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Requirement Culture at a Large Scale Medical Device Developer: A Case Study

Brandon Matthew DelSpina
Clemson University, bdelspi@g.clemson.edu

REQUIREMENT CULTURE AT A LARGE SCALE MEDICAL DEVICE DEVELOPER: A CASE STUDY

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Brandon Matthew DelSpina
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Accepted by:
Joshua D. Summers, Committee Chair
Committee (alphabetical):
John DesJardins
Mary Elizabeth Kurz
Gregory Mocko
Cameron Turner

ABSTRACT

This case study explores requirements evolution of a multimillion-dollar medical device under development for cancer therapy. The study focuses on the analysis of requirements across a twelve month window via interviews with involved parties and document analysis of the company's design requirements. Three engineering directors (mechanical, software, and systems) were interviewed contemporaneously with the analysis of eight revisions to the design functional specifications, consisting of over 1,000 total design requirements. Findings suggest 1) change in requirements leadership, 2) market strategy including scope towards regulatory approval, and 3) requirement learning curve with respect to writing testable requirements may lead to requirements change. From analysis of the interview transcripts and company requirement evolution, a requirements culture emerged highlighting a need for greater understanding of company requirements cultures *in situ*. Further, analysis of the company's biomedical requirement behavior align with those found in the avionics and automobile industries suggesting requirements evolution, and therefore problem understanding, occur similarly irrespective of domain or problem size.

DEDICATION

This thesis is dedicated to my mom, Lynda Nutt. Her love, support, and drive have taught me the tools necessary for success and the power of dauntless perseverance.

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Chapter One:
OPEN ISSUES IN REQUIREMENTS

Requirements change is an active research area for disciplines such as software engineering [1–4] with various tools developed for the managing of requirements change within software systems. However, a gap exists within the electromechanical field, as its design requirement tools do not adequately address the effects of change on development time and cost [5]. Requirement change must therefore be understood to enable the development of such a tool as often those provided by software engineering do not cover the needs of the mechanical design community [6].

The broad research objective is to examine the evolution of engineering requirements with a focus on the effects of change across requirements revisions to enhance the usability and value added by requirements. The following thesis addresses the question: *does a requirement culture exist at the company of study?* Specifically, *do personnel perceive cultural influences?* and *are influences observed in requirement artifact analysis?*

Engineering design research is a means of navigating, organizing, explaining, and using design know how [7]. Design research strives to enhance the comprehension of design phenomena and its intricacies. This is done via the delineation and development of design data, processes, and tools to build upon the knowledge of today [8]. Requirements change research furthers the discipline's mission by aiming to understand the influences on requirements and means to mitigate their change affects. Requirements change is defined in this thesis as the addition, deletion or modification of existing requirements [9].

While understanding in the engineering design methodology has promoted the creation of requirements to increase value and resultant solutions, it remains deficient to the complexity of large projects and organizations [10,11] - specifically the perspectives of the parties involved with requirements change.

As requirements are at the forefront of the design process, the requirements process supports many of the activities in the design process [11], for example verification and validation. Over the course of a project, it has been reported that as many as fifty percent or more of a system's requirements may change. Thus, in an effort to control costs and other expended resources, understanding of requirements change remains of high significance [6].

These requirements are not necessarily changed at a single point in time, a discrete step. Rather, a formalized requirement change is initialized via discussion and testing prior to becoming formally documented [10]. However, a complete understanding of engineering changes is not yet recognized [2,5,12,13] with findings suggesting that almost one third of an engineer's time can be reduced when appropriate controls are implemented during the change release process [12]. A motivation for this research therefore aims to greater understand why requirements change occurs from the perspectives of the involved parties.

Upon this increased understanding of requirements change, requirements may then be used to greater inform project-planning [14–16] through outlining the known problem space. However, one must first have the ability to anticipate how many requirements are in each category (for example maintenance or operation) and how many more one expects

to define [17], giving rise to the need for a means to gauge project impact resulting from the effects of requirements change. An expert in the field of software engineering at the company studied recently touched on this when he stated

> *"If we can do the tracing from requirements to design or design component… we can say somewhat rigorously if I change this piece what the impact on the rest of the system is. We can say how much is affected." (Tony, 3/8/16)*

This ability to gauge project completeness and perform impact analysis is especially important in some time critical systems or extended development products, such as the large-scale biomedical system studied in this report.

In summary, the challenge of requirement change is due to the change being stated in the "*problem domain"*, yet the response and employment of the changes occurring being made in the "*solution domain"* [3]. By bridging this gap, the focus of this study is to identify and understand the factors of requirement change in the context of a complex technology development, which may contribute to the estimation of impact analysis and project planning.

1.1 Research Tasks and Deliverables

The motivation for this research can be observed in Table 1.1. Each article can be found with a corresponding objective, result, and pointer to location within this thesis.

Table 1.1: Research Motivation

Article	Objective	Result	Thesis
A	Obtain qualitative prospective for industry requirement change at company of study.	Interviews with software, systems and mechanical engineers at the company of study.	Chapter Four
B	Obtain company requirements for industry requirement change analysis.	Artifact analysis on more than 1,000 industry requirements.	Chapter Five

Reviewing Table 1.1, may the fulfillment of the masters' requirements be measured by the products within this thesis.

1.2 Advantages of Understanding Requirements

Designers revert to various knowledge bases including existing and previous project documentation, spending a significant amount of time collecting and finding information which is not project progressive or mission critical, often resulting in project delays [11]. However, engineering design is not solely about decision making [18,19], but rather making decisions in the presence of risk and uncertainty [18], with a "*good design"* satisfying the "*functional requirements independently and simply"* [20]. Requirements have been defined in many ways such as;

- A single *"shall"* statement that defines a stakeholder's expectation which can be implemented, integrated, verified, validated and transitioned [21],
- "*Some capability that somebody needs or wants"* [17]
- An "*abstraction"* which encompasses the outcomes of "*creative thinking"* for development of the product [22].

Requirements are defined in this thesis as testable statements which are needed for stakeholder approval [6].

1.2.1 Requirements

As designers may spend up to eighty percent of their time searching for necessary information [11], analysis of the requirements document can help designers earlier predict where the difficulties may lay by outlining how much is known or understood about the state of the product design or project embarked on [17]. Moreover, as requirements documents are continuously updated, requirements may not only depict the starting point of the project but may also supplement planning documents as a current state of the design [11]. By doing this, requirements become a significant source of information regarding product properties once compiled, enabling enhancements on later projects, supplier negotiations, and rational for decisions [23].

While a "correct" requirements document does not assure a flawless product [10], it can invoke the participation of users earlier in the process. In invoking this participation, users may communicate their thoughts, needs, and wishes by providing a communal language to discuss the project goals and initiatives. This communication may then greater enable teams to focus the efforts of individuals to their areas of expertise [17].

Independent of the project's size, requirements are a key component to product development. This may be seen working on smaller isolated projects, where requirements may be used as a way to define an initial purpose, or larger interdisciplinary developments, where requirements may be used as a managerial tool for projects of increased complexity [10]. Requirements are an integral part to company practice since it allows for the "*capture, structure, and reuse"* of knowledge across various projects [11]. Moreover, as specifications frequently consist of a *"mixture of goal statements, necessary conditions for*

success, meaningful but optional desiderata, design decisions, and junk" [24], with the requirements documents continually evolving throughout the product lifecycle and often being used by multiple stakeholders [6], the ability to capture and reuse previous findings and lessons learned can have a significant impact.

Product use cases can be employed to relate requirements, enabling them to be clustered or grouped [17,25,26]. These clusters and groups can then be captured and archived for later retrieval and reuse. Studies have shown that up to fifty percent of the product development time and significant monetary resources can be spared by reusing acquired knowledge [11]. Lastly, as requirements are generally one of the earliest generated design artifacts, they are often subsequently drafted in contractual form to be used with clients and vendors to confirm assignment completeness [6,11].

1.2.2 Requirements Change

Within requirements change lies the lower levels of global, local, external, and internal requirement change as seen in Table 1.2 and defined by [6,27].

Table 1.2: Requirement's Change Origins

Topic	Definition
"Globalized requirement change"	The changes undergone to the specification document as a result of a changed requirement.
"Localized requirement changes"	The changes undergone in the individual requirement's syntactical framework. These may occur as a noun (i.e. device, component, system) or verb (i.e. task or activity).
"External requirement change"	External requirement changes may occur when new governmental or societal regulations are released, changing the barrier to entry for new product launches.
"Internal requirement change"	Internal requirements changes may occur when a component is over or undersized, resulting in a connected component's need to be changed, subsequently being reflected in the requirement documentation.

Referring to Table 1.2, understanding the levels of global, local, external, and internal requirement change may help in controlling costs and other expended resources through the ability to illustrate and comprehend how and why requirements go from an abstract framework to a concise functional specification [6], topics of merit to both industry and academia.

This ability could help assist designers in suggesting the proper time to satisfy requirements as one could posit that requirements with high interconnectedness should be addressed toward the project's completion as they are more susceptible to change, which would subsequently require re-satisfaction. By satisfying highly interconnected requirements later in the product's development, one may be able to reduce the expended resources incurred from performing undesired regression testing [6]. Understanding the levels of global, local, external, and internal requirement change may therefore provide insight on the sequential process for when requirements should be satisfied, a challenge that has yet to be understood in design practice.

For designers which are not in direct contact with other project designers or engineers, the ability to predict requirements change may be of particular aid and is an expected outcome of this greater understanding [6].

Requirements change can be prompted as a result of various occurrences such as those seen in Table 1.3.

Table 1.3: Prompts to Requirements Change

Requirement Change Initiator	Source(s)
Engineering redesign	[6]
Stakeholder needs	[6]
Competition	[6,28]
Internal improvement	[6]
Problem understanding	[6,28]
Technology	[6]
Trends	[6]
Perceptions	[6]
Regulations	[6,28]
Conflicting requirements	[28]
Technical difficulties meeting high specificity	[28]
Opportunities for function sharing and synergies	[28]
Unexpected funding demands	[6,28]

Referring to Table 1.3, these prompts and others can be further reviewed in [6,28] and have been omitted here for project scope. The company studied in this thesis found themselves an object of requirements change as a result of unforeseen shifts in customer preference and unexpected market demands. The original system, designed in partnership with a leading university provider of medical technology, was originally intended to perform using an older method of medical dose delivery (anonymized here as UBS) rather than the advanced one used currently (anonymized here as PBS), now the market choice and customer preference.

As stated by the company's software engineering director and observed by the thesis's author, early in the development process it was originally decided to pursue UBS. However, as time progressed there was a market shift away from UBS towards PBS. During this period, there was a pursuit of both UBS and PBS until "*it became clear that you would not be able to market the machine with [UBS] anymore*" resulting in a total company shift towards PBS, which "*was a big shift*". However, as time to market is a major driver in many businesses, often being tied to capital and market share, the company's timeline did not shift in kind, prompting a decision to move forward with the current architecture to provide PBS, which has resulted in technical challenges.

This in mind, one can begin to see how through no fault of one's own, a market shift resulting in requirements change can begin to set into effect requirement change and change propagation.

1.2.3 Requirements Propagation

Requirement change propagation is the subsequent requirement change incurred resulting from a change to a connected requirement, without which the changes would have not taken place [6]. Motivation exists for the ability to predict these subsequent changes and their propagating impact. The motivation and advantages for gauging these events is therefore outlined below.

The change type on a local, syntactical level for an individual requirement has yet to be adequately researched and may present opportunities for greater understanding of the global requirement change ecosystem as the local level provides the greatest granularity of requirement change achievable. A motivation therefore exists to greater understand and

identify requirement relationships with propagation characteristics through empirical analysis [6]. Once created, this requirements tool may be able to learn on itself using artificial intelligence, consistently improving from increasingly detailed data sets allowing the designer to greater understand areas of possible propagation independent of his or her level of familiarity with the product under development. In this, designers and companies may become greater aware of subsequent events which can occur if a requirement is revised, introduced or eliminated prior to implementing the change. From this position, designers can make greater informed decisions based on the expected consequence(s) or benefit(s) [6].

This research furthers the efforts for the development of an automated software tool. Development of such a tool may aid designers in predicting requirement change propagation via analysis of the requirement's syntactical elements. Expected benefits may include the ability to predict requirements change, analyze requirement sensitivity, and evaluate the resulting magnitude of impact [6]. As such, these benefits may be of interest when 1) responding to incoming competitors with greater capability in their products, as established companies could gauge which changes would yield the greatest benefits and least consequences to remain competitive in the marketplace or 2) when combining two technologies to develop a new product and introducing new requirements to an existing device.

Chapter Two:
RESEARCH APPROACH

The focus of this thesis is the characterization of requirement culture and change at a multimillion dollar medical device developer. The requirement culture was observed by conducting interviews with the company's software, systems, and engineering directors. These events were documented and transcribed to gain further insight into perspectives of industry personnel on the company's requirements culture, something unobtainable by document analysis alone. Requirement change has been observed through analysis of the medical developer's design functional specification (DFS) document, evolving over eight revisions leading to regulatory clearance. A coding scheme is defined, and is used for characterization and illustration of the company's requirements evolution. This requirement analysis has been employed to present quantitative insight into requirement change at the medical device company and is used in conjunction with the qualitative findings of the interview analysis. The case study methodology was implemented to aid in empirical characterization while enabling real time analysis of an ongoing industry project.

An illustration of the company's requirements evolution is coded via introduced, changed, unchanged, reintroduced, and duplicated. Requirement coding is presented alongside findings of the company's requirements culture. The research questions explored and posit of research are stated. Tasks and procedures to analyze the research questions are presented with summary of the research deliverables fulfilled.

2.1 Intent

The intent of this research is to characterize the influences on a requirements culture, a topic not well explored in the design literature. The research therefore uses a twofold analysis approach via personnel and artifact analysis using the case study approach. An interview protocol and document analysis protocol are developed to aid in future replicative studies of developing requirement cultures. As requirements are at the forefront of design and carried throughout product development, the requirement culture may be instrumental to the requirements process irrespective of the type of product under development. This research therefore lays the foundation for further research into the problem domain of engineering design requirements culture research as well as provides provisions for new organizations currently developing requirements cultures of their own.

In conducting this research, the deliverables fulfilled can be observed in Table 1.1. The deliverables are to 1) obtain qualitative engineering director perspectives at the company of study for industry requirement change and 2) obtain quantitative data for industry requirement change at the company via analysis of the company's design requirements. The research begins with the company of study's background and problem identification. Personnel interviews are then presented to display information which is unobtainable by document analysis alone, for example employee perspective into the developments of the emerging requirements culture. This research therefore examines the phenomena of an emerging requirements culture through the perspectives of its members and analysis of its requirement document artifacts. In performing this research, the development of a holistic representation for retrospective analysis has been created to

enable research into other developing requirements cultures, as well as assist in the formation of requirements cultures currently under development.

2.2 Scope

This study examines the requirements culture and evolution at a medical device developer. Requirement evolution is defined here as the addition, deletion, or modification of existing requirements over the project lifetime [9]. Culture defined in this thesis includes the *communication*, *people*, *symbols*, *activities*, and *values* of a group [29]. Specifically, a requirements culture emphasizes meeting system functionality and *performance characteristics* [30]. Symbols, people, and activities are the physical components of a culture. However, the underlying structure of a culture is nonphysical and only discovered through interpretation and communication by its internal members [31]. As a requirements culture consists of both people and artifacts, the analysis and consideration of both is necessary for the development of a holistic perspective on a developing requirements culture. It is for this reason that both personnel interviews as well as company document artifact analysis were conducted and are presented here.

The primary contributions of this research are the observations reached on influences to the company's developing requirement culture and requirement evolution at the medical device developer, laying the foundation for future requirement culture research in manifold industry environments.

2.3 Research Questions and Posits

A summary of the research questions and posits are presented in Table 2.1.

Table 2.1 Summary of Research Questions and Posits

Research Questions	I. Does a requirements culture exist at the company of study? a. If so, do personnel perceive cultural influences? b. If so, are influences observed in requirement artifact analysis?
Posits	Ia) Requirement culture exists at the company of study with personnel experiencing multiple influences during product development. Ib) Requirement culture exists at the company of study, and will be reflected over the course of requirement evolution in the requirements documents.
Approach	Ia) Conduct interviews with software, systems, and engineering directors at the company of study. Ib) Perform requirement artifact analysis over release of eight requirement document revisions consisting of more than 1,000 requirements.
Deliverable Articles	A and B of Table 1.1.

Referring to Table 2.1, one can see a summary of research questions, posits, approaches, and deliverable articles. Upon review of Table 2.1 and the contents of this thesis, one can observe that all deliverables have been satisfied.

2.4 Studies Performed

Analysis of requirement evolution, as previously discussed and presented in detail throughout Chapter Five, has been performed to further the development of a requirements change propagation prediction tool as presented in [6,32–34]. As put forth during proposal of the research discussed in this thesis, analysis of more than 1,000 requirements during industry product development is performed and found in Appendix C, with the document artifact analysis protocol located in Appendix B. Conduction and analysis of industry perspectives towards requirements and development of a requirements culture have been

completed. Findings and discussion of these interviews can be found in Chapter Four, with a complete interview protocol located in Appendix A.

Chapter Three: COMPANY RESEARCH STUDY BACKGROUND

The study presented in this thesis was comprised of both document and interview analysis and employed the case study methodology. A case study has been defined in this thesis as a study planned in advance so that data collected may be analyzed by others in a way which reduces the opportunity for bias, and is as intimately involved as possible with the phenomena of interest [35,36]. Case studies have shown to be a useful research tool, particularly when addressing topics which have previously lacked research attention [37]**.** Proponents of the method cite research advantages resulting from its composition of various tools, enabling it to gain greater depth into results and create a more robust study. Finally, case studies as a research method have been successfully employed to understand different engineering design phenomena within various contexts, for example [15,33,34,38–47]. It was for these reasons the case study method is chosen for this research.

The document analysis focused on eight revisions of a single document currently under stringent design control in an effort to quantitatively understand the changes that occurred to the individual requirements, resulting in the document's evolution.

The interview portion of the study empirically explores the requirements activities at the company under study. The focus of the interviews were to develop a contextual company background and understanding, something unachievable by retrospective document analysis alone. Specifically, insight was sought into the reasons for requirement change, the company resources in place to support requirements practices, and the requirement impact on the company's developing device. For anonymity, the interviewees have been assigned uniform gender aliases to avoid bias.

3.1 Case Study as a Research Method

Problems surface when practitioners face an event which has not yet established guidelines [48]. Case studies are generally employed during the early stages of problem discovery as they can be qualitative in nature, aiming to detail an event, object, or a small population [48]. An example of this can be seen in *case based research,* where case studies are being increasingly used in publications such as *The Journal of Engineering Design,* as well as approximately 47% of ICED conference papers [49]. They are also used for exploratory, descriptive, and explanatory situations [35,50], as well as situations where current events are wished to be studied but environments can either be minimally or not at all controlled [35,50]. Case study instruction can further be found in [35,51,52].

Adversaries of the method argue that generalizations cannot be reached from a single case [35,50], that they are biased [50], contain little rigor [35,50], and are time intensive [35,50], mainly in terms of the time necessary to plan, test, and implement them [50].

While it is true that generalizations cannot be reached from a single case [35,50], the method does not aim to generalize to a population, but rather to a *theoretical proposition* [35,50]. This is further ensured by the use of falsification logic, and the case, or set of cases, selected [35,50]. With respect to the argument of bias, the deployment of triangulation along with the use of falsification logic diminishes the concern, as the two allow for a multi-contextual perspective to be achieved. Addressing the concern for lack of rigor, this is not individualistic to case studies, but rather pertinent to all research methods within various degrees. With this in mind it, it is important to remember that the

responsibility for *well-defined protocols* [50] and *systematic handling of all evidence* [35] falls to the researcher, as it does with other methods. Lastly, the time spent on conducting a case study is researcher dependent, as the researcher prescribes the expended time and defines the goal of the study [35,50].

When performing an empirical study, the research approach is paramount to delivering credible results. This is the driving force to appropriating sufficient resources for the development of a conclusive research strategy [28], as outlined below.

3.1.1 Problem Definition and Investigation Planning

Case studies can be used to understand current issues, construct models to explain circumstances, and compare suggested models to new conditions [50]. Carefully defining the problem often leads to *the appropriate research methodology* [48].

Investigation planning consists of selecting *the subject or subjects of the case study, and choosing and testing the data collection methods* [48]**.** Within this, two types of subjects exist, *unique* and *typical. Unique subjects* often allow for something new to be learned, while *typical subjects* enable the ability to construct *a general theory*, something often referred to as *purposeful sampling.* However, no rule is in place for the number of subjects needed in a case study [48]**.**

3.1.2 Data Collection

To aid in objective data collection, three points are of interest. The first point is the collection of data from different sources. The second point is the systematic organization,

compilation, and analysis of the data. The third point is the maintenance of a backlog for the future reconstruction of events [35]. These are further expanded upon below.

First, researchers should employ methods that give them what they need for analysis [48,50]. One example of this is when researchers use triangulation**;** this is done by implementing multiple modes of measurement to ideally obtain convergence on an issue. By doing this, the study also becomes more rigorous, increasing the credibility of the results [48]**.**

Second, researchers should use a method which allows others to review the data such as *interviews, logs, visual protocols (videotapes and movies), and verbal protocols* [48]. Interviews should be set up ahead of time with a set location and time of convening to obtain greater reliable data. Often, it is helpful to open interviews with non-threatening questions to help ease the interviewee and to use a tape recorder for replay during interview transcription. Finally, one should: 1) write summary notes immediately following the interview while the subject matter is still "fresh" and 2) devise a set, or use a commonly used set, of abbreviations while taking notes during the interview as a form of short hand [48].

Third, in an effort to help deflect criticism with respect to bias and improve the likelihood of success, researchers should test their procedure prior to data collection. It is recommended that the investigator consult with others who can offer constructive feedback and develop a method which can be included in the research paper to provide the reader with an *audit trail***.** In doing this, the researcher increases his or her credibility through the

increased transparency and allows the reader to judge the credibility of the findings independently [48].

3.1.3 Data Analysis (Interpretation and Verification)

Ideally, data should be obtained *contemporaneously* with the activities of interest. Data should then be systematically analyzed to reduce the likelihood of researcher bias [48]. Techniques for analysis include: 1) *pattern matching* by looking at either *expected outcomes, rival explanations* or *simpler patterns,* 2) *explanation ,* or 3) *time-series analysis* [35].

Once the data has been analyzed, with the researcher being careful not to form premature conclusions of the data before all gathering is complete and analyzed conclusively [48], the investigator should then verify the findings by asking for input from either an outside rater, the subjects themselves, or surveying literature in the area. If a lack of agreement is seen to exist, this may be an indication that further review is needed into reasoning for the variance. However, if the different modes of analysis are shown to generally align, this may be an indication of increased finding credibility and decreased researcher bias [48] .

In summary, the researcher should be alert to configurations and/or groupings in the data [48] and should ensure that the analysis: 1) exhibits its reliance on the objective data, 2) accounts for any counter claims, 3) addresses the main point of interest, and 4) is composed of other expert knowledge [35].

3.1.4 Distribution of Results

As a research project is not complete until the results have been released [48], the release of results is critical to the case study method. This dissemination invites constructive criticism from other experts in the field. Researchers may increase their credibility by using qualifying statements such as "the research suggests that…" rather than "the research *proves* that…" [48]. Lastly, by releasing one's results, researchers can disperse their findings allowing for others to build further upon it. As Issac Newton once said, "*If I have seen a little further, it is by standing on the shoulders of Giants*" [53].

As it is often infeasible to investigate the topic of interest outside its real life setting or direct observation may be impossible [50], case study research is frequently used in engineering design [12] for its ability to generate awareness into activities and actions as well as enable posits for analysis [48]. While counter arguments do exist to the usage of case studies as a research method, the author has aimed to alleviate these concerns through the presentation of a stepwise method (Section 3.1) and empirical tools (Section 3.1.2). As design decisions often resulting from the designer's intuition cannot be quantitatively explained, these tools and method enable investigators significant insight without the introduction of adverse effects, which could otherwise impose biasing affects upon the topic of interest by including a different research method [50]. With that said, case studies are a helpful research tool [48] which allow researchers to probe design where design lives, in uncontrollable environments, where *variables and influences* are entangled [50].

3.2 Company Background

This study focuses on a U.S based company developing a multimillion-dollar system for cancer treatment, anonymized in this thesis as MedTech LLC. The iso-certified company, established in 2011, was founded by experts in the field of medical imaging and medical device development. MedTech employs approximately 100 professionals including five systems engineers, twenty mechanical/electrical engineers, five physicists, twenty software engineers, four "*dedicated testers*", 10-15 people "*moonlighting*" as testers, and several performing routine business functions.

MedTech recently received its FDA 510(k) medical device clearance and has one system installation in operation and a second under construction. As still a self-identified "*startup*", MedTech has remained nimble in its processes. With MedTech's agility, changes are often initiated through informal discussions or meetings, subsequently generating an engineering change notification or other design artifact. Within MedTech's environment, an opportunity exists to study requirement change and culture at a medical device developer.

3.3 Initial Data Investigation

In an effort to greater understand the resources that are available for analysis during the case study, MedTech's systems engineering director, Oakley, was approached for his company and requirement domain knowledge. Prior to Oakley's service at MedTech, Oakley has had over twenty years in the design of electrical and mechanical instruments, has been intimately involved with the product's requirements daily, and is currently in charge of their control.

During this informal discovery meeting, Oakley, who has been with MedTech for more than three years, expressed the various design influences which have gone into the development of the company's medical device, the BG-95.

These included influences such as MedTech's: 1) strategic vision that includes key intellectual property and market competitiveness, either internally developed or licensed, 2) staff (physicists, engineers, consultants, and clinicians), and their experience, and 3) a survey of currently available devices of similar functionality and intended use.

In further discussions of the pertinent requirements, Oakley pointed the researchers to two requirement documents: the design functional specifications (DFS) and user requirements. These documents were then further suggested for analysis due to their increased activity rate resulting from MedTech's efforts to achieve regulatory clearance. Several of the requirements themselves were generated from regulatory guidelines and International Electrotechnical Commission (IEC) standards for medical devices, providing a rich testing ground for researcher investigation into requirements evolution at the medical company.

Through this initial discovery meeting and Oakley's longstanding history with the company and its workings, contextual background including key personnel changes were learned by the researchers allowing for a greater understanding of the interconnectedness to be achieved. These were then further observed through triangulation of the data and are further developed in the following sections.

3.4 How Requirements are Handled

MedTech's design functional specifications originally started as a Microsoft Word document before admission to Jazz[1], a lifecycle management program. These specification documents present the requirements for MedTech's medical device. When the company first began, the preliminary requirements were generated from medical physicists, clinicians, and later marketing people and service personal.

As the director of engineering stated:

> *"We had a lot of [domain] experts that really helped shape the product from the beginning. So it was really about getting all the requirements out of their head onto the paper." (Hayden, 3/8/16)*

Hayden, the company's Director of Engineering was the fourth person to join the organization, and has had previous work experience with the automotive industry and airbag inflators, microfluidics, and regulatory approval on an ultrasound device.

Elaborating on the company's handling of requirements, as stated by MedTech's Systems Engineering (SE) director:

> *"This started as a [Microsoft] Word document and so yeah there were lots of Word documents that floated around that were passed to many people and then they would make comments and stick their name or date at the end of it." (Oakley, 3/11/16)*

Referring to this statement, seven temporary revisions were stored on the company's shared Microsoft Cloud[2] , selectively accessible to MedTech employees based

1 https://jazz.net/products/clm (accessed 2017.02.14)

2 https://products.office.com/en-us/office-365-home (accessed 2017.02.14)

on the employee's company position and role. However, these versions were omitted from study due to their relevance with the background information for the device, but no listing of engineering requirements. These omitted documents contained sections such as purpose, description, and definitions, but lack information on requirements.

Oakley further relayed the inefficiencies and limitations of using such an uncontrolled environment and process of uploading individual revisions to the Microsoft Cloud. One such limitation was stated to be reviewers having to perform document comparisons to identify comments and consolidate changes. Jazz was stated to have helped with resolving this issue by facilitating a controlled database which everyone could interact with in real time.

The Design Functional Specification (DFS) is driven by the user requirement specification (URS), hazard analysis, and all other regulatory requirements, with the aim of satisfying and meeting these three records. While both the BG-95's physical and system design are critical to the product's success, as the physical design encompasses the layout, assembly and packaging of specific parts, the output of which leads to the client's facility system design, the DFS addresses the system design only. However, the DFS and URS are not mutually exclusive and have a certain level of interconnectedness. An example of this would be the designer's goal to enable increased patient workflow and throughput. For MedTech this means the patient waiting rooms have been placed within a sixteen foot distance from the building entrance, the patient changing stations are within ten feet of the waiting room, and the treatment rooms are less than ten feet from the changing stations.

This facility setup allows for increased patient comfort, simultaneously increasing patient throughput. The controlled document is currently on its eighth revision.

MedTech currently maintains four data repositories these include: Microsoft's Cloud, Oracle's Agile[3], Rational Rhapsody[4], and Jazz. These are accessible both on-site, through the local network, and off-site, through the company's VPN, allowing developers and other stakeholders to have a live feed of current project activities. Specifically, Microsoft's Cloud is maintained and used for informal document storage but is not the main repository. As such, Jazz is the company's legal repository where requirements are maintained, software tests are run, and linking between hazards and risks are accomplished.

To better understand this, Tony, MedTech's Director of Software Engineering was interviewed. Tony has been with MedTech for more than five years and formerly worked for the world's leading manufacturer and developer of cancer imaging systems. Tony further explains that:

> *"Getting that [Jazz] setup was a big deal for us… all our tests are being constructed in Jazz so that the ability to run the tests are in Jazz. The ability to record the tests are in Jazz and the ability to link test to requirements are in Jazz…very uniform handling. It is getting more and more powerful. So it fun to see that it's really taking some big steps forward." (Tony, 3/8/16)*

This was then further confirmed by MedTech's engineering director who stated,

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3 https://www.oracle.com/applications/agile-product-lifecycle-management/process/index.html (accessed 2017.02.14)

4 http://www-03.ibm.com/software/products/en/ratirhapfami/ (accessed 2017.02.14)

"Now having it [the repository] setup and established and everybody using it, it is the right system for us." (Hayden, 3/8/16)

Oracle's Agile houses all company documentation, and acts as MedTech's official product lifecycle management (PLM) tool. Requirements are first registered in Jazz later being output as a Word or text file which can then also be stored in Agile.

While Rational Rhapsody is available, it is implemented in limited capacity and is planned to be more widely deployed in future product development. This tool in principle will allow the designer to use high-level software language to construct a functional framework, subsequently outputting the code to perform the task.

Chapter Four:
INTERVIEW STUDY

Interviews can vary widely being high or low in specificity, lasting for longer or shorter periods of time, and can be highly or loosely structured. This can be seen when asking more open ended questions, which enables and invites a broader range of answers; or can be closed or targeted, tending to elicit more specific responses which are generally easier analyzed. Interviews may be of the unstructured, semi structured, or fully structured framework [54,55]. Unstructured interviews are generally more open and exploratory in nature. Semi-structured tend to have a mix of open and closed questions and aim to be more descriptive and explanatory; they also do not have to be asked in the same order as listed on the interview guide, allowing for greater spontaneity and improvement throughout. Fully structured interviews are generally characterized by their closed questions and descriptive and explanatory aim. These are planned out prior to the interview, similar to that of the semi-structured framework. However, fully structured interview questions are asked in the same order as that marked on the interview plan [54].

4.1 Interviewing as a Research Tool

Interviewing is considered to be an important data-gathering tool by many qualitative researchers [48]. While there are many reasons for this, the tool's affordance of transcriptions, allowing others to review the conversation and perform post interview analysis, are one example. Interviewing has shown itself to be instrumental at obtaining insight to attitudes and events before and after an outcome; as well as, *facts, opinions, goals, plans and* other internalizations which may be unavailable otherwise [48]. Similarly,

interviewing can aid in developing an interviewees response more comprehensively [48,50].

Those against the use of interviewing cite that interviews are at risk to investigator disposition, that the framing of the question influences obtained response [48], and that interviews can be time intensive; both in terms of time to conduct the interview, as well as transcribing it afterwards. In summary, proponents of interviewing cite the pros of interviewing to be transcription, personnel insight, and situational awareness. However, adversaries cite the potential for bias, freedom in question framing, and time required as potential cons.

Reflecting on these cons, the use of a tape recorder can help in diminishing the claim of researcher bias by allowing others to retrospectively review the interview. The employment of triangulation during interviewing and throughout the case study method can reduce or eliminate the concern for question framing by presenting more objective questions and presenting the same question to multiple interviewees [48]**.** Finally, the time needed for case study research is researcher dependent as the onus is on the investigator to scope the topic at hand and filter out superfluous information [35,50]

While there is no formalized list of interviewing guidelines for the case study method in engineering design, the following suggestions are proposed best practices when conducting an interview [48]:

1. Create a professional relationship with the interviewee
2. Maintain eye contact
3. Be responsive to the interviewee's comments
4. Do not interrupt the interviewee, allowing enough time for a complete response and implementing appropriate pauses to draw out greater details

5. Implement follow up questions such as “What happened next?”
6. Gain clarification when necessary through questions such as “Can you elaborate on that further please?”
7. Thank the interviewee for their time and help
8. Type up notes and transcribe the interview as soon as possible

Reviewing the above this, it should be noted that interviews often follow the semi-structured or even unstructured framework [54]. Suggested literature surrounding interviewing as a research tool can be found in [56–59].

4.2 Overview of Interviews

When planning this study, an *a prior* protocol was created to direct the discussions during the interviews. These semi-structured interviews lasted between 45 and 90 minutes, were audio recorded, and subsequently transcribed. As interviews provide contextual information which cannot be achieved through document analysis alone, they are often considered to be an important data-gathering tool by many qualitative researchers [37]**.** Three interviews were therefore performed within the case study to triangulate upon the high-level causation for requirements change. A summary of the interview approach is captured in Table 4.1.

Table 4.1: Interview Summary

Item	**Description**
Number of Interviewees	Three
Description of Interviewees	Engineering Directors
Interviewer(s)	Two person team
Duration of Interview	45 – 90 minutes
Period (time frame) of interviews	Spring of 2016
Location description	On-site in the interviewee's office
Type of interview (level of structure)	Semi-structured
Materials used during interview	*A prior* interview protocol
Selection strategy (for interviews)	Extensive, systematic sampling approach [10]
Role of interview in study	Intentional
Additional methods (document analysis, observation)	Ethnological, document analysis
Timeline of interviews/research	Twelve months
Volume of collected information	Eight DFS, Interview transcripts
Verification strategy	Summaries provided and reviewed by organization
Recording strategy	Voice recorder via iPhone six
Example Questions (topics)	• Reasons for change in the specification documents • Interviewee background • Company management process for requirements • Company outlook on requirements
Example Answers/Responses	*"A lot of pre-conceptions about what this thing should do." (Oakley, 3/11/16)*
Strategy of Analysis	Triangulation

When reporting on the interview, it is important to provide details about the atmosphere of the interviews and a thorough discussion over the interview context. By providing transparency into interviews, readers can gauge the study's level of rigor and researchers can perform replication studies. Reverting to Table 4.1, a summation has been provided whereby the number of interviewees, description of interviewees, and other pertinent interview details can be known with greater discussion found in the following sections.

4.3 Interview Details

Interviewees were first selected using a systematic sampling approach as discussed in [10]. Once interviewees were selected, the individuals were approached for interviewing request and subsequent interviewee acceptance, the interview questions were then generated and tested. A subset of the questions asked during the interviews is presented in Table 4.2 with the complete set located in Appendix A.

Table 4.2 Subset of Interview Questions

Question	Motivation
How much organizational support would you say there is for your work with the requirements documentation?	Obtain insight into company requirements culture from member perspective
Do you find that there is general support for your work with requirements?	
Has the endorsement for using requirements fluctuated over your time at MedTech?	
What kinds of people (engineers, marketing etc.) or classes (management, directors etc.) do you find to have the most interest in requirements?	
How does the requirement practice currently fit into MedTech's business outlook?	
How would you characterize the benefits received to yourself and/or the larger MedTech company in practicing requirement documentation?	Obtain insight into value placed on requirements by personnel
What is the role of requirements, what are they meant to accomplish?	
What do you find to be key components of requirements to make them most useful?	
What are the benefits and advantages of using requirements during the engineering design and technology development process?	
What are shortcomings, disadvantages and limitations of the requirement practice?	
Did you have previous experience or interaction with engineering requirements prior to coming onboard at MedTech? If so, can you please briefly expand on this?	Obtain insight into employee interaction with requirements
Can you please describe your interaction with the requirements found in D*11 [URS] and D*345 [DFS]?	
Can you recall a specific example where you have referred back to a requirement for design or testing justification?	
What is your motivation for interacting with requirements?	
Can you give any insight as to why the large decrease in requirements between Revisions Three and Four?	Obtain insight into reasons for requirement change between revisions
Can you please provide insight as to why the large increase in requirements documentation from Revisions One to Two?	
Does MedTech have a defined requirements process? If so can you please direct me to the document and expand on it?	
In order to change a requirement does it have to be approved or have any formalities to be officially changed? What would this process be?	

Examining Table 4.2, one can review a subset of the interview questions communicated during interview conduction along with their corresponding research

motivation. The questions presented in Table 4.2 are clustered to illustrate triangulation. Using the method of triangulation, answers to research questions II and III of Table 2.1 are greater understood.

The framework of the semi-structured interview was implemented and is outlined as follows.

1) The company employed researcher was to summarize the research of interest and the questions under study. To ensure completeness, an introductory script was written.
2) As the company employed researcher was already familiar with the interviewees' background, the university researcher was to probe the interviewees about their background.
3) Once a mutual rapport had been established, each researcher was to deploy their preassigned questions.
4) Concluding remarks were to be communicated; with each researcher expressing their appreciation for the interviewee's time, help, and involvement.

Ending the interview protocol, the interview audio file was to undergo transcription and be made available to the interviewee to review for accuracy.

4.4 Findings

The researchers carried out interviews with three of MedTech's directors. These industry experts stretch the disciples of software, biomedical, and systems engineering. These were geared to achieve triangulation onto MedTech's processes of requirements change and propagation mitigation as well as obtain greater situational awareness which in unachievable from document analysis alone. For confidentiality and intellectual property, these transcripts are not included; however, may be made available in redacted form upon request. Anonymized quotations have been implemented in the following discussions.

Employing transcription analysis from [60], three influential reasons were uncovered leading to the requirements change: 1) change in requirement leadership, 2) strategic change in regulatory scope, and 3) MedTech's learning curve on requirements with; specifically, the need to form and document testable requirements. These are subsequently outlined in the proceeding sub sections.

4.4.1 Requirements Comptroller

Through interviews with the company directors, it was discovered that a shift in requirements ownership occurred when MedTech's current system's engineer took over the document's control. This was also confirmed through document analysis of the Design Functional Specification (DFS) where it was identified that the change took place between Revisions Three and Four. This was further described by one director who described the document's former owner's understanding of requirements as one which *"almost anticipated design"* (Tony, 3/8/16), essentially stating a design solution rather than a testable requirement. Similar comments were echoed to the company employed researcher by the company's president outside the interviews, and again during an interview with the company's current systems engineer, Oakley.

4.4.2 Government Regulation

Continuing through the transcription analysis, it was discovered that scope of the regulatory submission was also a major influence in the company's requirements documentation and played a role in the requirements change experienced. This was corroborated by the company's president who stated

> *"We used an essential requirements strategy for 510(k) submission; however, all requirements are a part of V&V prior to first patient treatment." (Micah, 2/28/17)*

Micah has presided over the company of study since its inception in 2011, as well as founded and sold a medical company prior to co-founding MedTech.

It should be stated here that MedTech has received regulatory clearance since the interviews were conducted, a result of four years of technical development. As guided by government regulators through numerous communications, MedTech enlisted to take a modular approach to the release of its requirements to the government agency. This further contributed to the change observed through document analysis and is corroborated in statements such as

> *"There was a timeframe also for in the FDA submission; we are doing this in a modular way. So we are trying to chunk down the pieces given in an orderly fashion that gives them time to, let's say, look at your requirements okay fine. So now let me look at your design and let me look at your test results. So there was a desire to close on the requirements, in time for, in order for us to meet the timeline." (Tony, 3/8/16)*

Similar comments have also been conveyed though companywide meetings led by upper management and observed by the thesis's author.

4.4.3 Requirements Learning Curve

Through triangulation of the interview descriptions and document analysis, a requirements learning curve has also been observed by the researchers and directors. This was disclosed by one director who stated "*certainly the increase in requirements I think is just the fact that we were getting to learn how to write requirements"* (Tony, 3/8/16), when

questioned as to a possible cause for the increase in requirements from Revisions One to Two. Revision One had 556 requirements, while Revision Two had 786 requirements. Oakley further elaborated on this learning curve stating

> *"… a lot of requirements were placed on those designers that probably should have never been there to begin with. I think paying attention to X, Y, and Z we're going to force these requirements on you. In the end, those requirements really weren't requirements. They were strong design suggestions." (Oakley, 3/11/16)*

In this statement, we can see a learning period was necessary for team members and designers to align their perspectives and objectives to achieve a state of equilibrium. Moreover, it was suggested that the removal of these constraints were a possible reason for the large decrease in requirements observed from Revision Three to Four when the same director stated

> *"Some of them weren't requirements at all. They were choices made to implement the design. So they were design outputs instead. Results of doing the design itself and knowing this really was never a requirement to begin with, [rather] a choice you made." (Oakley, 3/11/16)*

Elaborating further to the possible cause for requirement reduction between Revisions Five and Six, it was stated that

> *"A lot of it was the same thing. A lot of it was duplicate requirements, or requirements that were saying essentially the same thing, or things that were at the wrong level." (Oakley, 3/11/16)*

Taking a deeper dive into this topic and that of the requirements learning curve, a greater issue arose within the requirements documentation, that of the need to document testable requirements.

While the need to form testable requirements is documented throughout the literature, this is still an issue which is present in the company of study. A recent example of this was highlighted in the requirements document analysis and employee interviews where one director stated,

> *"I think part of that was actually looking at the tests. I think people didn't realize at some point these requirements need to be testable." (Tony, 3/8/16)*

Continuing to this point, as stated by another director

> *"The other thing that has had the biggest impact on change of requirements at the DFS [document] level is how testable they are. What you really don't want is a bunch of subjective requirements because they are very difficult to test. It's really open to the tester to figure out what the heck you're testing, and you don't guarantee that you have a good design. So that's the refinement of requirements that's been done for test purposes. No one was writing test purposes a year ago or two years ago." (Oakley, 3/11/16)*

The director went on to state

> *"…and now version 6 all [requirements] are being influenced by the way they are going to be tested." (Oakley, 3/11/16)*

Through the use of triangulation, these comments are directly reflected in analysis of the requirements documents.

4.5 Interview Analysis Discussion

Cultural differences may be found in the communication, people, activities, and/or values of a group. Symbols, people, and activities are the physical components of a culture. However, the underlying structure of a culture is nonphysical and only discovered through interpretation and communication by its internal members. Over the course of the interviews a requirements culture began to appear.

Upon performing analysis over the interview transcripts, it was found that there appears to be a culture generally centered on the management and formulation of requirements. However, an underlying significance to team *values* was also discovered which was embodied in the ambiguity of control, regulatory influences, and writing. This *layered* culture is in line with [61] as culture can be decomposed into two levels; *a visible behavior and artifacts level* and an underlying *invisible values level*. *Values* makeup the underlying structure of a culture. Values therefore denote member's thoughts on the way things *ought to be* and may therefore influence behavior [29]. Thus, in order to understand a culture one must understand the multiple layers.

4.5.1 Requirement Control

Perhaps the challenge with respect to requirement control at an early stage in new product development can be best represented by the director of engineering's comments when probed about things he would do differently looking back he stated:

> *"Knowing what we needed for the core device and really pushing for stakeholder requirements and competitive benchmarks out and marketing benchmarks out and just core device requirements. … having documents for all these different types of requirements, and having that staged out that would have been a big deal." (Hayden, 3/8/16)*

The reader can see the worth placed on a concise requirements document by the director, but such a concise document may not have been possible at the earliest development stage of the team. This is a reference to the phenomena of *requirements creep* used in literature to denote the tendency of requirements to expand over the course of a project [21,62–64]. This was echoed by MedTech's software engineering director in the statement

> *"If we had actually managed our requirements process better we would have saved a lot of time. We would have saved a lot of time and energy. We discovered these things, a little bit the hard way." (Tony, 3/8/16)*

This has also been observed in literature where the most influential variable on the cost of requirements stems from change management with a significant amount of time also spent collecting and finding information which is inconsequential to the accomplishment of activities and tasks [11]. This was further triangulated by the company's Systems Engineering director in his statement

> *"Very inefficient to do that. [B]ecause then you had fourteen documents floating around that somebody has to go back and do a word compare and look for comments and try to consolidate. Jazz helped a lot with that and made it so there was a database everybody was interacting with in real time." (Oakley, 3/11/16)*

As designers look to various knowledge bases including existing and preexisting project records [11], this is a notable point tying in with comments made by the other directors. As delays are often a result of the time expended during data acquisition [11], the time expended by team members to perform cumbersome document comparisons were both manual and cumbersome, simultaneously not furthering project development. As a result, the company installed state-of-the-art document control and requirements tracing tools and validated them.

From these comments, one can begin to see a general consensus by the directors for clarity on the requirements management practice and the importance of a dedicated requirements comptroller.

4.5.2 Regulatory Influence

Requirements documents progress from internal documents in the early stage product development to external documents available to outside government agencies and vendors. This suggests a duality of purpose to requirements. This transmutation may therefore introduce an external regulatory influence into the internal requirement culture, thus not only directing a requirements culture but also forming it. There may therefore be a need for both an inward facing requirements culture and outward facing requirements culture, with the company recognizing this duality. Oakley explained the significance of these regulatory documents for the BG-95 stating

> *"All those things [regulatory documents] feed into the way we conduct our hazard analysis. When we create it, when we add to it, the way we review it, and how we demonstrate control of the risks that the device proposes." (Oakley, 3/11/16)*

The regulatory influence on a developing requirements culture is therefore not inconsequential. Having such deep roots within the "*when*", "*why*" and "*how*" requirements are approached by the company, one can see this regulatory influence may not only direct a developing requirements culture but also shape it.

While this influence may come in the form of explicit guidance such as the regulatory documents described above, it may also influence the development time allotted to the team or company. One director explains this as, "*Releasing those [requirements] are kind of tied to some milestones in our company.*" (Hayden, 3/8/16), referencing the fact that regulatory approval is tied to critical milestones and competitive strategy. Another director explained this as "*Some of those revisions are coming from clarity, some of it is driven by the need to close.*" (Tony, 3/8/16), again referencing the relation between regulatory clearance, competitive strategy, and requirement scope.

The regulatory influence on a developing requirements culture can be seen not only in tangible form such as the guidance documents but also in a deeper nontangible form such as the timeline imposed when completion of regulatory clearance becomes an organization milestone. A variable to the timeline is scope of user requirements that will directly impact the number of design requirements and validation necessary. As development progresses and the competitive marketplace develops, the scope of requirements should be expected to change. This regulatory influence may therefore not only direct a new requirement culture but also develop it as requirements transcend from internal to external documents. This duality imposed from transcendence of an internal document to an external document, raises the question; is there an inward/outward facing

requirements culture? Moreover, within engineering design literature, little research exists towards the regulatory influence on requirements culture at medical device developers.

4.5.3 Requirement Writing

With respect to the writing of requirements, MedTech began with a unique design problem as *"There was a pre-existing device that worked well but wasn't ready for distribution or marketing."* (Oakley, 3/11/16). The company recognized the need for detailing this problem through requirements. However, MedTech's former comptroller authored solution-based requirements which were untestable, leading to confusion.

This was detailed by the company's current comptroller as

> *"A lot of pre-conceptions about what this thing should do…. [and] unfortunately the requirements had certainly flowed from that design in some respect. And that's part of why the requirements kept growing because there was …this pre-conceived notion of a design. ... If we had start perhaps with a concise set of requirements closer to what we have now, things probably would have gone a little faster. I think they definitely would have gone faster." (Oakley, 3/11/16)*

In this, the director repeats the notion that the requirements defined the solution. This was again reinforced by a director when he stated, with respect to the requirements

> *"I think certainly almost everybody probably appreciates now that the way that we did it originally was not the way it was supposed to be done." (Tony, 3/8/16)*

The directors' comments further suggest a learning curve in the requirements writing. This was again repeated by a separate director who recalled company activities where

> *"There would be a series of discussions about specs and there would be someone who was like you want me to do what? I don't even know how to test that? It's written so amorphous that it doesn't mean anything to me. So, somebody might say, I can't even test that one system the way that you've written that." (Hayden, 3/8/16)*

This created confusion and frustration with respect to requirements to the point where some saw no real value in engaging with requirements writing until improvements were made in structure and control. Hayden's statement further aligns with interviews conducted in [28] where it was suggested that the leading issue with respect to the understanding of requirements was the misinterpretation of requirements resulting from their ambiguity. This ambiguity was then found to lead to further issues during the verification phase where the ambiguity produced problems in understanding how to meet or exceed the requirement [28]. This aligns with other researcher's findings that a large quantity of time is expended towards the team synthesis of a mutual cognitive architecture [65].

These comments made by MedTech's directors fall in line with the findings of a study conducted on an automotive company in [10] where it was found that requirements transform from ambiguous and unstructured statements to greater defined, *traceable requirements*. It was further found that the greatest issue with respect to the requirements were their interpretation; which lead to confusion resulting from the vagueness of the requirements. The comment made by the company's engineering director, with respect to the test writing of requirements in [10], further highlights the importance, stating "*the meaning of a requirement is dependent on the prescribed verification method*" [10]. This

comment therefore suggests that testing of the requirement is critical to understanding how to meet or exceed the requirement.

Further, in the early phases prior to the establishment of any formal requirements specification, a preliminary specification was used which was founded on the "*state-of-the-art technical knowledge and assumed overall prerequisites*" which was also seen to be partial towards solutions. The requirements were not formulated until the solutions were already well known and the automotive development "*is characterized by evolution rather than revolution*" [10].

In a study of eleven industries across seven European countries (seven of which had between five and 100 employess, with the remaining four having greater than 100 employees), approximately 70% of the companies with an in-house or commercial requirements management systems controlling more than 1,000 requirements are still not implemeting requirements techniques for the extraction or discussion of requirements [66]. Reviewing these other studies in non medical device developments, one can see the challenges of requirements writing and ambiguity are not contained to that of medical device developers.

Chapter Five:
QUANTITATIVE STUDY

Archived specification documents are an example of third-degree type data, meaning they are existing artifacts that are independently analyzed by the researcher [54]. This data type is frequently comprised of documents such as: organizational charts, meeting minutes, technical documents, financial records, managerial papers, and reports. The approach needed for data of this type is multi-faceted and interconnected; therefore being impossible to give a detailed description as to how analysis should always be done [54]. However, there are commonalties throughout. For example, the analyst should strive to: recognize high level patterns, sequences, and relationships through abstraction and iteration; facilitating a clear chain of evidence to be established for the reader to evaluate the study's credibility. This can only be done by remaining systematic in one's process [54] further facilitating the need for a clearly defined protocol.

When defining the requirement analysis protocol for this thesis, an early decision was made to automate as much of the process as possible. This was done in an attempt to reduce the: cognitive load, introduction of human error, and enhance the rigor and repeatability for analysis of the large data set. For these reasons, Latent Semantic Analysis[5] and Excel were employed as detailed below.

To analyze the requirement change between revisions, Latent Semantic Analysis (LSA) as discussed in [67–76], was used for its ability to simultaneously compare

5 http://lsa.colorado.edu/

requirements and identify their similarities and differences as seen in Table 5.1 & Table 5.2.

Table 5.1 Analysis Between Revisions One and Two Where Requirement Remained Semantically Unchanged

ID	Revision 1	Revision 2
4543	*The TRCS shall provide a human user interface for the following operations, which are not necessarily carried out in the order indicated and may not be supported to occur concurrently. This interface either controls the operation fully or initiates and monitors the operation on another system.*	*The [BG-95] shall provide a human user interface for the following operations, which are not necessarily carried out in the order indicated and may not be supported to occur concurrently. This interface either controls the operation fully or initiates and monitors the operation on another system.*

Inspecting Table 5.1, while one will notice the noun change between Revisions One and Two, changing from *TRCS* to *BG-95*, both requirements address control of the device and do not change the meaning of the requirement. It can therefore be observed that the requirement remained semantically unchanged across the two revisions and receives a similarity score of one by the LSA program suggesting uniform meaning between the two requirements.

Table 5.2 illustrates that of a semantically changed requirement.

Table 5.2 Analysis Between Revisions One and Two Where Requirement Semantically Changed

ID	Revision One	Revision Two
4346	*The design of communication within the device shall not permit communication between any units not dedicated to the same Treatment Room, except communication among TRCS computers is permitted.*	*The design of network communication within the device shall be structured to limit the likelihood of a component responding to commands intended for a different component, or intended for a different treatment room.*

The semantically changed requirement has been marked and annotated for reader comparison. A semantically unchanged requirement has been defined in this thesis as a requirement receiving a score less than one by the latent semantic analysis program. For example, when evaluating the Revision One column, the information in red text is not found within the Revision Two column. Likewise, when analyzing the Revision Two column, the red text is not found in the Revision One column. In this, the rater is directed to the changed requirement, highlighted in red, and the area which received the change, written in red text. The Latent Semantic Analysis program was then run to compare requirements from: Revision One with Revision Two, Revision Two with Revision Three, Revision Thee with Revision Four, Revision Four with Revision Five, Revision Five with Revision Six, Revision Six with Revision Seven, and Revision Seven with Revision Eight. The results were then placed into the Excel document as described below.

Analysis continuation was then performed using an Excel workbook containing the eight Design Functional Specifications (DFS) revisions. Each revision was then placed on a separate Excel worksheet, producing eight worksheets plus an additional worksheet comprised of the document analysis, giving nine total. This ninth worksheet, the document analysis, is a compiled worksheet of the unique requirements identifiers, organized by revision number, whereby the quantitative analysis was performed.

Specifically, a column was created with the number of every requirement that exists across all eight revisions. There were then eight columns, one for each revision. The requirements that did not show up until revisions after the first were given a black box to designate the requirement did not yet exist. Requirements which were deleted were

followed by a red box. Redundant requirements, requirements which showed up multiple times in the same revision, were emboldened. Unchanged requirements were filled in green, reintroduced requirements were filled in dark blue, and new requirements were marked in light blue.

Requirements which were identified as changed from the previous document version were filled with yellow. Table 5.3 illustrates this further. It should be noted here, these are not representative of actual requirements in the document but rather, a means to explain the procedure.

Table 5.3: Requirement Analysis

Revision 1	Revision 2	Revision 3	Revision 4	Revision 5
1234	1234	1234	1234	1234
1235	**1235**	**1235**	**1235**	**1235**
			1235	**1235**
1236	1236	1236	1236	1236
1237	1237	1237	1237	1237
		1238	1238	1238
			1249	1249

Legend:

= unchanged requirement
= deleted requirement
= introduced requirement
= unintroduced requirement
= changed requirement
= reintroduced requirement
Bold = duplicate requirement
= requirement ID

From Table 5.3, Requirement 1234 was introduced and remained unchanged from Revision One to Revision Two. It then changed from Revision Two to Revision Three. It was then modified again from Revision Three to Revision Four. Finally, Requirement 1234 received no modifications from Revision Four to Revision Five, staying semantically the same when compared to Revision Four. Referring to Requirement 1235 one can see it is a duplicate requirement as it has been emboldened.

Referencing Requirement 1238, one can observe that it was not introduced until Revision Three where it was then deleted in Revision Four and reintroduced in Revision Five. This process can be repeated for each requirement that appears in the document analysis.

5.1 Document Analysis as a Research Tool

Document analysis can be another key component of the case study method, especially when the people of interest for the topic understudy cannot be reached [50].

Noting this, while documents alone do not provide all the contextual data needed for an understanding of the event as a whole [50], the inherent paper trail left can help others learn of past outcomes and gain a greater understanding of certain issues prior to facing a similar event [48].

Archived data is an example of *third-degree type* data, meaning they are existing artifacts that are independently analyzed by the researcher. Archived data includes documents such as: *meeting minutes, technical documents, management documents, organizational charts, financial records and reports* [54]. When working with these documents and *other third-degree data sources,* the investigator should remember that these documents were not originally created for analysis in a research case study. Meaning, it may include irrelevant data or omit other important data for political reasons or confidentiality. On the same note, *the researcher can neither control nor assess the quality of the data.* For this reason, other collection and data analysis methods must be implored to make up for the missing areas of interest [54].

5.2 Findings

Upon performing analysis of the requirements the above coding scheme was implemented to obtain Appendix C. A subset of Appendix C is presented here as Table 5.4.

Table 5.4: Presentation of Coding

Rev 1	Rev 2	Rev 3	Rev 4	Rev 5	Rev 6	Rev 7	Rev 8
Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier
4853	4853	4853	4853	4853	4853	4853	4853
4853	4853	4853	4853	4853	4853	4853	4853
	16645	16645	16645	16645	16645	16645	16645
		20846	20846	20846	20846	20846	20846

Requirement #16645 was unintroduced prior to Revision Two and would therefore add to the unintroduced requirement count (Table 5.5). Similarly, Requirement #20846 remained unintroduced prior to Revision Three and would therefore add to the unintroduced count for Revisions One and Two.

An example of an introduced requirement can also be seen in Table 5.4 where Requirement #16645 became an introduced requirement at Revision Two. Similarly, Requirement #20846 became an introduced requirement at Revision Three. Requirement #16645 was reintroduced at Revision Five since it was introduced in Revision Two, deleted in Revision Four and then reintroduced in Revision Five.

A deleted requirement example can be seen in Table 5.4 where Requirement #16645 became a deleted requirement in Revision Four, and then remained a deleted requirement for Revisions Six, Seven and Eight.

An unchanged requirement can be seen in Table 5.4, where Requirement #16645 remained semantically unchanged from Revision Two to Revision Three. Similarly, Requirement #20846 remained semantically unchanged from Revision Four through Revision Eight.

An example of a duplicate requirement can also be seen in Table 5.4, for Requirement #4853. Where, the requirement was in two locations for Revision One, however was deleted from one location in Revision Two.

Using the coding scheme found in Table 5.3 and Table 5.4, a summary of results is created in Table 5.5. Reverting to Table 5.5, the reader is presented with the number of requirements in each revision, number of unintroduced requirements, number of introduced requirements, number of deleted requirements, number of reintroduced requirements, number of modified requirements, number of unchanged requirements from the previous revision, cumulative number of requirements changes, global change from previous document and total number of requirements generated to date.

Table 5.5: Quantitative Summary of Requirement Data

	R1	R1-R2	R2-R3	R3-R4	R4-R5	R5-R6	R6-R7	R7-R8
No. of requirements in revision	556	786	780	354	491	354	353	356
No. of unintroduced requirements	447	195	175	77	10	10	4	0
No. of introduced requirements	556	252	20	98	67	0	6	4
No. of deleted requirements	0	22	26	524	17	154	8	1
No. of reintroduced requirements	0	0	0	0	87	17	1	0
No. of modified requirements	0	175	182	252	258	252	33	9
No. of unchanged requirements from previous revision	556	359	578	4	79	85	313	343
Cumulative number of requirements changes, CRC	0	175	357	609	867	1119	1152	1161
Global change from previous document	N/A	230	-6	-494	137	-137	-1	3
Total number of requirements generated to date	556	808	828	926	993	993	999	1003

Five critical events are identified from Table 5.5 1) the number of introduced requirements from Revision One to Revision Two shown in orange, 2) the number of requirements in Revisions Four, Six, Seven and Eight shown in green, 3) number of deleted requirements in Revisions Four and Six shown in blue, 4) number of modified requirements in Revisions Four and Six shown in purple and, 5) number of unchanged requirements from the previous revision in Revisions Four and Six shown in red. The five events primarily surrounded the time frame between Revision Four and Revision Five, leading to a new question: *what are the influences on requirement behavior?*

With the observations found from analysis of Table 5.5, a plot of company events with requirement revision release was created as seen in Figure 5.1. Figure 5.1 can also be seen in larger format in Appendix D.

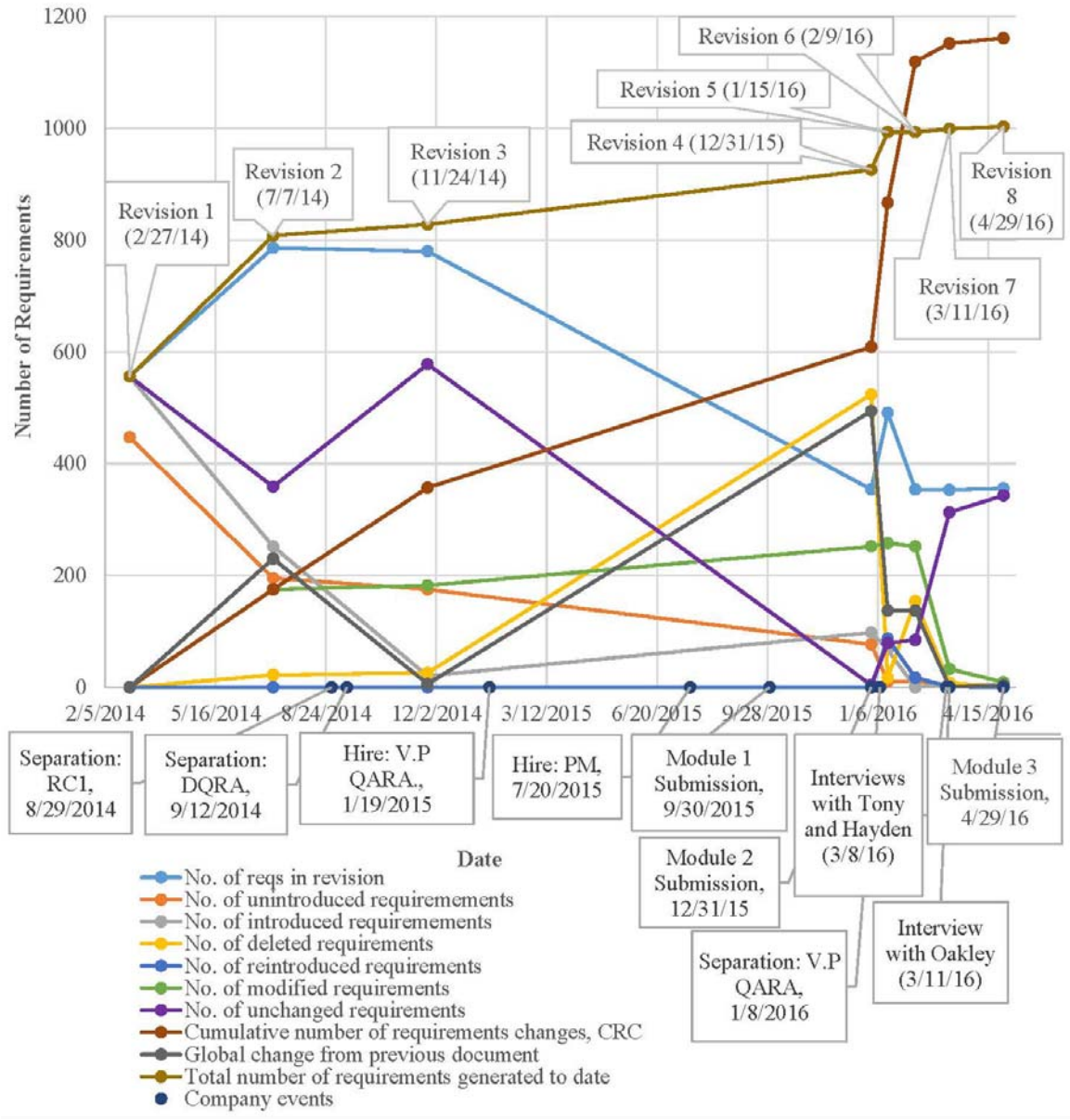

Figure 5.1: Longitudinal View of Data Analysis

Inspecting Figure 5.1, from Revision One to Revision Two it can be seen that a positive trending exists between the total requirements generated to date, number of requirements in revision, global change from previous document, cumulative number of requirement changes and number of deleted requirements. However, a decreasing trend exists between the number of introduced requirements, number of unchanged requirements, and number of unintroduced requirements. No reintroduced requirements exist between Revisions One and Two. This was a 130 day span. Inferences of what these observations may mean are further discussed in Section 5.3

During the timespan from Revision Two to Revision Three an increasing trend is shared between the total number of requirements generated to date, number of modified requirements, number of unchanged requirements and cumulative requirements changes. However, a decreasing trend can be seen between the number of requirements in revision, number of unintroduced requirements, number of introduced requirements and global change from the previous document. A near parallel tracking between 1) the number of unchanged requirements and cumulative number of requirements changes, and 2) the number of introduced requirements and global change from the previous document can also be observed. No reintroduced requirements exist. The reader can also observe the separation of the company's first requirements comptroller (RC1 in Figure 5.1), and Director of Quality and Regulatory Affairs (DQRA in Figure 5.1). This was a 140 day span.

Reviewing the timeframe between Revision Three and Revision Four, an increasing trend between total number of requirements generated to date, cumulative number of

requirements changes, number of deleted requirements, global change from previous document, and number of introduced requirements can be observed. However, a decreasing trend between number of requirements in revision, number of unintroduced requirements and number of unchanged requirements is observed. No reintroduced requirements exist. During this period the company also brought on board a Quality Assurance & Regulatory Affairs member (V.P QARA in Figure 5.1), project manager (PM in Figure 5.1), and submitted Module 1. This was a 402 day span.

Moving to the time span between deployment of Revisions Four and Five, an increasing trend was observed between total number of requirements generated to date, cumulative number of requirements changes, number of requirements in revision, number of reintroduced requirements, number of unchanged requirements and number of modified requirements. Decreasing trends were found to exist between the global change from previous document, number of deleted requirements, number of introduced requirements, and number of unintroduced requirements. During this time span, Module Two was submitted, and separation between MedTech and its Vice President of Quality Assurance & Regulatory Affairs (V.P QARA in Figure 5.1) occurred. This was a 15 day span.

Analyzing the timeline between Revisions Five and Six, an increasing trend was shared between the cumulative number of requirements changes, number of deleted requirements, and number of unchanged requirements. However, a decreasing trend was found between the number of modified requirements, number of requirements in revision, number of reintroduced requirements and number of introduced requirements. This was a 25 day timespan. No company events are reported.

Looking at the timespan between Revisions Six and Seven, an increasing trend can be seen between the total number of requirements generated to date, cumulative number of requirements changes, number of unchanged requirements, and number of introduced requirements. However, a decreasing trend exists between the number of modified requirements, number of deleted requirements, global change from previous document, number of reintroduced requirements, number of requirements in revision, and number of unintroduced requirements. Interviews with Tony, Hayden, and Oakley also occurred during this time. This is a 31 day time span.

Looking at the period between Revisions Seven and Eight, an increasing trend exists between the cumulative number of requirements changes, number of unchanged requirements, total number of requirements generated to date, number of requirements in revision, and global change from previous document. However, a decreasing trend exists between the number of modified requirements, number of deleted requirements, number of introduced requirements, number of unintroduced requirements, and number of reintroduced requirements. Upon completion of this 49 day time span, Revision Eight and the final regulatory module were submitted. Section 5.3 further discusses possible meanings to these observations.

5.3 Analysis Discussion

The approach taken for data analysis was both manifold and interconnected. Through this approach commonalties were observed via generalizations with respect to patterns, relationships, and sequences in the data. These generalizations suggest the subsets of requirements comptroller, government regulation, and requirements learning curve.

Subsets were then found to be housed under the greater structure of an emerging requirements culture. These observations were seen through iteration and are further supported by the chain of evidence established via synthesis of the interview and document artifact analyses. Deeper discussion to the requirements comptroller, government regulation, and requirements learning curve inherent to MedTech's developing requirements culture is presented in the following sections.

5.3.1 Requirements Comptroller

Graphical display of the number of newly introduced requirements over the eight revisions can be found in Figure 5.2

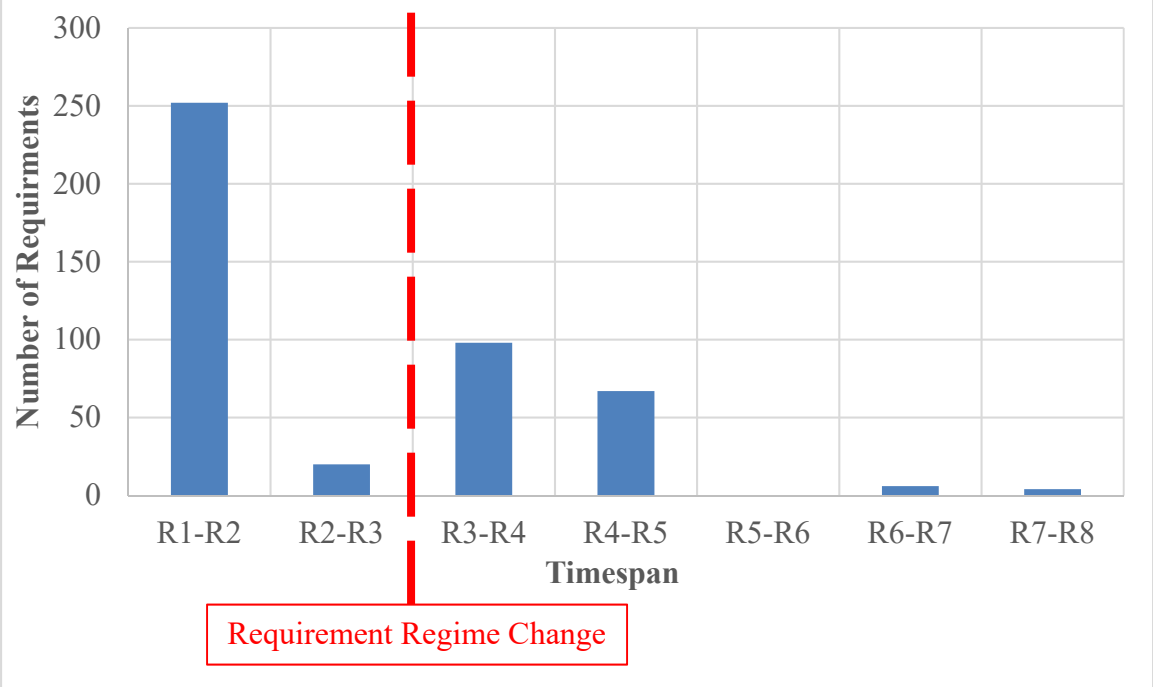

Figure 5.2 Number of Newly Introduced Requirements

Referencing Figure 5.2, these are the requirements which are new to the design, ones which had not been generated previously. These requirements may therefore be interpreted as the "new knowledge" or "new insight" coming into the problem/product interaction. As one would may expect, a large quantity of new knowledge occurs early in the design process and is visually seen in Figure 5.2 during the period between: Revisions One and Two, Revisions Three and Four, and Revision Four through Revision Five. However, a noticeable difference can be observed over the time period between Revisions Two and Three. Analyzing further and reverting to Figure 5.1, this is the same time period in which the company's Director of Quality and Regulatory Affairs separated from the company and the beginning of the current comptroller's control over the requirements document for the duration of the design period. It can be posited here that a transition was in place as ownership of the documents changed. This transition was then further supported when it was seen that Medtech's first comptroller's name had been replaced with the company's current comptroller name from Revision Three to Revision Four. One should also note the separation of MedTech's former requirements' comptroller during this period suggesting a flux within the company as requirement control transferred, further substantiating a correlation between requirement change and requirements comptroller.

Document analysis further presented the influence of requirement comptroller as depicted in Figure 5.3.

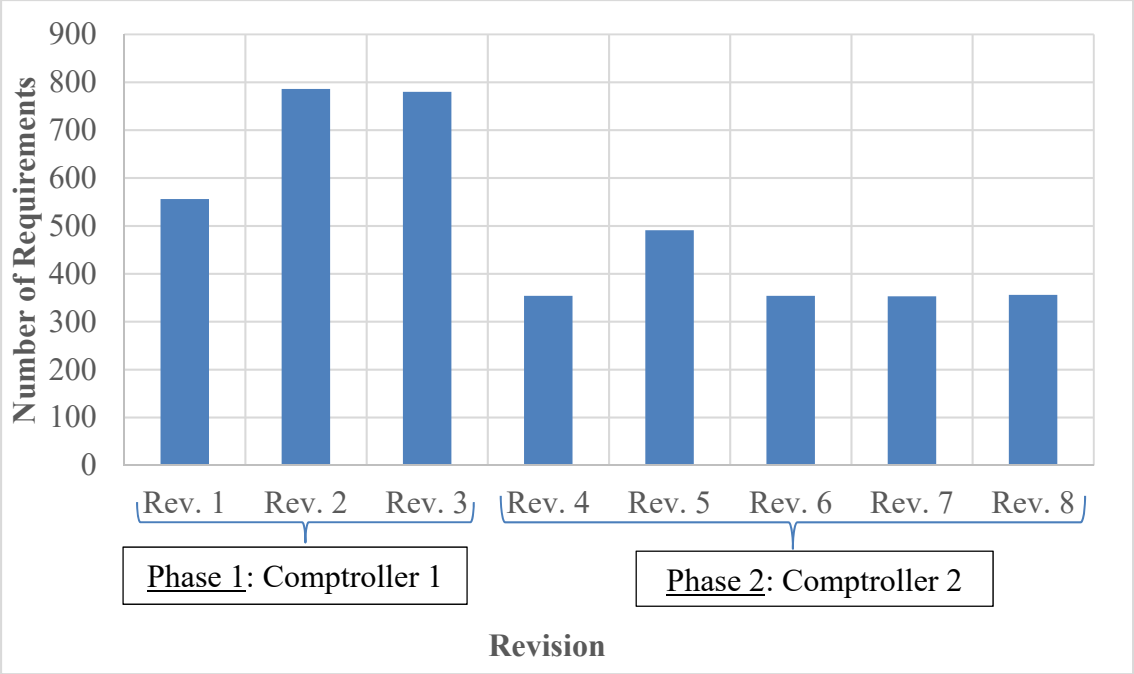

Figure 5.3 Number of Requirements in Each Revision

Upon project deployment 556 requirements were introduced. During Revisions Two & Three requirements increased by over 200 and maintained steady at ~780 requirements/ revision. Reviewing Figure 5.3, one can see that during the period of Revision One through Revisions Three, now referred to as Phase One, marked the era of the former requirements comptroller. Transitioning into Phase Two, consisting of Revisions Four-Eight, it can be seen that the number of document requirements was nearly cut in half with Revision Four now consisting of 354 requirements. This marks a clear shift in comptroller influence as further substantiated by one director's statement that the document's former owner's understanding of requirements was one which "*almost anticipated design*" (Tony, 3/8/16), essentially stating a design solution rather than a testable requirement. One can further see a possible pattern emerging when comparing the

two phases, thus comparing requirement behavior under the different comptrollers' command. On can see a requirement foundation set in the beginning revision releases, followed by a subsequent increase in requirements during the middle revision releases, with a decline in requirements during the final revision releases.

Table 5.6 Takeaways

Takeaways	Design Period
Largest introduction of design requirements occurs during project initiation and time period immediately proceeding change in requirement comptroller.	Revision 1-Revision 5
Introduction of novel design requirements decays with time.	Revision 1-Revision 8

5.3.2 Business Influence on Requirements Scope

Highlighting the time frame between Revision Three and Revision Five, Figure 5.4 was created.

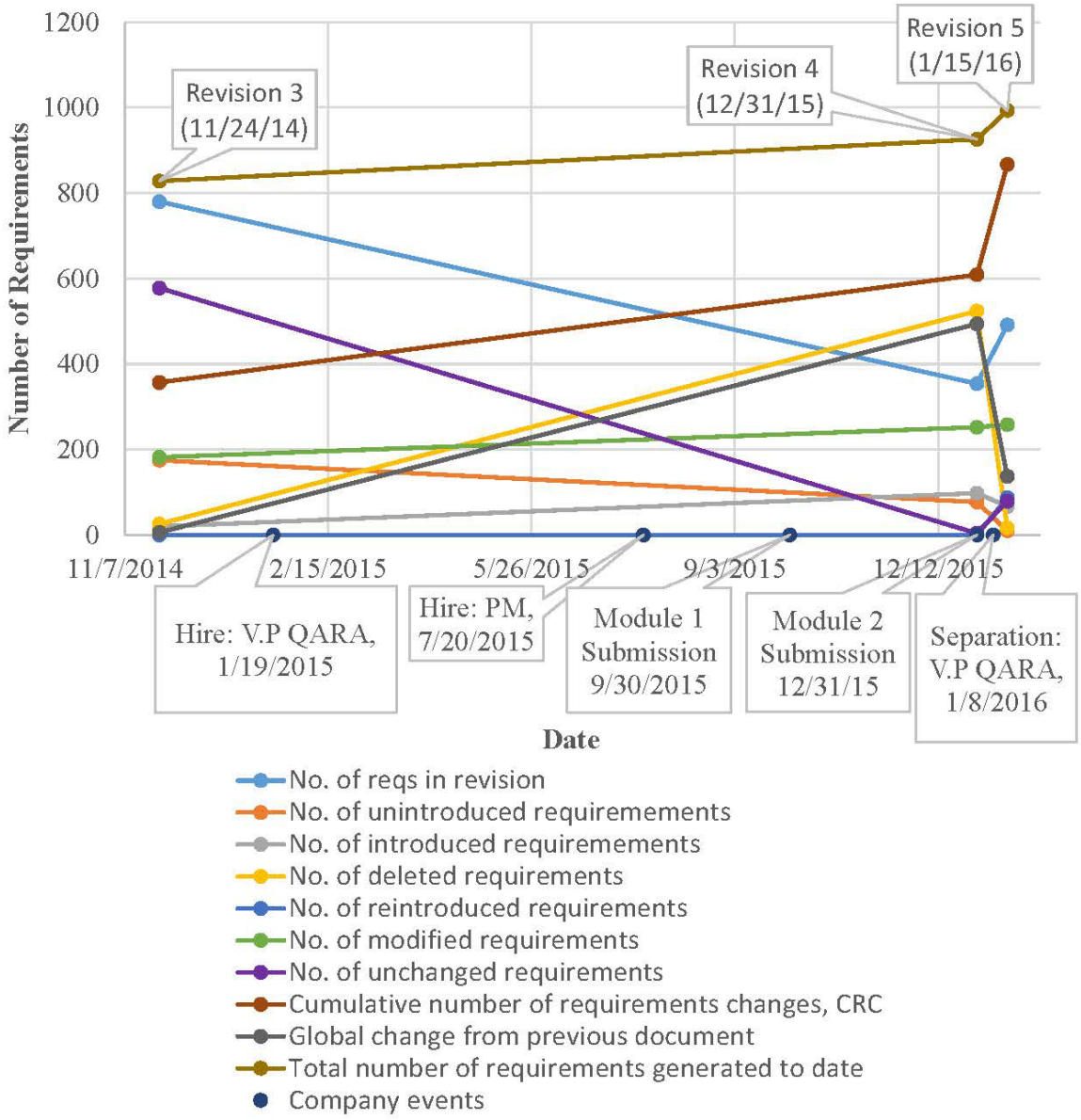

Figure 5.4 Design Timeline Between Revision Three and Revision Five

Reviewing Figure 5.4 further it can be seen that two of the three module releases were submitted during this timeframe with the company experiencing significant requirements change between Revisions Three and Five as 524 requirements were deleted in the company's Revision Four when compared with Revision Three. Behavior of the

deleted requirements over the eight revisions was therefore extracted and is presented graphically in Figure 5.5.

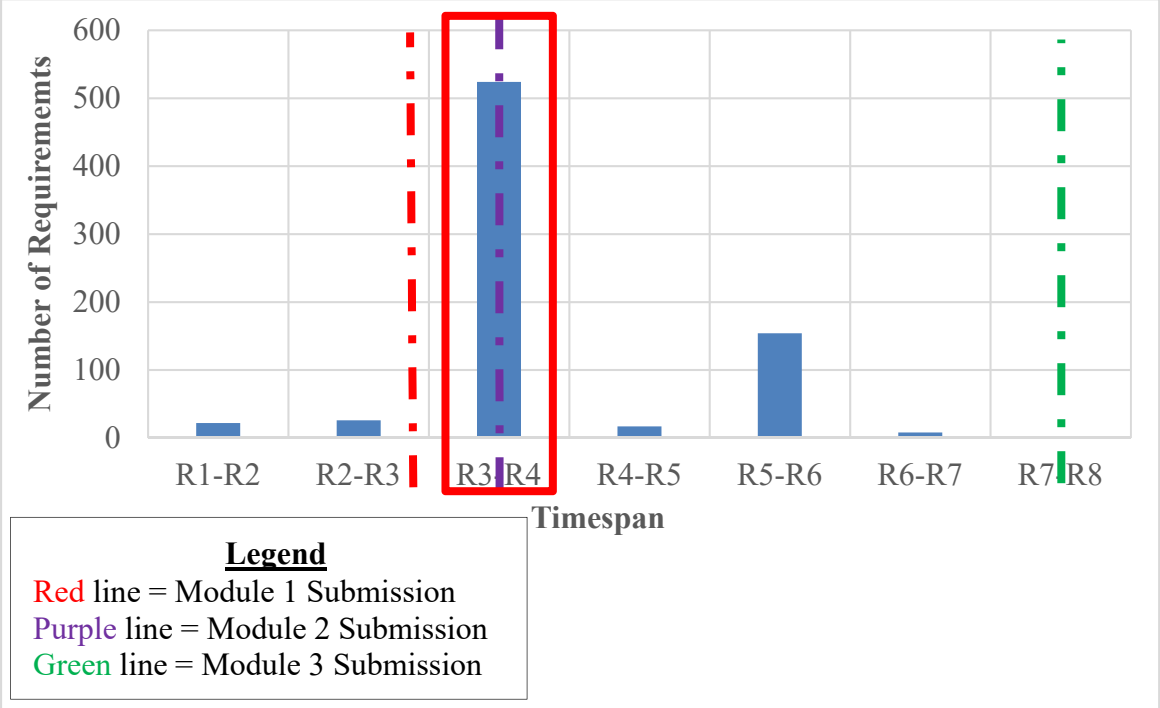

Figure 5.5 Number of Deleted Requirements Over Eight Revision Releases

In performing this deletion in conjunction with the addition of 98 new requirements, the DFS decreased from 780 requirements in Revision Three to 354 requirements in Revision Four. As requirements are the "fence" surrounding the design space, the designs permissible may have greatly increased as requirements reside in the problem domain. However, as ideally designs converge on a single solution, therefore imposing new requirements while maintaining old requirements, with decreasing fluctuations as time elapses, the deletion of nearly halve the total requirements document became a point of interest. Upon analysis of this reduction, a shift in design focus became evident as the design space nearly doubled. Following the trend line in Figure 5.4 further,

it was seen that the number of reintroduced requirements increased in the release (Revision Five) following the previously mentioned release (Revision Four) as seen in Figure 5.6.

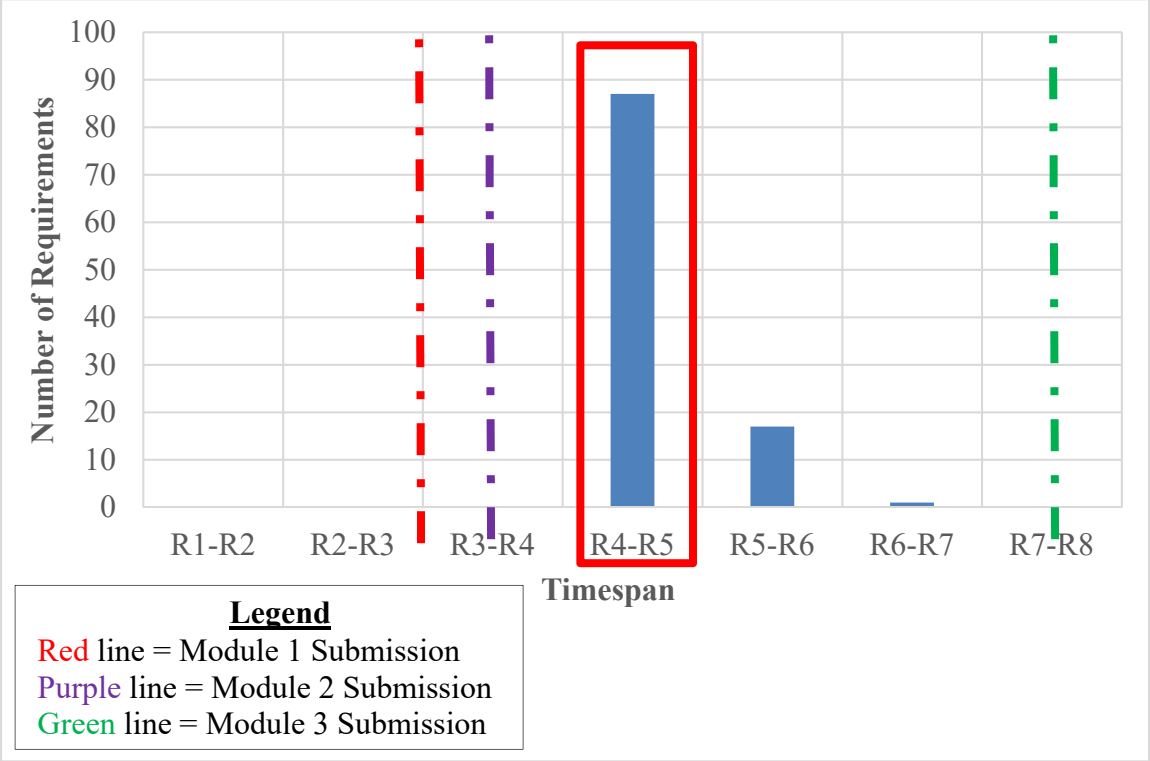

Figure 5.6 Number of Reintroduced Requirements

Reviewing Figure 5.6, 105 reintroduced requirements are seen to exist over the project lifetime, with 87 of those occurring between Revisions Four and Five. This is important to note as past and present requirements should be properly documented and retained (including those which have previously been deleted) as deleted requirements often come back later in the project [77].

Synthesizing Figure 5.6 with Appendix C, it can be observed that each of the 87 reintroduced requirements of Revision Five were deleted in Revision Four. However, each was also subsequently re-eliminated in Revision Six. Reflecting on this period further, the

period between Revisions Three and Four experienced the largest amount of deleted requirements of any requirement release and was therefore posited that a shift in product vision had occurred. Through follow up questioning with MedTech's President, a "*business and strategic influence on requirements scope*" was learned aligning with the empirical document findings and researcher posit.

5.3.3 Requirements Learning Curve

Reflecting on the comments obtained during interview analysis, a requirements learning curve was identified and was subsequently supported upon document analysis as presented in the following discussion.

Using Table 5.5, an illustration of the number of modified requirements was created as seen in Figure 5.7

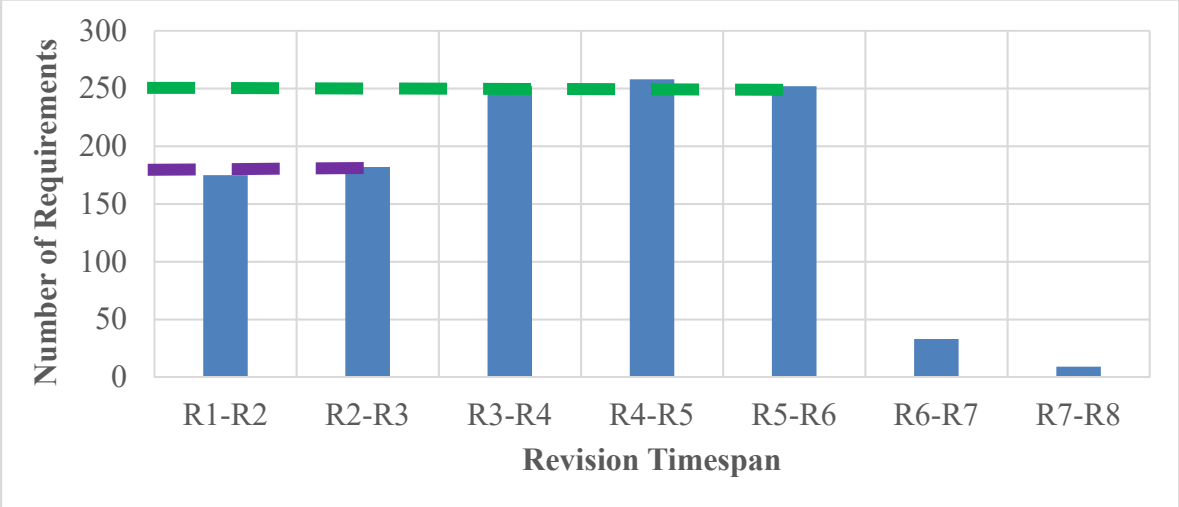

Figure 5.7 Number of Modified Requirements for Each Revision

Reverting to Figure 5.7, the reader can see that the number of requirement modifications during the first two revision releases remained ~175 modifications for each

revision. However, as the organization's understanding of requirements increased during the period between release of Revision Three and Revision Six, they were forced to "retool" their requirements to reflect this greater understanding. As time continued to progress however, their requirement modifications decreased and their quantity of unchanged requirements increased as shown in Figure 5.8

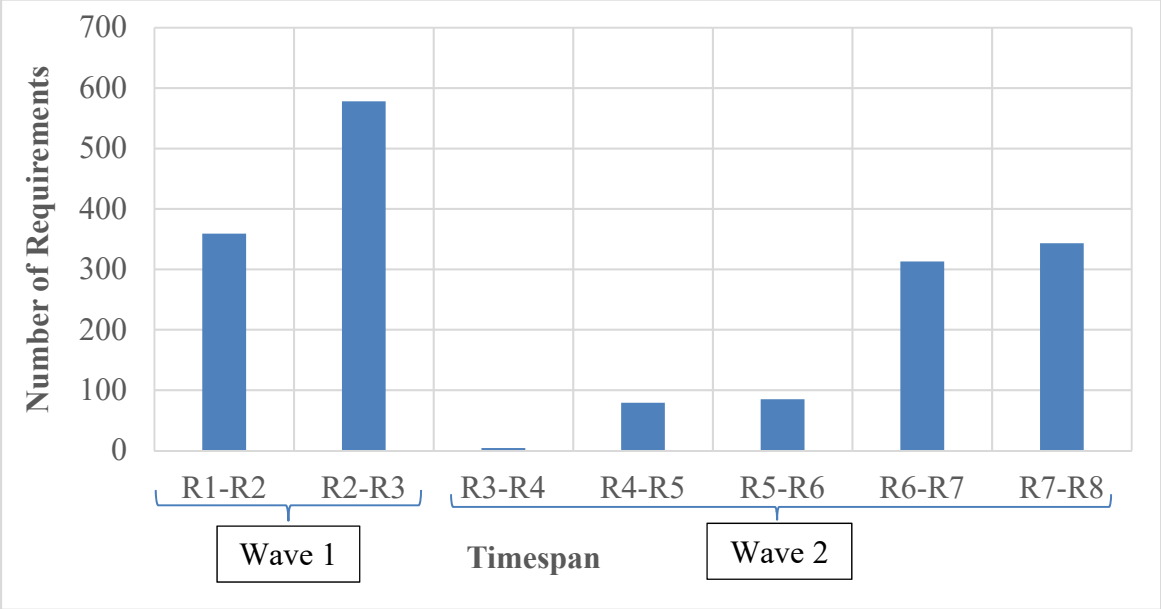

Figure 5.8 Number of Unchanged Requirements

While it may seem obvious to some that if the company's number of modified requirements decreases, their number of unchanged requirement increases. However, this is not always the case. Figure 5.8 depicts that just because a requirement is not modified does not necessarily mean it is unchanged, as it may also become deleted. Figure 5.8 therefore illustrates the requirements which are strictly unchanged for each revision, quantitatively documenting the company's learning process. Reflecting further on

Figure 5.8, one should note the wave like formation observed. The first wave, consisting of Revisions One through Three, suggests convergence on a solution as a high number of requirements remain unchanged, suggesting little change in problem understanding as requirements exist in the problem domain. This is further important to note when observing how early this is in the development process where it is posited that requirements are highly volatile and consistently changing. This high volatility of requirements however is seen in the second wave consisting of Revisions Four through Eight. It is the belief of this author that this is where the company's requirement learning truly begins and is further illustrated in Figure 5.9.

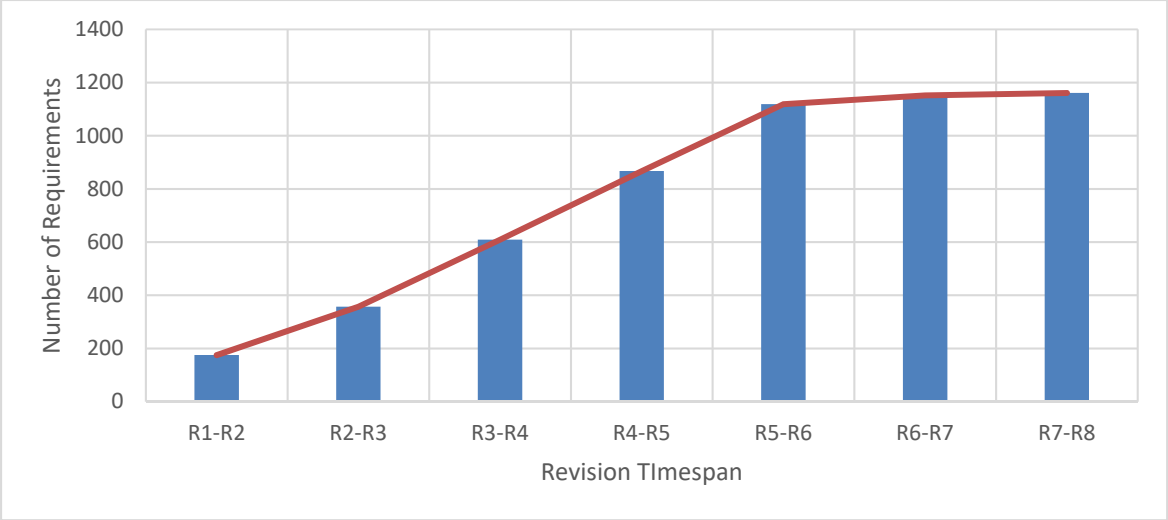

Figure 5.9 Cumulative Number of Requirements Changes

Investigating Figure 5.9, one is presented with a global view of the number of requirements changes. It can be seen from Figure 5.9 that an inclining slope of requirement changes occurs early in the design process until Revision Six where Revisions Six through

Eight flatten, showing little change in requirements and therefore problem understanding by the company.

5.3.4 What this Suggests

Reviewing Figure 5.2, Figure 5.3, and Figure 5.5-Figure 5.9, a state of requirement equilibrium emerges as the number of: newly introduced requirements, revision requirements, deleted requirements, reintroduced requirements, modified requirements and unchanged requirements settle during Revisions Seven and Eight. To further analyze this phenomena Figure 5.10 was created.

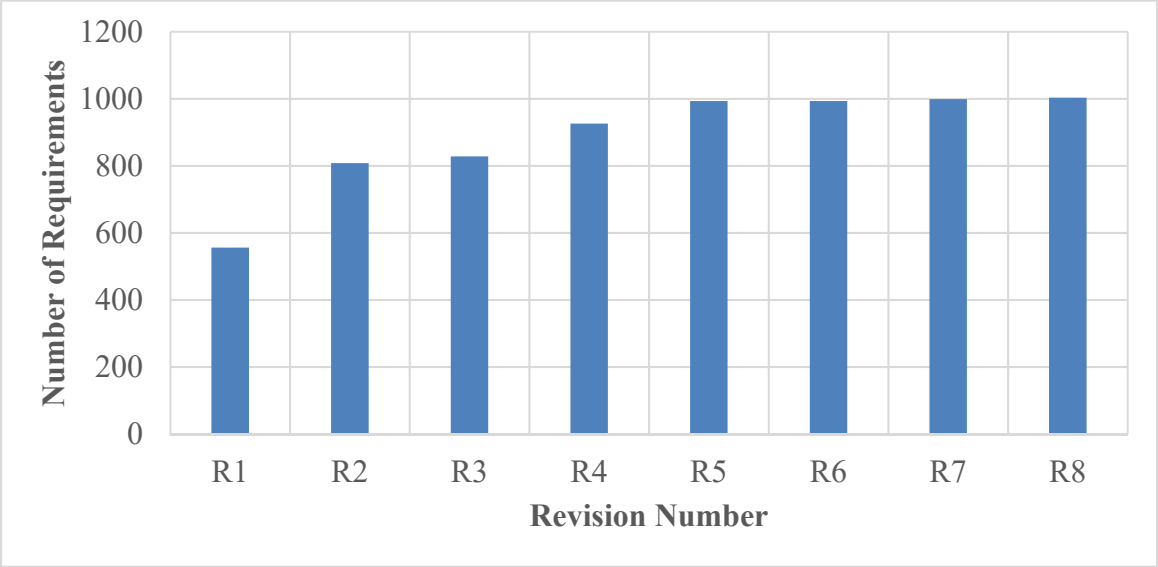

Figure 5.10 Total Number of Requirements Generated to Date

Through creation of Figure 5.10, a global view of requirement activity is captured. In this capture, one can see that a problem understanding appears to be reached by Revision Five as shown by the flat lining of generated requirements from Revision Five through Revision Eight. This suggests that although problem details were developing post Revision

Five, problem understanding was achieved upon Revision Five's deployment. One should also note the similar findings from an avionics case study in [2], where it was found that the total requirement count increased over the course of project development. From observation of Figure 5.10, it became of interest to investigate the lifetime of individual requirements. Findings from this investigation are shown in Table 5.7.

Table 5.7 Requirement Lifetimes

# reqs living 8 revs	# reqs living 7 revs	# reqs living 6 revs	# reqs living 5 revs	# reqs living 4 revs	# reqs living 3 revs	# reqs living 2 revs	# reqs living 1 revs
185	62	8	83	78	292	170	125

Reviewing Table 5.7, one can observe that 185 requirements lived for eight revisions, 62 requirements lived for seven revisions, eight requirements lived for six revisions, 83 requirements lived for five revisions, 78 requirements lived for four revisions, 292 requirements lived for three revisions, 170 requirements lived for two revisions, and 125 requirements lived for one revision.

One should note here that the values in Table 5.7 account for how many times the requirement appeared throughout its lifetime. For example, if a requirement was introduced in Revision One and was maintained though to Revision Eight, only being changed or modified, it is considered to of lived for eight revisions. If a requirement was introduced in Revision Four, deleted in Revision Five, reintroduced in Revision Six and then remained deleted in Revisions Seven and Eight it is accounted as having a two revision lifetime. That is, it lived during Revisions Four and Six.

Referring back to Table 5.7, this means that 185 of the 356 requirements in Revision Eight were present from the beginning, although they may have been modified throughout the design's development. In essence, ~50% of the requirements of Revision Eight came from Revision One, although they may have been modified throughout the development process. Similar findings have been obtained during analysis of automotive requirements in [6], where it was found that as many as fifty percent or more of a system's requirements may change prior to project completion. Thus, similar requirement evolution behavior can be seen to cross discipline boundaries. It became of interest to investigate the requirements which were introduced and remained unchanged throughout their lifetime's totality. For example, in order for a requirement to qualify as unchanged for eight revisions it must have been introduced in Revision One and received no changes through Revision Eight according to the Latent Semantic Analysis conducted and discussed earlier in Chapter Five. In order for a for a requirement to qualify as unchanged for five revisions, it must have been introduced in Revision Four and remained unchanged according to Latent Semantic Analysis though Revision Eight.

The same can be said for that of the others analyzed and presented in Table 5.8. Essentially, these are the requirements which engineers got right the first time.

Table 5.8 Number of Requirements That Were Introduced and Consecutively Remained Unchanged Over Their Lifetime

unchanged for 8 revs	unchanged for 7 revs	unchanged for 6 revs	unchanged for 5 revs	unchanged for 4 revs	unchanged for 3 revs	unchanged for 2 revs	unchanged for 1 revs
3	0	0	23	0	0	6	4

Reviewing Table 5.8, it is shown that three requirements remained unchanged throughout all eight revisions, 23 requirements remained unchanged throughout five revisions, six requirements remained unchanged throughout two revisions, and four requirements remained unchanged throughout one revision. As requirements exist in the problem domain, these findings suggest that the problem space these three requirements enclose were known from the project's beginning. The problem space that the 23 requirements enclose which were unchanged for five revisions suggest that this space was understood by designers from Revision Four forward. The requirements referred to in Table 5.8 can be seen in Appendix C and Appendix E and are saved for future analysis during the author's doctoral studies.

Chapter Six: EPILOGUE

Despite research into requirements engineering practices, companies are largely not adopting these practices [78]. This, coupled with the fact that many of the requirements evolution challenges are cultural in nature, suggests the need for further research into current company requirements cultures. This need has further been identified in literature, resulting from intercultural research becoming progressively more important in globalized industry settings [29]. However, in spite of this increasing significance, academics and scholars rarely employ empirical cultural studies to analyze their findings. This lack of use should not be overlooked, as empirical cultural studies are necessary to interpret differences in culture at a deeper level than behavior [29]. Moreover, as no mutually accepted definition of *culture* or a means to measure it currently exists, a debate persists regarding the soundness of the current data used to define *culture* and its definition [29].

As this is a single study at a medical device developer, one should exercise caution when extrapolating to alternative environments and organizations. In an effort to provide increased transparency and rigor, the case study methodology has been implemented throughout. In this, systematic and traceable research has been conducted to enable replication by other researchers. Interview and document analysis protocols were created, and are available in Appendix A and Appendix B for reader review. Moreover, triangulation of: personnel (Software, Systems, and Engineering directors), document analysis (requirements and transcripts), and literature was conducted.

In performing requirement culture studies, cultural awareness learned from one environment may assist others in different environments by providing insight into overlapping issues and challenges. As engineering design remains deficient to the complexity of large projects and organizations [11,28], a major recommendation from this study is that there exists a need to greater understand company cultures *in situ*, especially as they relate to views and influences on requirements. Similar requirement behavior was found to exist across medical, avionic [2], and automotive domains [6], irrespective of project size; this work therefore provides quantitative and qualitative insight to the posit that requirement evolution may occur similarly across domain boundaries despite project size.

6.1 Conclusions

Concluding this thesis, findings suggest the emergence of a requirement culture at the company of study. Moreover, findings suggest requirement change influences stemming from requirement comptroller, government regulation, and requirement learning curve.

Answering the question "does a requirement culture exist at the company of study?", findings suggest that a requirement culture does exist at MedTech. Justification for this inference can be found when looking to the components of *communication, people, symbols, activities, and values* inherent to a culture, with a requirements culture emphasizing meeting system functionally and performance characteristics.

In review of the requirement culture aspects above, one can see MedTech's involvement in each cultural aspect. Specifically, MedTech's involvement with requirement meetings, emails, and discussions fulfill the *communication* component. An example triangulation on the *communication* component can be seen in Oakley, Hayden and Tony's comments below.

> *"This started as a [Microsoft] Word document and so yeah there were lots of Word documents that floated around that were passed to many people and then they would make comments and stick their name or date at the end of it" (Oakley, 3/11/16).*

> *"Every time there was an iteration of these requirements we had a systems engineer that would meet with those individuals that were responsible for that particular design and really kind of hammered in is this requirement what we need and how does it need to be shaped." (Hayden, 3/8/16)*

> *"A new review of the document, it goes to multi- stakeholders for review and it's circulated internally before them" (Tony, 3/8/16)*

Reviewing Oakley, Hayden, and Tony's comments above, one can see how the *communication* component of a requirement culture is fulfilled at MedTech through the performance of communication throughout the departments. Next, the company's personnel involvement of physicists, clinicians, and engineers fulfills the *people* component of a requirement culture. An example triangulation on the *people* component can be seen in Oakley, Hayden, and Tony's comments below.

> *"The systems engineering group here, which is five people, we discuss changes to that document if they are necessary. Looking at ramifications for test and hazard." (Oakley, 3/11/16)*

"We had a lot of [domain] experts that really helped shape the product from the beginning. So it was really about getting all the requirements out of their head onto the paper" (Hayden, 3/8/16).

"Definitely there is multi-stakeholder review. So we have for that process all the different areas represented we identify so somebody then can take a look at the change request take a look at the defect and identify where it comes from." (Tony, 3/8/16)

Reviewing Oakley, Hayden, and Tony's comments above, one can see how the *people* component of a requirement culture is fulfilled through the incorporation individuals across multiple domains. MedTech's performance of verification and validation (V&V) consisting of testing, documenting, and output of requirements documents outlining system functionality and performance characteristics fulfills the *activities* component. An example triangulation on the *activities* component of a requirement culture can be seen in Micah, Oakley, and Tony's comments below.

"We used an essential requirements strategy for 510(k) submission, however, all requirements are a part of V&V prior to first patient treatment." (Micah, 2/28/17)

"The other thing that has had the biggest impact on change of requirements at the DFS level is how testable they are. What you really don't want is a bunch of subjective requirements because they are very difficult to test… So that's the refinement of requirements that's been done for test purposes. No one was writing test purposes a year ago or two years ago." (Oakley, 3/11/16)

"I think part of that was actually looking at the tests. I think people didn't realize at some point these requirements need to be testable" (Tony, 3/8/16)

Reviewing Micah, Oakley, and Tony's comments one can see how the *activities* component of a requirement culture is fulfilled through the importance placed on the activity of verification and validation. Finally, the member's thoughts on how requirements ought to be specific and testable with a shared requirement architecture throughout the company fulfills the underlying *value* cultural component. An example triangulation on the *values* aspect of a requirements culture can be seen in Oakley, Hayden, and Tony's comment below.

> *"In the end those requirements really weren't requirements. They were strong design suggestions. Some of them weren't requirements at all. They were choices made to implement the design. So they were design outputs instead. Results of doing the design itself and knowing this really was never a requirement to begin with. A choice you made." (Oakley, 3/11/16)*

> *"So there was a requirement must be in metric. Well that's not really an FDA requirement. But manufacturing wanted everything in metric. It's easier for them. So I understand but that's more of a stakeholder requirement. That's what kind of happened over time it just started kind of really trying to deliver and write objective tests to these requirements … So we can start parsing out what's a stakeholder requirement or a marketing requirement or it's a competitive benchmark. (Hayden, 3/8/16)*

> *" So we paid a little bit of the price there because we had as people now started getting into actually using these requirements it became clear that these were not requirements at all. So we actually had to go through a fairly painful process of retooling our requirements" (Tony, 3/8/16)*

Reviewing Oakley, Hayden, and Tony's comment above, one can see how the underlying *values* aspect of culture is fulfilled through the company's value placed on authoring testable requirements. It should be stated here that the requirements themselves, as analyzed in this thesis, fulfill the *symbols* cultural component. Recognizing the cultural

elements (*communication, people, symbols, activities,* and *values*), with an emphasis on meeting system functionality and *performance characteristics*, it is inferred that a requirement culture exists at the company of study, answering the question "does a requirement culture exist at the company of study?".

Referencing MedTech's inferred requirement culture, one can observe influences from the culture resulting in requirement change, as outlined in this thesis. Interview and document analysis findings suggest influences from MedTech's requirement culture on its requirements to be requirement comptroller, government regulation, and requirement learning curve. A shift in requirements comptroller resulting in requirement change suggests an internal governance component to MedTech's requirement culture, as discussed in Sections 4.4.1, 4.5.1, and 5.3.1. Government regulation prompting change to business and requirement scope suggests an external governance component to the company's requirements culture, as discussed in 4.4.2, 4.5.2, and 5.3.2. Team synthesis towards a shared requirement understanding suggests an education component to MedTech's requirement culture as discussed in Sections 4.4.3, 4.5.3, and 5.3.3. This aligns with the literature, as one can see the criticality and motivation for proper documentation, and facilitation of requirements rooted in a sound requirements culture.

As changes to requirements may result in prolonged development, increased costs, and unnecessary expenditure of company resources, greater understanding of requirements cultures may lead to increased understanding of requirement change influences. An interview protocol is developed for interviews across systems, software, and engineering directors at the company of study, and may be used for replicative studies in other domains.

A requirement document analysis protocol is developed for use by other requirement researchers to analyze requirement evolution. This thesis lays the foundation for future work in requirements research as discussed in Section 6.2.

6.2 Future Work

When surveying current requirements change literature, one can see the predominate area aim to greater understand the change of requirements by looking at the entire specifications document and identifying individual requirements which may be most susceptible to change. However, little effort is expended to understand the phenomena of the change. This is further compounded when one sees the greater need for developing tools and techniques to manage the change. Specifically, a deeper dive in needed into the realm of local requirement change, which could afford a greater global accuracy analysis to be conducted when aiming towards greater requirement change propagation prediction [6].

Future expansion from this thesis could include local syntactical requirement analysis on the MedTech requirement data set using the requirements change propagation predication tool (RCPPT) developed in [6]. In using the RCPPT, nouns, verbs, and user selected keywords may be analyzed to research the ability of requirements to be used to predict requirement change propagation. In this first approach, one may ask the research question *can MedTech's medical device requirements be used to predict change propagation at the company of study?* Through use of the company's eight requirements documents, consisting of more than 1,000 requirements, one may feed the requirements into the RCPPT to investigate possible relationships between requirements which may aid

in the prediction of requirement change propagation. In performing this second approach, one may ask the research question *what types of relators exist between MedTech requirements which may predict change propagation at the company of study?* In answering this second research question, one may discover relators between MedTech requirements which may aid designers in a greater ability to gauge the impact of proposed requirement changes. Requirement relators may exist in the form of part of speech relationships, such as noun, verb, or user selected keyword. In greater understanding these requirement relators, one may then obtain the ability to develop a weighting system to be implemented for the ranking of requirements in terms of likelihood of requirement change. In this, a third research question may be *can a weighting system be implemented on MedTech requirements to gauge likelihood of requirement change at the company of study?* In approaching this third research question, one may develop a weighting system which characterizes the likelihood of requirement change at the company of study. This weighting system may then be validated on the company's eight requirement revision dataset, and subsequently verified on other requirement datasets such as the Toho, Pierburg, and EVRAZ datasets outlined in [6]. If a pattern is found to exist amongst these industry case studies, one may then wish to impose these three research questions on senior design project requirements to compare and contrast the similarities and differences in senior design requirements with that of industry requirements. This analysis on senior design requirements may then prompt a fourth research question, *do senior design project requirements behave similar to that of the MedTech, Toho, Pierburg, and EVRAZ datasets?* A summary of future research questions may be seen in Table 6.1.

Table 6.1 Future Research Questions

FRQ Number	Future Research Question (FRQ)
1	Can MedTech's medical device requirements be used to predict change propagation at the company of study?
2	What types of relators exist between MedTech requirements which may predict change propagation at the company of study?
3	Can a weighting system be implemented on MedTech requirements to gauge likelihood of requirement change at the company of study?
4	Do senior design project requirements behave similar to that of the MedTech, Toho, Pierburg, and EVRAZ datasets?

6.3 Summary

Summarizing the contents of this thesis, Table 6.2 was created.

Table 6.2 Summary of Research

Research Question	I. Does a requirements culture exist at the company of study? a. If so, do personnel perceive cultural influences? b. If so, are influences observed in requirement artifact analysis?
Posits	Ia) Requirement culture exists at the company of study, with personnel experiencing multiple influences during product development. Ib) Requirement culture exists during company formation and will be reflected over the course of requirement evolution.
Approach	Ia) Conduct interviews with software, systems and engineering directors. Ib) Requirement artifact analysis over release of eight requirement document revisions consisting of more than 1,000 requirements.
Summary of Conclusions	Upon interview and requirement document analysis, a requirements culture was evinced to exist with cultural influences being that of a requirements comptroller, government regulation, and requirements learning curve.
Conclusion Justification	Findings of *communication, people, symbols, activities,* and *values,* with an emphasis on meeting system functionality and *performance characteristics,* suggests a requirement culture exists at the company.
Deliverable Articles	Chapter Four & Chapter Five of thesis.
Future Research Questions	1) Can MedTech's medical device requirements be used to predict change propagation at the company of study? 2) What types of relators exist between MedTech requirements which may predict change propagation at the company of study? 3) Can a weighting system be implemented on MedTech requirements to gauge likelihood of requirement change at the company of study? 4) Do senior design project requirements behave similar to that of the MedTech, Toho, Pierburg, and EVRAZ datasets?

Reviewing Table 6.2, one is presented with the posit, approach, conclusion, and deliverable article answering the question "*does a requirements culture exist at the company of study?*". In this, may the research requirements for masters in mechanical engineering be evaluated by the contents within this thesis.

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APPENDICES

APPENDIX A. INTERVIEW PROTOCOL

Summary

This research examines the evolution of engineering requirements with a focus on the effects of change across and among requirements revisions and sections to enhance the usability and value added by requirements activities.
Two research questions are presented:

Primary: How do requirements evolve during the development of a multimillion dollar physics, software, and engineering based medical device?

Secondary: What are outlooks on requirements activities from a systems, software and biomechanical engineering perspective?

Three interview sessions will be conducted across the span of a single work day and will last 45 to 90 minutes each. Each interview session will consist of one interviewee and two interviewers. The three interviewees to be interviewed are Hayden (*Director of Engineering*, MedTech LLC), Tony (*Director of Software Engineering*, MedTech LLC) and Oakley (*Director of Systems Engineering*, MedTech LLC). Moreover, these semi-structured interviews, will be conducted face to face in the interviewee's office and recorded via an Iphone 6. A summary table can be found at the end of this report.

Introductory script

Thank you for your time today and for offering your help and experiences. As you are aware aside from my work at MedTech, I am a mechanical engineering masters student at Clemson University with a focus on Systems Engineering and requirements activities. This is Sarah Katherine, currently a senior mechanical engineering undergraduate at Clemson, who is actively looking into the engineering design graduate program and participating in the design course which this case study is for under the advisement of our professor and my advisor Dr. Joshua Summers.

We are scheduled for around an hour and would greatly enjoy hearing about your experiences and interactions with requirements, specifically the way in which they change and evolve as well as your outlook and perspective on the need and usage of requirements during technology development. Before we begin though, would it be alright if we tape recorded our discussion for later transcription and analysis?... (*wait for response*)…Thank you, If at any point you wish for us to stop the recording or discussion please feel free to say so and we will do so promptly. All your responses will be and remain confidential, and only used for us to listen more now and conduct deeper analysis and comprehension later. We will also provide a written transcription of our discussion prior to paper submission as well as a final copy of our case study prior to any publishing. The objective of our study is to examine the evolution of engineering requirements with a focus on the effects of change across and among requirements revisions and sections to enhance the usability and value added by requirements activities. We thank you again for all your help in furthering our research focus and graduate and undergraduate studies!

Let us begin!

Background Information on Interviewee

Date:
Name:
Job Title:
What are the primary functions of your position?
When did you first come onboard with MedTech?
Did you have previous experience or interaction with engineering requirements prior to coming onboard at MedTech? If so, can you please briefly expand on this?
Can you please describe your interaction with the requirements found in D*11 and D*345?
How much organizational support would you say there is for your work with the requirements documentation?
How would you characterize the benefits received to yourself and/or the larger MedTech company in practicing requirements documentation?
Do you find that there is general support for your work with requirements?

General Questions With Respect to Requirements Documentation

Some people have been critical of the requirements documentation process during project development. In your experience, what are some specific challenges you have observed and encountered with respect to requirements? How has MedTech dealt with requirements challenges it has encountered?
What is your motivation for interacting with requirements?

- What do you feel to be your role in this interaction?

I'd like to greater understand your view of requirements- how they work. How do you characterize the workings of requirements?

- What is the role of requirements, what are they meant to accomplish?
- How do decisions get made with respect to requirements? For example if something is or is not a requirement, if a change is necessary…etc.
- How does the requirement practice currently fit into MedTech's business outlook?
- What do you find to be key components of requirements to make them most useful?
- Can you recall a specific example where you have referred back to a requirement for design or testing justification?

What are the benefits and advantages of using requirements during the engineering design and technology development process?

What are shortcomings, disadvantages and limitations of the requirement practice?
Can you give any insight as to why the large decrease in requirements between Revisions Three and Four?
Can you please provide insight as to why the large increase in requirements documentation from Revisions One to Two?
Has the endorsement for using requirements fluctuated over your time at MedTech?

- What kinds of people (engineers, marketing etc.) or classes (management, directors etc.) do you find to have the most interest in requirements?

- What do you believe are these people or classes' motivation for using requirements?

- Who do you find to be the key players in the usage of requirements?

Can you describe what you believe would help increase the interest and uptake of requirements engineering by industry?
What do you find to be the most significant reason for MedTech to support the practice of requirements activities?

- Developing innovative solutions?

- Complying with regulation

- Continuing the status quo?

How is change propagation currently mitigated at MedTech?
What tangible and intangible benefits do you find in industry for supporting the continuation of requirements activities?

- Team focus?

- Efficient resource allocation?

Does MedTech have a defined requirement process? If so can you please direct me to the document and expand on it?

- Who is to generate requirements?

- What all should employees know with respect to requirements?

- Maintenance of requirements?

In order to change a requirement does it have to be approved or have any formalities to be officially changed? What would this process be?

Do you find there to be a continuity of significance placed on requirements between classes and disciplines?

- For example managers and directors or engineering and physics?

APPENDIX B. REQUIREMENTS ANALYSIS PROTOCOL

1) Copy requirements from original MedTech document
2) Paste requirements text into new Excel Worksheet
3) Format document to have headers as shown below
    a. Note: the requirement segment should include any associated "discussion" text

	A	B	C	D	E	F	G
1	Sect. 8						
2		Sect. 8.1					
3			Sect. 8.1.1				
4				Sect. 8.1.1.1			
5					Non numererized section header		
6						Unique requirement Identifier	Requirement and Discussion information

Figure 6.1: Excel Worksheet Outline

4) Label worksheet tab the revision number followed by the ECN number
    a. For example: Rev 1 ECN00370
5) Conduct steps 1-3 for all requirement revisions
6) Copy the unique identifier and requirement data (columns F & G) in Figure 6.1 from each revision worksheet and past into a single compiled revisions worksheet
7) Sort requirements in ascending order , putting black cells where requirements that are not yet generated go
    a. Note: space requirements accordingly using the "= cell" command to help prevent a mistake
8) Label this new compiled worksheet "Compiled List"
9) Once all requirement revisions have been compiled
    a. Mark newly generated requirement cells in light blue
    b. Mark deleted cells in red
    c. Mark duplicate requirements as bold
    d. Mark reintroduced cells in dark blue
    e. Note: one can not mark changed or unchanged requirement cells in yellow or green yet since this has not yet been analyzed
10) Create folder named "Formatted Requirement Word Documents"

11) Copy the unique identifiers and requirements data for first revision from the excel worksheet labeled “compiled list”
12) Paste this into a blank Word document
13) Label word document Rev # ECN#
    a. For Example Rev 1 ECN00370
14) Save word document in “Formatted Requirement Word Documents” Folder
15) Perform steps 11)-14) for each requirement revision
16) Open Beyond Compare 4 program
17) Click “+” sign in the bottom left corner to create a new folder
18) Name this folder “Formatted DFS D*345”
19) From the main screen
    a. Click session
    b. New Session
    c. Text Compare
20) Load prior and post requirement revision word documents from the “Formatted requirements word documents” folder
    a. For example, if I wanted to analyze requirements revision 1 and revision 2, I would navigate to the “formatted requirements word documents” folder and upload “Rev 1 ECN00370” for the left side of the screen and again with “Rev 2 ECN00562” for the right side of the screen
21) Perform steps 19)-20) for all revision analysis
    a. Note: Be sure to save these under the “Formatted DFS D*345” folder created in Beyond Compare for later retrieval at a later date
22) Return to the Excel Program
23) Create a new worksheet (within the same workbook used earlier)
24) This worksheet will be used for documenting the analysis of the prior requirement revision to the post requirement revision, label this worksheet “Rev # vs Rev #” where the first “Rev #” (shown here in blue) is the prior requirement revision and the second “Rev #” (shown here in orange) is the post requirement revision
    a. For example, when documenting the analysis between Rev 1 and Rev , create a worksheet labeled “Rev 1 vs Rev 2” OR when documenting the analysis between Rev 2 and Rev 3, create a worksheet labeled “Rev 2 vs Rev 3”
    b. Note: the second Rev #, shown above in orange, should always be higher than the first Rev #, shown above in blue.
25) Perform steps 23)-24) for all revision analysis
26) Once the newly created worksheets from steps 23) & 24) have been generated, copy prior and post requirement revisions from the “Compiled List” tab into the new analysis tab.
    a. For example: When analyzing Rev 1 and Rev 2, copy the unique requirement identifiers and requirement text (including any discussion)

columns for Rev 1 and Rev 2 from the “Compiled List” tab and paste this into the newly generated tab labeled “ Rev 1 vs Rev 2”

27) Check that all unique requirement identifiers match up using for example the command “if(colB=colE,0,1)”
28) Perform steps 26) & 27) for all revisions
29) Now looking back at the Beyond Compare Analysis from the Beyond Compare 4 Program document these changes and similarities for each revision analysis within the corresponding Excel Worksheet.
    a. Color code:
        i. Newly generated requirements cells in light blue
        ii. Reintroduced requirement cells in dark blue
        iii. Unchanged requirements cells in green
        iv. Deleted requirement cells in red
        v. Ungenerated requirements cells in Black
        vi. Mark changed text in red text
        vii. Mark duplicate requirements in bold
30) For Latent semantic analysis refer back to step (9), after completing step (9) place a column after each compared version marked Cos, this is where the LSA scores will go
31) Proceed to Latent Semantic Analysis at CU Boulder website http://lsa.colorado.edu/cgi-bin/LSA-sentence.html
32) Input requirements for comparison by placing previous version requirement and current revision requirement into textbox for comparison. For example if comparing Requirement 4346 from Revisions One and Two. Place requirement from Revision One and Requirement from Revision Two into onscreen text box.
33) Click “Submit Texts”
34) Record Cos value in corresponding Excel worksheet cell.
35) Perform steps (30)-(34) for all requirements of all revisions

APPENDIX C. RESEARCH DATA

Rev 1	Rev 2	Rev 3	Rev 4	Rev 5	Rev 6	Rev7	Rev 8
Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier	Unique Identifier
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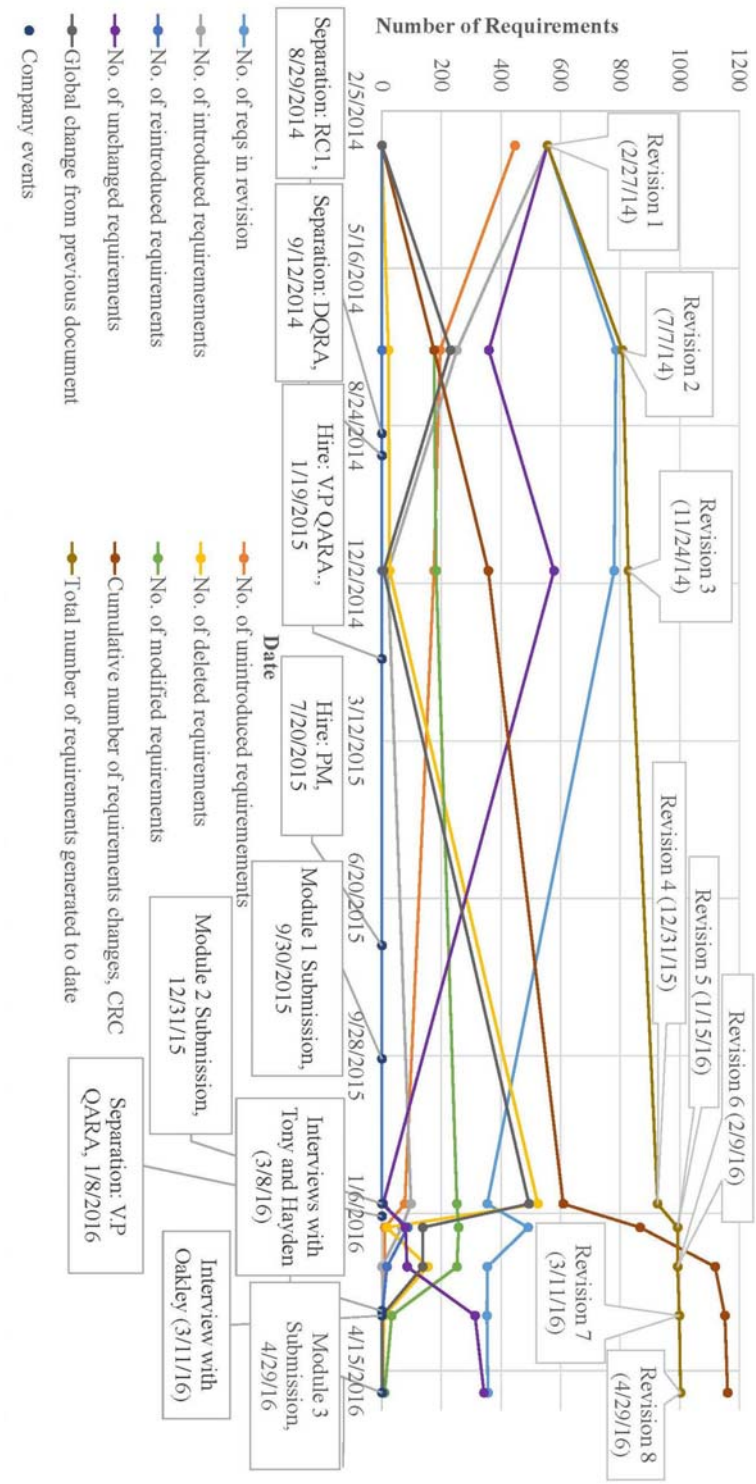
APPENDIX D. LONGITUDINAL VIEW OF COMPANY EVENTS



APPENDIX E. REQUIREMENTS WHICH CONSECUTIVELY REMAINED SEMANTICALLY UNCHANGED OVER THEIR LIFETIME

Table 6.3 Number of Requirements That Came in and Consecutively Remained Semantically Unchanged Over Their Lifetime From Their Inception

unchanged for 8 revs	unchanged for 7 revs	unchanged for 6 revs	unchanged for 5 revs	unchanged for 4 revs	unchanged for 3 revs	unchanged for 2 revs	unchanged for 1 revs
3	0	0	23	0	0	6	4

Table 6.4 Semantically Unchanged for Eight Revisions

Unique Identifier	Requirement
4466	Designs of compressed gas elements shall contain appropriate pressure safety and flow limiting features .
4477	All controls necessary to complete a therapy including patient positioning imaging and registration shall be available in the External Therapist Station
4879	Distal dose falloff for the [BG-95] shall be less than or equal to 025 g/cm2 above range straggling in patient

Table 6.5 Semantically Unchanged for Five Revisions

Unique Identifier	Requirement
22409	The BG-95 shall produce documentation suitable for manufacture of BLDs
22413	The BG-95 accelerator shall provide a [domain] beam range constant to within 005 g/cm2
22414	The BG-95 BPS design shall provide methods for confirming the settings of [domain] beam transport elements
22420	The BG-95 shall provide a method for confirming that the patient presenting for treatment is the patient whose treatment has been selected
22424	The BG-95 TRCS shall provide an interface by which it informs each System that a treatment has been completed
22442	BG-95 user messages shall be classified by severity as either Debug Informational Warning or Error ·Debug messages are intended primarily for development and diagnostic use These entries shall be suppressed during normal operation They may be enabled in Service Mode ·Informational messages require no action by the user An example would be a message stating that a particular System has changed state ·Warning messages do not

	require immediate action but should be reviewed by personnel with appropriate knowledge of the system to determine whether or not additional actions are required An example would be a message indicating that a system parameter was drifting (though still in tolerance) ·Error messages indicate a requested action has failed or a fault has occurred Error messages require acknowledgment by the user
22471	The ME part of the Device shall comply with IEC 60601-2-64 [15]
22472	The ME part of the Device shall comply with IEC 60601-1-6 "Medical electrical equipment – Part 1-6 General requirements for basic safety and essential performance – Collateral standard Usability"
22473	Device electronics contained within the non-ME parts shall comply with IEC 61010 Edition 3 "Safety Requirements for electrical equipment for measurement control and laboratory use – Part 1 General requirements"
22474	Device electronics enclosures in the Treatment Room Control Room shall comply with IEC 60950-1 Edition 2 "Information technology equipment – Safety – Part 1 General requirements"
22505	The BG-95 shall provide a method for diverting the beam from the BPS trunk beamline to the BMS beamline
22613	The BG-95 shall provide two independent methods for monitoring the delivered dose
22651	In Treatment Mode an Enable signal in artifact 4400 shall also indicate that a System is set up in accordance with the treatment plan
22674	All units of the Positioning System shall comply with the tensile safety factors including an evaluation of potential mechanical protective devices
22829	The ME part of the Device shall comply with IEC 60601-1 [14]
22870	The BG-95 shall provide for a Source-to-Axis Distance (SAD) of at least 20 meters
23058	The BPS shall provide a [domain] beam with intensity adjustable with resolution no larger than 01 nA in a range between 10 nA and 199 nA and with resolution no larger than 10 nA in a range between 20 nA and 200 nA
23486	The BG-95 shall provide documentation to address hazards associated with servicing the Device
23488	The BG-95 for each Treatment Room shall not allow the Kicker Magnet associated with the Treatment Room to be energized unless all Device System ENABLE signals are present
23489	The BG-95 for each Treatment Room shall not allow the Kicker Magnet associated with the Treatment Room to be energized unless all Device System WATCHDOG signals are present
23495	The User Manual shall address radiation safety
23540	The DDS shall provide a method to deliver dose to an array of spots on a layer by layer basis

23542	The BG-95 shall provide a method after delivering dose to a spot and before delivering dose to the next spot to confirm the delivered dose spot size location and dose were within tolerance.

Table 6.6 Semantically Unchanged for Two Revisions

Unique Identifier	Requirement
25433	The Dose Monitoring Method response to Gantry angle shall have less than 05% deviation over the span of angles stated in artifact 4779
25482	The BG-95 shall log information sufficient to reconstruct dose delivered to an interrupted treatment
25483	The BG-95 shall terminate irradiation when the last layer dose for a treatment has been delivered
25484	After all spots for a layer have been delivered the BG-95 shall interrupt irradiation if the dose delivered to the layer has not been delivered within 15% of prescribed layer dose
25485	The BG-95 shall prevent treatment from occurring/interrupt treatment if in progress if the vacuum pressure exceeds 10 x 10-4 Torr
25486	The BG-95 shall require an override with Authentication for correction vectors greater than those allowed (see artifact 23944)

Table 6.7 Semantically Unchanged for One Revision

Unique Identifier	Requirement
25633	The BG-95 shall disable X-ray imaging associated with a Treatment Room if an Imager error is detected
25634	The User Manual shall address hazards associated with the moving floor
25635	The User Manual shall address hazards associated with external (non-BG-95) RF sources in the treatment room
25645	The BG-95 shall prevent a user assigned only to the Device Role of "RTT" from accessing the Device in Physics and Service Modes

APPENDIX F. REQUIREMENT EXAMPLES FOR CODING OF TABLE 5.4

ID	Rev 1	Rev 2	Rev 3	Rev 4	Rev 5	Rev 6	Rev 7	Rev 8
4853	Each System design shall produce a list of units of the [BG-95] which require periodic calibration by the staff of the customer facility.	Each System design shall produce a list of elements which require periodic calibration	The [BG-95] shall produce a list of items which require periodic calibration The list shall include for each item the calibration frequency (or interval) and an indication of whether calibration is to be done/arranged by service or facility personnel .	Each System shall produce a list of items which require periodic calibration The list shall include for each item the calibration frequency (or interval) and an indication of whether calibration is to be done /arranged by service or facility personnel	The [BG-95] shall produce a list of items which require periodic calibration The list shall include for each item the calibration frequency (or interval) and an indication of whether calibration is to be done /arranged by service or facility personnel	The [BG-95] shall produce a list of items which require periodic calibration The list shall include for each item the calibration frequency (or interval) and an indication of whether calibration is to be done /arranged by service or facility personnel	The [BG-95] shall produce a list of items which require periodic calibration The list shall include for each item the calibration frequency (or interval) and an indication of whether calibration is to be done /arranged by service or facility personnel	The [BG-95] shall produce a list of items which require periodic calibration The list shall include for each item the calibration frequency (or interval) and an indication of whether calibration is to be done /arranged by service or facility personnel
4853	Each System design shall produce a list of units of the [BG-95] which require periodic calibration by the staff of the customer facility							
16645	Each System design shall produce a list of units of the [BG-95] which require periodic calibration by the staff of the customer facility	The Building Requirements Document shall mention the need to anticipate hazardous materials storage including service materials for preparing patient-specific treatment accessories and activated items after the end of therapy	The Building Requirements Document shall mention the need to anticipate hazardous materials storage including service materials for preparing patient-specific treatment accessories and activated items after the end of therapy		The BRD shall mention the need to anticipate hazardous materials storage for items activated during the course of Device use			
20846	[redacted]	The Building Requirements Document shall make specific mention of the contribution of the building to overall electrical isolation from supply mains compliant with the requirements of IEC 60601-2-64 clause 2018111	The BRD shall include information to support installation of Device electrical equipment that requires isolation from electrical mains	The BRD shall include information to support installation of Device electrical equipment that requires isolation from electrical mains	The BRD shall include information to support installation of Device electrical equipment that requires isolation from electrical mains	The BRD shall include information to support installation of Device electrical equipment that requires isolation from electrical mains	The BRD shall include information to support installation of Device electrical equipment that requires isolation from electrical mains	The BRD shall include information to support installation of Device electrical equipment that requires isolation from electrical mains