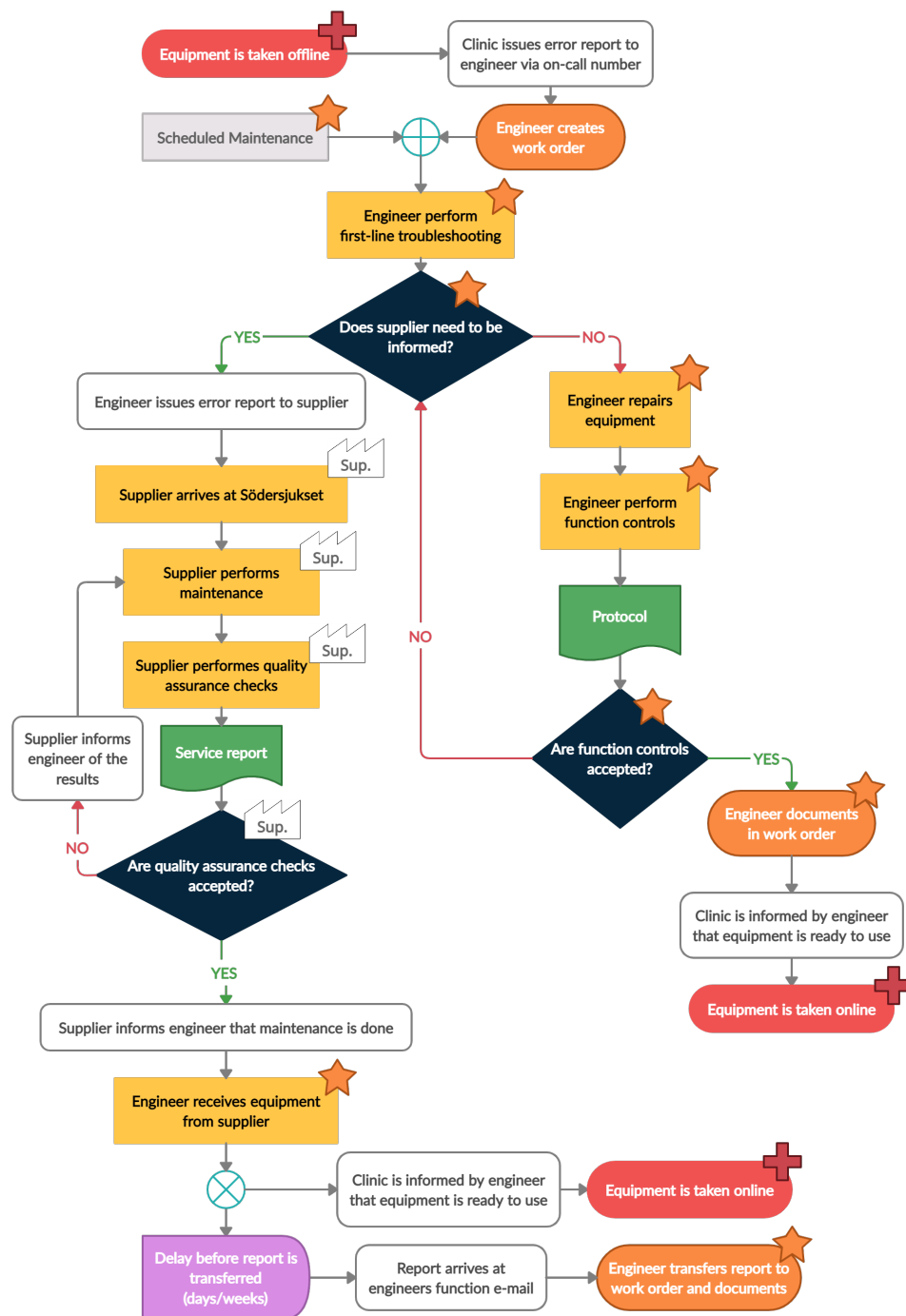


Figure 4.6: The model for unscheduled maintenance in solution 2.

4.7 Workshops

The results from the workshops will be stated below in corresponding sub-sections. They were held in the same order as they are presented in this section.

In general, the workshops received positive feedback. The workshops were however pressed on time and extending the workshops to a total length of 1 hours and 30 minutes, or alternatively 2 hours, would have been preferred. However, due to the limited resources at the hospital during the corona-virus pandemic, the workshops remained one hour long.

4.7.1 Workshop with Leadership Staff

When reviewing the pair of pre-study models and filling in the corresponding section in the form, there was a consensus that the workflow was not very process oriented. However, the participants felt that controls on equipment, both checking all equipment and equipment after service, was well above a sufficient level. Arguing that it was redundant with such large amounts of controls. What was also raised was the fact that the controls made by hospitals physicists, were in a sense something that was not grounded in research of the actual equipment. Making the controls in themselves somewhat unreliable. What would have been better, is controls that are connected to the routines and whitepapers of the suppliers. Thus, ensuring that the same controls and guidelines are being followed.

When reviewing the first solution models, a strong advantage of the solution was that the workflow is based around the knowledge of the suppliers. Utilizing their measurement boundary values and protocols. This workflow would also make the difference between the work roles of hospital physicists and biomedical engineers clearer. The participants found it hard to evaluate the risk for operator error. The motivation being that is something that varies from operator to operator. However, the conclusion was reached that the risk for operator error probably go down, as the number of different stakeholders for a single case would decrease.

Finally, when reviewing the second solution models and filling the corresponding section in the forms, a problem with the layout of the workshop appeared. Both participants felt that it would be easier to track cases from start to finish with the second solution. However, since they had already scored a maximum at the previous solution model, there was no way of indicating that they wanted to score this solution higher than the previous corresponding answer. There was also a concern that initial documentation would become

problematic when in high-stress situation. And that an expansion of the existing solution model would need to be made in the form of a decision-making part of the model, which addresses this dilemma adequately.

The general feedback for this workshop was that the questions sometimes were a bit confusing and that having a facilitator guiding them through was helpful. It would have been better to go through all the models, both pre-study and solutions, at once. Reviewing them side-by-side, rather than one-by-one. Also, it proved a good idea having hospital physicists and biomedical engineering staff together in the same workshop, as it was conducive to a good discussion.

4.7.2 Workshop with Hospital Physicists

When reviewing the pre-study models and filling in the forms, in contrast to the leadership staff, the hospital physicists found it hard to gauge how process-oriented the workflow was. This was because they had a tough time defining the term process-oriented, even though they admitted that processes were something they had encountered frequently in their careers. They also expressed strong opinions about the workflow not being rigid enough to serve as a decision-making function. Mainly due to the fact that they felt traceability was poor.

When reviewing the first solution model and filling the corresponding form, a lot of discussion about communication ensued. They felt that this workflow would lead to better communication between stakeholders as the number of stakeholders was reduced and that the risk of miscommunication would decrease as a consequence. They expressed that hospital physicists are in the process of validating the supplier's methodology when performing controls and that it would be preferable to only have controls done by the supplier. They also mentioned that earlier, a few years ago, biomedical engineers used to perform these controls instead of hospital physicists. However, due to new regulations from SSM demanding that hospital physicists performed the controls, the work task was changed. Thus, if biomedical engineers were to perform the controls, then the senior staff would be accustomed to procedure. It was also pointed out that this would give biomedical engineers an increased capability to act in the case of an error was found. But it would come with increased responsibility too. The scenario being, after the engineers performed service and found something that might jeopardize the radiation dosages. Then they could validate this error themselves and escalate the troubleshooting further accordingly.

Finally, when reviewing the second solution models and filling out the corresponding form, a discussion of tracking cases ensued. Previously, before the inventory system Medusa was a part of the workflow at the radiology department, the biomedical engineers relied on logbooks. They required the clinicians to fill in said logbooks with what had occurred, in the beginning of the troubleshooting process. This slowly disappeared as Medusa was introduced, requiring the biomedical engineers to fill in said information after receiving a case. This in combination with the fact that workhours are being filled in Medusa, as a way for leadership to retrieve statistic from employees, led to the logbook function disappearing. Replaced with a workhour tracking system. Which from an operational standpoint is negative since no other stakeholder than the engineer who first received the case, can know what the original problem description of the equipment was. Now if this logbook function were to be introduced again, then it would give the clinicians a better possibility to view the status of the equipment. It would also give other engineers than the one who received the case an opportunity to review the original error information.

The general feedback in the end of the workshop was that both the solutions models would lead to a decrease in the number of workhours put in by the hospital physicists and a slightly smaller increase for biomedical engineers. Something they felt would align well with previous workflows at the department. Making it clearer what the work roles were of the different professions.

4.7.3 Workshop with Biomedical Engineers

After going through the pre-study models and filling the corresponding form, a discussion about unscheduled maintenance ensued. It was pointed out that unscheduled maintenance in itself can be somewhat scheduled. In the case where something breaks down in the equipment, but the equipment is allowed to continue being used in production, until it is taken offline at an appointed time. There was a strong consensus that the current workflow is resource ineffective and that it is hard to find documentation due to there being multiple forms of documentation stored at multiple places. The participants also found it hard to know who was responsible at different steps in the process, due to there being a lot of stakeholders involved in the workflow.

When going through the first solution model and filling corresponding form, the participants pointed out that much of the workflow is dependent on a high level of competence amongst biomedical engineers. There was a certain

worry that a lot of the responsibility associated with maintenance would fall solely on the biomedical engineers and that they maybe would be placed in situation without sufficient training from suppliers. They also found it hard to gauge the risk of operator error, since they felt that it was an effect on the layout of the protocols rather than the layout of the workflow.

Finally, when going through the second solution model and filling in corresponding form, there was an extended discussion regarding initial documentation of cases. The point brought up was that if one were to do initial documentation, then it would probably lead to increased downtimes of the equipment in emergency cases. However, there would be decreased downtimes in prolonged cases, especially those of which the engineer who received the case suddenly became ill or went on vacation. The participants also brought up the point that the existing implemented processes were those of the entire biomedical engineering department, which is an overarching hospital organization. Whilst what was being investigated, was the workflow of biomedical engineers at the radiology department. Which in itself was a separate section of the engineering department. The point being, the biomedical engineers are supposed to follow the guidelines of the biomedical engineering department, but in reality, was working after their own sectional workflow.

The general feedback was that they thought it would be interesting to involve the clinicians further in this workflow. Ensuring that the workflow is appropriately taking all stakeholders into consideration. This would be especially interesting in the case of responsibilities regarding patient care and the communication of error messages. Also, they made clear that in some cases, the suppliers directly went to the clinicians and told them that the equipment was clear for use, without going to the biomedical engineers first. Something which was not considered in any workflow.

4.7.4 Results from Questionnaires

Figure 4.7, Figure 4.8, and Figure 4.9 are the results from the questionnaire of requirements used in the workshops. Each requirements score can be seen with boxplots displayed in a column fashion with the legend indicating which requirement corresponds to respective boxplot. Each diagram corresponds to a certain pair of models, scheduled and unscheduled maintenance, being evaluated. A score of 1 indicates that the evaluated model pair is not aligned with the requirement, whilst a score of 5 indicates good alignment.

In Figure 4.7 are the results from the section of the questionnaire pertaining

to the pair of pre-study models. In general, the scores are poor with a lot of scores with a mean around 3. However, the models fared well in one regard. That was the requirement that all equipment is supposed to be checked and the requirement that equipment should be checked after service, which is reflected in requirement 10 and requirement 11 respectively.

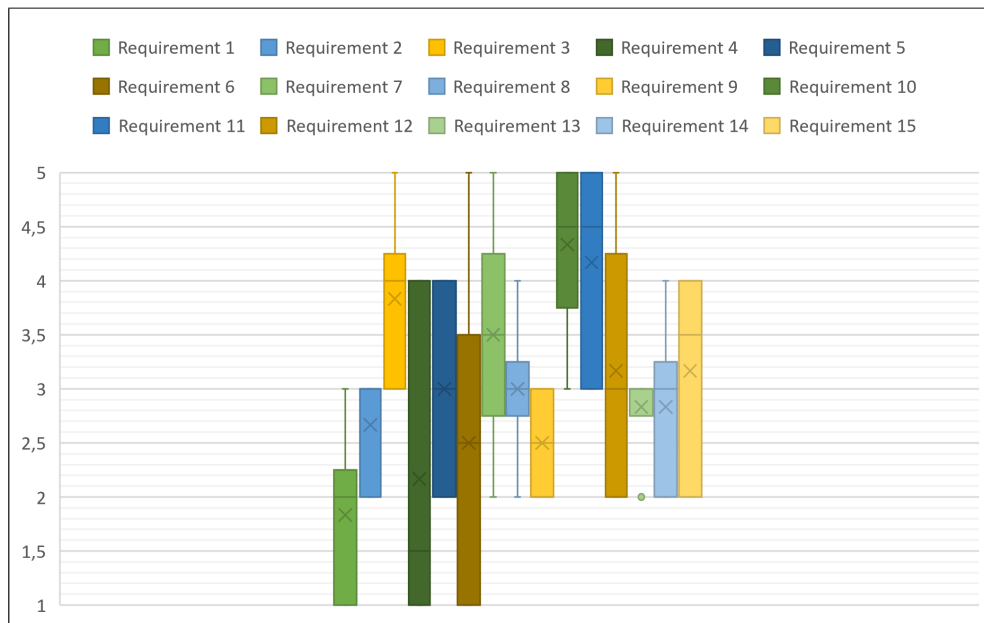


Figure 4.7: Boxplot of the results from the questionnaire about Pre-Study Model.

In Figure 4.8 are the results from the section of the questionnaire pertaining to the pair of models for solution 1. What can be observed is a general increase in the scores of the requirements which was quite stark in contrast to Figure 4.7. Implying that the interviewees found solution 1 to be superior to the existing workflow modelled in the pre-study model. In fact, the results from solution 1 outperforms the pair of pre-study models in all requirements except for requirement 10, where the results are mostly similar. Thus, confirming that the solution model should be implemented in the clinical workflow.

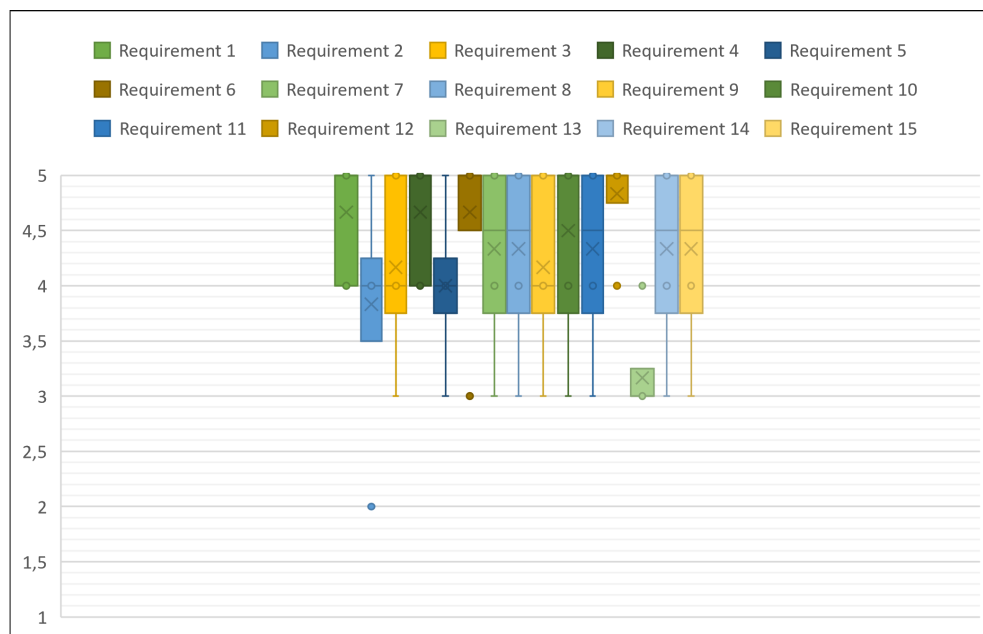


Figure 4.8: Boxplot of the results from the questionnaire about Solution Model 1.

In Figure 4.9 are the results from the section of the questionnaire pertaining to the pair of models for solution 2. This model did not perform as well as solution 1. Especially in requirement 4 and 6 which pertains to resource-effective workflow and low operational downtime of radiology equipment, respectively. This is probably a reflection of the added step of documentation initially in the workflow, which will de-facto require more time allocated on each case by the stakeholders. Thus, increasing operational downtime and decreasing resource effectiveness.

Also, there was a drop in the score of requirement 14 which pertains to the alignment of the model with other decision-making functions. This was also mentioned in the feedback sessions of the workshops and reflects the need for a decision-making function to be modelled for initial documentation. The argument being, if in a high stress situation, the stakeholder has to decide whether to document initially or troubleshoot initially depending on the severity of the unscheduled maintenance. This would however not be a problem in regard to scheduled maintenance as severity of maintenance is regulated beforehand.

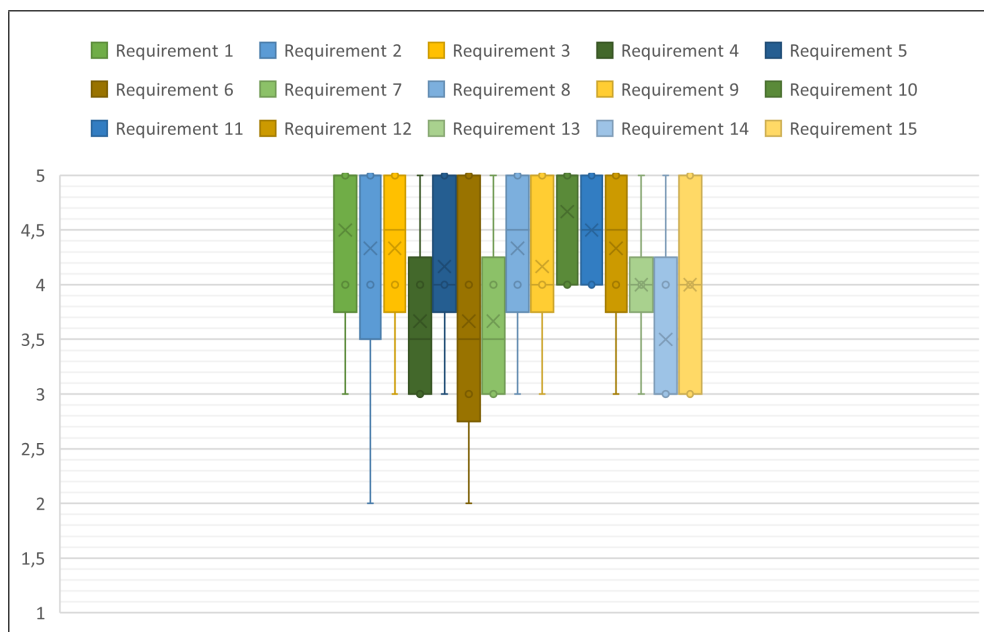


Figure 4.9: Boxplot of the results from the questionnaire about Solution Model 2.

Finally, in Table 4.2, the different requirements and their results from the pairs of pre-study-, solution 1- and solution 2 models can be seen. The rows indicate which requirements is being evaluated and the columns show the different mean scores for the model pairs. Following a row, one can see the requirement description, the means of the pre-study models for that requirement and the means of the different solutions respectively for that requirement. Allowing for requirements to be easily compared across models by analyzing the rows of the table.

This data aligns with the points deduced from Figure 4.7, Figure 4.8 and 4.9. Thus, serving as a form of sanity check for the conclusions drawn from the figures. Additionally, it can be observed more explicitly that requirement 10 and requirement 11 performed well across the board. This reflects the fact that a lot of double work is performed in the pairs of pre-study models when it comes to function controls of radiology equipment. The requirements are therefore scoring high across all models, as the level of function controls is initially at a very high level. In fact, some stakeholders argued that the level of controls is at an excessive level in contrast to the demands stated in the regulations from [SSM](#).

Table 4.2: Table showing the requirements and their mean scores.

<u>Requirement</u>	Pre-Study Mean	Sol. 1 Mean	Sol. 2 Mean
1. Any documentation this is produced during controls is storable and findable in a single place.	1.83	4.67	4.50
2. The system facilitates tracking of cases from start to finish.	2.67	3.83	4.33
3. Facilitates minimization of potential radiation dose in regard to malfunction or incorrect settings.	3.83	4.17	4.33
4. Allows for a resource-effective workflow.	2.17	4.67	3.67
5. The workflow is setup in a process-oriented manner.	3.00	4.00	4.17
6. Facilitates low operational down-time of radiology equipment.	2.50	4.67	3.67
7. The workflow is easy for the stakeholders to adhere to.	3.50	4.33	3.67
8. The workflow is easy the stakeholders to learn.	3.00	4.33	4.33
9. The system explicitly tells users which stakeholder is responsible at any given point of time.	2.50	4.17	4.17
10. Facilitates that all radiology equipment in the hospital can be checked at an appropriate time-interval.	4.30	4.50	4.67
11. Facilitates that all radiology equipment is checked after a service is performed on the equipment.	4.17	4.33	4.50
12. Rigid enough to serve as a function that decides if the equipment can be put in clinical use.	3.17	4.83	4.33
13. The system ensures that the risk of operator error is minimized.	2.83	3.17	4.00
14. System facilitates alignment with other decision-making functions.	2.83	4.33	3.50
15. System has a technical framework that allows it to accommodate a decision-making function.	3.17	4.33	4.00

4.8 Chosen Solution

Solution 1 was chosen as the optimal solution to be proposed for implementation, based on the results from the workshop. It scored higher on almost all requirements and was furthermore the preferred model based on the feedback from the discussions during the workshops. This was mainly due to the addition of a documentation step being seen as nuisance, with little extra value being added to the workflow. The documentation step was also something that was not asked for by the stakeholders. It was a product of analyzing the workflow independently which could have contributed to its poor performance in the workshops.

It should be noted that solution 1 is easier to implement to the current workflow, as it involves less changes to the current workflow. Nonetheless, both solutions need to be implemented incrementally. That is why the solutions are described in branches being engineer or supplier driven. Whereas the supplier driven branch of the solutions are easier to implement. As it only requires that hospital physicists evaluate and validate the routines and measurement data from suppliers.

When it comes to the engineer driven branch, then there are two factors which needs to be considered for a successful implementation. Firstly, the engineers have to be trained on how to perform the measurements by the physicists. And secondly, the engineers will have an increased workload as they take on the measurement tasks of physicists. Which in turn will lead to discussions of compensation for increased workload and workload distribution within the engineering team itself.

4.8.1 Premises for the Chosen Solution

In order for the solution to be viable, the following premises needs to be met:

Supplier checks and controls need to be reviewed and approved by the hospital physicists. The solution is dependent on that if the suppliers is the one is performing the controls, then those controls are trusted. And in order to build this trust, the hospital physicists must be able to vet the routines and protocols of the suppliers. **The biomedical engineers need to be educated by the hospital physicists and suppliers, on how to perform the checks and generate protocols after service on radiology equipment.** This is a cost-driven transition process which is of crucial importance to the quality assurance. If the biomedical engineers are not properly trained, then the quality of the controls may end up wanting.

A function that generates workorders on equipment not checked needs to be integrated into Medusa. Thus, to ensure that all equipment in the inventory is being checked regularly. It is in the very core of the solution. Ensuring that the same work is not done twice by the means of a digital solution, whilst adhering to the demands of [SSM](#).

An agreement needs to be met between the supplier and the clinic, that states that the above points are enough to meet their standards. It ensures that the stakeholders are aware of the commitment each party is undertaking and the consequences of non-adherence.

Chapter 5

Discussion & Conclusions

In this chapter a discussion will be held of the different sections of the thesis. It serves to bring up both positive aspects and negative aspects of the thesis. Evaluating what went well and what can be improved upon. Firstly, the methodology of the thesis will be discussed, followed by a discussion of the results of the thesis. Lastly, a look into the future implications of the thesis will be done. With emphasis being put on how the thesis can be improved upon and what implications the outcomes have on quality assurance in radiology.

5.1 Discussion of Methodology

The methodology had a clear step-by-step flow throughout the different sections of the thesis. Information was gathered from multiple sources by the means of a semi-structured literature review and mapping of the current workflow was performed involving the stakeholders. Thus, generating data which had not been visualized for the hospital staff before. Solution models and a list of requirements were then generated in conjecture to the information found, laying the basis for the workshops. With this solid foundation for a workshop, both the pre-study- and the solution models could be compared with metrics grounded in scientific literature. Giving clear results of which pair of models is most suitable to implement at the hospital.

There is however a problem with positive bias in the thesis. When the pre-study models were generated, the stakeholders were the ones feeding the information of what the process model should look like. So, when they were asked to evaluate the pre-study models against the solution models, they had a positive bias towards wanting a change from the existing workflow. Since they already wanted a change from the existing workflow. Thusly, reinforcing the

positive change perceived from the pre-study models to the solutions models in the results. It should be noted that the positive bias was lower when evaluating the solution models to each other. Since these models were generated without the participation of the stakeholders. To counteract this bias, a third-party evaluation groups could have been used. This was however not done during the thesis.

In order to expand the understanding of the stakeholders, the thesis could have utilized user stories. User stories serve to capture the soft values of the stakeholders and are frequently used in software development. It would have added to the capabilities of the multi-actor system analysis. Providing an alternative to the use of explicit placement of stakeholder in the process models. However, in the interest of time, user stories were skipped. Deeming that the current multi-actor analysis was sufficient in order to produce solution models of desired quality. Also, the stakeholders were heavily involved in the pre-study modelling, in which their soft values were at multiple times expressed. Albeit, not written down and analyzed. Thusly, incorporating their soft values into the solutions models.

The pre-study sessions did not include sessions with the suppliers. This was realized in hindsight and an interview with suppliers was contemplated. But again, in the interest of time, disregarded. The motivation being that the workflow is heavily clinic favored and that the suppliers would not have all that much to add to the solution models. It would be interesting to see what they would have to say about the existing workflow and if there are models within their internal organization which depicts a similar view of the workflow. It could be entirely possible that two different workflows, one in the clinic and one from the suppliers, is intersecting within the clinic in an improper fashion due to a poorly configured workflow supplier-side.

5.2 Discussion of Results

The thesis fared well in both the modelling of existing workflows, of which all the involved parties were satisfied, and in offering plausible solution models to the problem at hand. What the thesis did not take into consideration, and which is a major factor for project management in clinical setting, is the process of implementing the solution models into the current workflow. The solution models were simply modelled, proposed, and preliminarily evaluated, never actually implemented.

However, if the solution models were to be implemented in a clinical setting. Then the workshops indicate that it would be better to implement

them incrementally. The argument being that it would minimize the risk of compromising patient safety and operational uptimes. Thusly, a new workflow should be phased in. Starting with the aspects of the workflow which are the easiest to implement. Creating a proper project plan in coordination with the clinic would probably be the best course of action. This was however, out of the scope of the thesis.

The solution models all had the baseline of utilizing Medusa in the processes. Thusly, the solutions are dictated by the use of Medusa. Where one pair of solution models are trying to extend its usage with the implementation of case handling as an added layer on top of the workorders. This was not received well by the leadership staff of the biomedical engineers. Arguing that a work order level of handling cases, is sufficient. The question remains to be explored if it is effective to stay on a work order level, or to implement case handling in the way that Medusa was designed by the developers.

The tool in itself allows for management of medical inventory equipment in a standardized fashion across engineering workgroups. Its usage is also heavily rooted in the existing processes of the engineering team. Therefore, it would have been unwise to propose solutions without incorporating it. Otherwise retraining of the engineering workforce has to be employed with whichever substitute that is deemed appropriate to base the process models on. However, there are other inventory management vendors on the market and an in-house solution could also be developed. Potentially having an even better production site fit. But these options weren't explored in the thesis. Thus, making it impossible to draw any conclusions from the of the thesis results on the topic.

There exists a dilemma of patient safety in the thesis, as one could regard it as the primary and sole reason for performing quality assurance on radiology equipment. The solutions models provide a way of eliminating down-time of equipment by reducing the amount of double work that is done during service. However, the same double work could be viewed as a way of increasing the patient safety in the internal processes. Basically, functioning as a double check gate, ensuring that no quality assurance check is done incorrectly by the performing stakeholders. What it boils down to, is a trade-off between minimizing operator error in the internal processes and the potential patient harm caused by lowered operational up-time. Faulty quality assurance can lead to patient harm, but delayed production flow in the hospital can cause the same. This is something managerial staff have to weigh when choosing solution model for implementation. Weighing in the opinions of the hospital physicists on the matter is probably critical. Since they have intimate knowledge of what

the quality assurance checks actually entails and the risk of performing them incorrectly. These quality assurance checks were not explored in-depth during the thesis.

It was surprising to see the resistance towards the initial workorder step in solution model 2. When constructing the model, there was a certain expectance that this would be a welcome addition to a workflow that is heavily backloaded when it comes to documentation. This was however not how it was received during the workshops. The general response from leadership staff and biomedical engineers was that it would hinder the ability to handle emergency cases. Making it a nuisance. However, one of the hospital physicists, that had previously worked as a biomedical engineer, pointed out that working with an initial documentation step in a logbook had been a standard before the introduction of the inventory system. However, since workhours are being cross-referenced with the inventory system, the use of it for documentation diminished and it became more of a workforce managerial tool. Thusly, the logbook function faded.

5.3 Future Outlook / Future Implications

It would be beneficial to follow-up on how long it takes to actually implement the improved workflow completely. The solution in itself comes with its premises which are not necessarily simple to address and development projects within Södersjukhuset, have historically needed a long time to be finished. Important factors being the number of parallel projects being ran at the hospital during implementation and the number of available resources. It is not unheard of that a project gets stopped mid-way due to reprioritization.

Once the workflow is deployed and documentation is fully digitalized, then the workflow can be improved by the means of process mining. This is in a sense one of the hoped-for outcomes of improving the workflow at the radiology department. Digitalizing in order to prime for process mining. However, process mining is still a new technique, and it will probably take a long time before something of the likes can be attempted in a production setting. And if process mining were to be implemented, then it would probably be implemented in the clinical workflows of the hospital primarily. Much like other process modelling techniques being implemented in clinical workflows first.

A follow-up after one year of implementation would be beneficial to evaluate performance. If such a follow-up were to be held. Then it would be preferable to do workshops in much the same way as done during this thesis.

It would give a good measurement of before and after. Allowing one to truly evaluate the performance of the improvement.

5.4 Conclusions

This thesis was able to model the current workflow of radiology equipment at Södersjukhuset using flowcharts and in turn, identify a plethora of areas of improvement and redundancies. Showing that multi-perspective process modeling can reveal a lot of redundancies in a complicated sociotechnical system, such as a radiology department.

Furthermore, the thesis managed to create a list of requirements for both current and improved workflows. This list was used to evaluate respective workflows in workshops. Generating both qualitative and quantitative measurements of the workflows, with the use of a questionnaire. Measurements showing which improved model and software solution is the most suitable to address the redundancies found.

Thus, the methodology of multi-perspective process modelling proved to be a potent tool to identify, generate, evaluate, and ultimately improve a workflow in a clinical radiology department.

References

- [1] M. Karami, “A design protocol to develop radiology dashboards,” *Acta Informatica Medica*, vol. 5, no. 1, pp. 341–346, 2014. doi: 10.5455/aim.2014.22.341-346
- [2] M. Karami and R. Safdari, “From information management to information visualization: Development of radiology dashboards,” *Applied Clinical Informatics*, vol. 7, no. 2, pp. 308–328, 2016. doi: 10.4338/ACI-2015-08-RA-0104
- [3] J. F. Donnelly, “Quiri (quality improvement and research in imaging) program: a means to promote and coordinate research and quality-improvement activities in radiology,” *Pediatric Radiology*, vol. 41, no. 1, pp. 413–416, 2011. doi: 10.1007/s00247-011-1993-7
- [4] J. B. Kruskal, S. Anderson, C. S. Yam, and J. Sosna, “Strategies for establishing a comprehensive improvement program in a radiology department,” *RadioGraphics*, vol. 29, no. 1, pp. 315–329, 2009. doi: 10.1148/rg.292085090
- [5] C. Mohan, “Quality program in radiology: Persue or perish,” *Indian Journal of Radiology Imaging*, vol. 27, no. 1, pp. 1–3, 2017. doi: 10.4103/ijri.IJRI_99_17
- [6] D. L. M. och D. Schauer, “The alara principle in medical imaging,” *AAPM Newsletter*, vol. 40, pp. 38–40, 01 2015.
- [7] Strålsäkerhetsmyndigheten SSM, “Strålsäkerhetsmyndighetens författningssamling, pp. 6, 4 §.” 2018, <https://www.stralsakerhetsmyndigheten.se/publikationer/foreskrifter/ssmfs-2018/ssmfs-20181/>.
- [8] Södersjukhuset AB, “Årsredovisning för Södersjukhuset AB: Räkneskapsår 2019-01-01 - 2019-12-31,” 2020.

- [9] SoftPro, “Medusa,” <https://softpromedical.com/medusa/>, accessed: 18 May 2021. [Online].
- [10] I. Bider and E. Perjons, “Design science in action: developing a modeling technique for eliciting requirements on business process management (bpm) tools,” *Software and Systems Modeling*, vol. 14, no. 1, pp. 1159–1188, 2015. doi: 10.1007/s10270-014-0412-6
- [11] L. M. Kipper, L. B. Furstenau, M. K. Scott, J. R. Lopez-Robles, F. D. Giraldo, and J. M. Cobo, “Process modeling for smart factories: using science mapping to understand the strategic themes, main challenges and future trends,” *Business Process Management Journal*, vol. 27, no. 5, pp. 1391–1417, 2020. doi: 10.1108/BPMJ-05-2020-0181
- [12] C. D. Francescomarino, G. Adamo, and C. Ghidini, “What is a process model composed of?” *Software and Systems Modelling*, 2021. doi: 10.1007/s10270-020-00847-w
- [13] S. Chalupa, M. Petricek, and Z. Ulrych, “The use of business process management in hotel direct sales improvement,” *TEM Journal*, vol. 10, no. 1, pp. 215–220, 02 2021. doi: 10.18421/TEM101-27
- [14] J. Ward, J. P. Clarkson, and G. T. Jun, “Health care process modelling: Which method when?” *International Journal for Quality in Health Care*, vol. 21, no. 3, pp. 214–224, 2009. doi: 10.1093/intqhc/mzp016
- [15] K. Zarour, D. Benmerzoug, N. Guermouche, and K. Dira, “A systematic literature review on bpmn extensions,” *Business Process Management Journal*, vol. 26, no. 6, pp. 1473–1503, 2020. doi: 10.1108/BPMJ-01-2019-0040
- [16] G. G. Gable, W. Bandara, M. Tate, and M. Rosemann, “A validated business process modelling success factors model,” *Business Process Management Journal*, vol. 27, no. 5, pp. 1522–1544, 2019. doi: 10.1108/BPMJ-06-2019-0241
- [17] M. Abubakre, A. Fayoumi, and I. Eleburuike, “Implementing process improvement initiative: the role of visualisation and standardisation methods,” *Business Process Management Journal*, vol. 27, no. 3, pp. 965–986, 2021. doi: 10.1108/BPMJ-10-2020-0474
- [18] J. Gomes, F. Portela, and M. F. Santos, “Introduction to bpm approach in healthcare and case study of end user interaction with ehr interface,”

- Procedia Computer Science*, vol. 141, no. 1, pp. 519–524, 2018. doi: 10.1016/j.procs.2018.10.132.
- [19] OMG, “Object management group,” <https://www.omg.org/about/index.htm>, accessed: 18 May 2021. [Online].
- [20] M. Simonette, M. Magalhaes, E. Bertassi, and E. Spina, “Beyond resilience in sociotechnical systems,” in *2019 International Symposium on Systems Engineering (ISSE)*, 2019. doi: 10.1109/ISSE46696.2019.8984570 pp. 1–4.
- [21] J. Turnley, A. Wachtel, K. Munoz-Ramos, M. Hoffman, J. Gauthier, A. Speed, and R. Kittinger, “Modeling human-technology interaction as a sociotechnical system of systems,” in *System of Systems Engineering Conference (SoSE)*, 06 2017. doi: 10.1109/SYSESE.2017.7994934
- [22] J. Ludtke and A. Purkus, “A systemic evaluation framework for a multi-actor, forest-based bioeconomy governance process: The german charter for wood 2.0 as a case study,” *Forest Policy and Economics*, vol. 113, no. C, 2020. doi: 10.1016/j.forpol.2020.102
- [23] N. Wang, P. W. Heijnen, and P. J. Imhof, “A multi-actor perspective on multi-objective regional energy system planning,” *Energy Policy*, vol. 143, 2020. doi: 10.1016/j.enpol.2020.111578
- [24] M. Schoon, M. Falayi, and J. Gambiza, “Unpacking changing multi-actor and multi-level actor ties in transformative spaces: Insights from a degraded landscape, machubeni, south africa,” *Land*, vol. 9, no. 7, p. 227, 2020. doi: 10.3390/land9070227
- [25] J. Newig, J. Leahy, and N. Juerges, “A typology of actors and their strategies in multi-scale governance of wind turbine conflict within forests,” *Land Use Policy*, vol. 96, no. 1, p. 104691, 07 2020. doi: 10.1016/j.landusepol.2020.104691
- [26] O. Stan, C. Avram, I. Stefan, and A. Astilean, “Integrated innovative solutions to improve healthcare scheduling,” in *IEEE International Conference on Automation, Quality and Testing. Robotics (AQTR)*, 05 2016. doi: 10.1109/AQTR.2016.7501301 pp. 1–6.
- [27] I. A. Alrashed and P. S. Kang, “Applying lean principles to health economics transactional flow process to improve the healthcare

- delivery,” in *2017 IEEE International Conference on Industrial Engineering and Engineering Management (IEEM)*, 2017. doi: 10.1109/IEEM.2017.8290018 pp. 879–883.
- [28] M. Baslyman, D. Amyot, and Y. Alshalahi, “Lean healthcare processes: Effective technology integration and comprehensive decision support using requirements engineering methods,” in *2019 IEEE/ACM 1st International Workshop on Software Engineering for Healthcare (SEH)*, 2019. doi: 10.1109/SEH.2019.00014 pp. 37–44.
- [29] A. Prasad, A. Kurup, J. K., G. Abhisek, and A. K. Samanta, “Lean six sigma solutions for quality improvement in healthcare sector: a systematic review,” in *2020 International Conference on System, Computation, Automation and Networking (ICSCAN)*, 2020. doi: 10.1109/ICSCAN49426.2020.9262289 pp. 1–5.
- [30] M. Baslyman, D. Amyot, and Y. Alshalahi, “Lean healthcare processes: Effective technology integration and comprehensive decision support using requirements engineering methods,” in *2019 IEEE/ACM 1st International Workshop on Software Engineering for Healthcare (SEH)*, 2019. doi: 10.1109/SEH.2019.00014 pp. 37–44.
- [31] T. Ilangakoon, S. Weerabahu, and R. Wickramarachchi, “Combining industry 4.0 with lean healthcare to optimize operational performance of sri lankan healthcare industry,” in *2018 International Conference on Production and Operations Management Society (POMS)*, 2018. doi: 10.1109/POMS.2018.8629460 pp. 1–8.
- [32] L. Tritos, S. Premaratne, and A. Dotun, “Prioritizing lean supply chain management initiatives in healthcare service operations: A fuzzy-ahp approach,” in *2013 IEEE International Conference on Industrial Engineering and Engineering Management*, 2013. doi: 10.1109/IEEM.2013.6962410 pp. 236–242.
- [33] P. J. Resetarits, “The application of lean management principles to fields other than manufacturing,” in *2012 Proceedings of PICMET '12: Technology Management for Emerging Technologies*, 2012, pp. 1705–1742.
- [34] F. Mannhardt, M. de Leoni, H. A. Reijers, and W. M. P. van der Aalst, “Measuring the precision of multi-perspective process models,”

- in *International Conference on Business Process Management*, vol. 256, 09 2015. doi: 10.1007/978-3-319-42887-1_10
- [35] A. Tarhan and T. G. Erdogan, “Systematic mapping of process mining studies in healthcare,” *IEEE Access*, vol. 6, no. 1, pp. 24 543–24 567, 2018. doi: 10.1109/ACCESS.2018.2831244
- [36] S. S. Shumilin, A. A. Rybakov, A. D. Chopornyak, and G. I. Savin, “Process mining: Realization and optimization of process discovery algorithm,” *Lobachevskii Journal of Mathematics*, vol. 41, no. 12, pp. 2566–2574, 2020. doi: 10.1134/S199508022012032X
- [37] T. Grisold, J. Mendling, M. Otto, and J. vom Brocke, “Adoption, use and management of process mining in practice,” *Business Process Managment Journal*, vol. 27, no. 2, pp. 369–387, 10 2020. doi: 10.1108/BPMJ-03-2020-0112
- [38] C. Esposito and O. Tamburis, “Process mining as support to simulation modeling: A hospital-based case-study,” *Simulation Modelling Practice and Theory*, vol. 104, 2020. doi: 10.1016/j.simpat.2020.102149.
- [39] K. Williamson, “Questionnaires, individual interviews and focus group interviews,” *Research Methods: Information, Systems, and Contexts: Second Edition*, pp. 379–403, 01 2018. doi: 10.1016/B978-0-08-102220-7.00016-9
- [40] M. A. Carey, “Focus groups,” *International Encyclopedia of the Social & Behavioral Sciences (Second Edition)*, pp. 274–279, 12 2015. doi: 10.1016/B978-0-08-097086-8.10543-4
- [41] “ISO 9001:2015(E) - Quality Management Systems,” International Organization for Standardization, Geneva, CH, Standard, 2015.
- [42] “ISO 13586:2016 - (Medical Devices) Quality Management Systems: Requirements for regulatory purposes,” International Organization for Standardization, Geneva, CH, Standard, 2016.