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Requirements Change & Propagation: 12 Month Case Study at a Multi-Million Dollar Medical Device Development Company

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Biography

Brandon DelSpina is a graduate mechanical engineering student from Knoxville, Tennessee. Mr. DelSpina arrived at Clemson with a Bachelor of Arts (B.A) from Maryville College. Upon arriving he completed his Bachelor of Science (B.S) in Mechanical Engineering at Clemson University where he met Dr. Joshua Summers during senior design and began his graduate work. Mr. DelSpina has worked in and out of the medical field, is a member of ASME and is currently focused on requirements change and propagation over the evolution of medical device design and development.

Overview:

This case studies the requirements evolution of a $40M medical device currently undergoing development at a U.S based proton therapy manufacturer. A 12-month longitudinal case study methodology was implored, fully embedding the author onsite for approximately five months. Three engineering directors (mechanical, software and systems) were interviewed contemporaneously with the analysis of the six current design functional specifications, consisting of over 1,000 requirements in total. From this, significant requirement change was observed and is further explained throughout the report. With this in mind, this work is part of the greater joint National Science Foundation (NSF) funded requirements research currently ongoing between Clemson University and the Florida Institute of Technology to further the development of a requirements change propagation predication tool for electromechanical product development.

Motivation

At a time when nearly 70% of the product's life cycle cost is determined early in the design process [1], numerous companies have begun employing the practice of large scale customization through various means, for example the internet. This has been done in an effort to allow potential customers to design their personalized product in hopes of increasing sales and promoting higher revenue [2]. Moreover, as requirements are at the forefront of the design process, the foundation upon which the product is built, the requirements process subsequently supports many of the activities in the design methodology [3].

As time and money are often sensitive resources, it is important to note that the most influential variable on the cost of requirements stems from change management [3]. Within this change management, the use of requirements is employed due to its high interconnectedness and ongoing evolution within the design process; which, if left unchecked, could have disastrous project outcomes [4]. Requirements can be used as a project planning tool but one must first have the ability to size how many requirements are in each category and how many more one expects to obtain [5]; giving rise to the need for a means to gauge project impact resulting from the effects of requirements change propagation.

Change propagation, the subsequent requirement changes incurred resulting from a change to a connected requirement, without which the changes would have not taken place [4], must not be marginalized as greater than 50% of a device's requirements will be altered prior to completion of the project. Thus, in an effort to greater control costs and other expended resources, management of requirements change remains of high significance [4].

An expert in the field of software engineering with a specialty in biomedical imaging for cancer treatment recently touched on this when he expressed the significance to industry to be able to perform impact analysis and conduct the necessary tracing from requirements to design or design component; enabling the company to gauge what a change in one component could have to the rest of the system.

This is especially important in some time critical systems or extended development products such as the large scale biomedical system studied in this report where multiple employees expressed the criticality to obtaining regulatory approval, needed to market a medical device in the US, which has been an ongoing process. Reflecting on this, it can be seen the importance of being able to scale the time for development to ensure adequate resources are made available to achieve successful product development and deployment. With this in mind, the researcher aimed to greater understand the current company requirement process through the usage of the Engineering Design case study methodology, the details of which are stated in the main report.

State of the Art

While requirements change is an active area of software engineering with various developed tools for the management of requirements change within software systems, a gap exists within the electromechanical field as no such tools currently exist. The type of change experienced must therefore be greater 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 [4].

Intellectual Merit

The focus of this study is to examine the evolution of engineering requirements with an emphasis on the effects of change across and among requirements revisions and sections to enhance the usability and value added by requirements activities. With this in mind, the research question sought here aims to answer the question: How do requirements evolve during the development of an approximately $40-million-dollar physics, software, and engineering based medical device?

On a larger scale, this work further aligns with the development of an automated requirements change propagation prediction tool which can be further seen in [6] and is now a joint effort between the Clemson University and Florida Institute of Technology design labs.

Broader Impact

Once created, the requirements change propagation prediction tool could be able to advance autonomously, 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 can become greater aware of subsequent events which may 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) [4].

Expected benefits of this research therefore include the ability to predict requirements change, analyze their sensitivity and evaluate the resulting magnitude of impact [4]. As such, these could be of especial 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, for example as seen in the merging of Positron Emission Tomography (PET) and Computed Tomography (CT), to make the PET/CT.

Research Approach

When defining the case study, the authors placed careful consideration into the study's design. This was done by first conducting a preliminary discovery session with the company's systems engineer to survey the company's current design landscape, followed by identifying possible case study variables, designing the case study addressing those variables, identifying who and what to study, conducting interviews with three engineering directors, and ending with the generation of protocols necessary to conduct the empirical method.

Findings to Date

A timeline of company events can be seen in Figure 1.

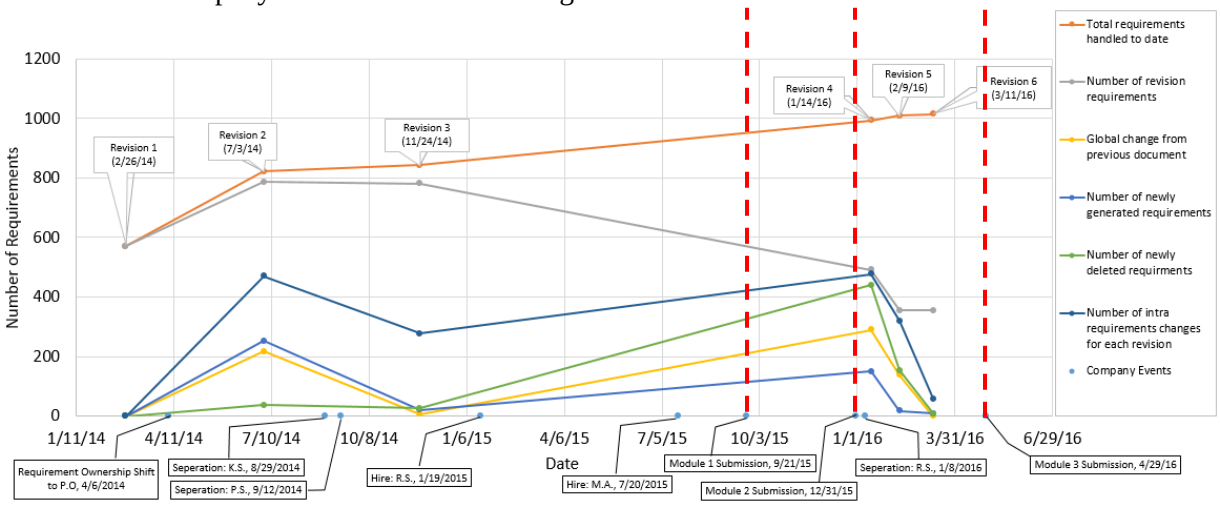

Figure 1: Requirements Synopsis

Looking to Figure 1, the: total number of requirements handled to date, number of revision requirements, global change from the previous document, number of newly generated requirements, number of newly deleted requirements, number of intra requirement changes for each revision, and company events can be seen.

Moreover, throughout the course of the study the following were observed:

- Patterns
  - Convergence and divergence pertaining to requirements generation and deletion
- Change Initiators
  - Change in requirements leadership

  - Regulatory timeline
  - Requirements learning curve → testable requirements
- Possible Correlation
  - revision, number of newly deleted requirements, number of newly generated requirements and number of global changes from the prior Design Functional Specification (DFS) document
    - Trending of convergence (deleting of requirements) and divergence (adding of requirements)

Conclusions

The change in requirements leadership, push for regulatory approval, and requirements learning curve especially with respect to writing testable requirements are identified as initiators of requirements change.

With this in mind, while due to the qualitative nature of case studies and the often uncontrollable and unrepeatable nature of many companies, three main findings and observations can be generalized for future review.

1) Early pairing of requirements to their respective tests can provide higher quality requirements. This was reinforced by one director who stated "we certainly have a better set of requirements now because they've been vetted against the tests. Some people are understanding now how to write a requirement that's really a requirement that's specific and is testable."

2) Properly stating requirements can save valuable company resources and as stated by one director "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."

3) Using requirements appropriately earlier can save valuable time and was further detailed by one director who when probed about using quality requirements earlier stated "certainly, it sure would have. Let me rephrase that a little bit. I'm not sure it would have had a huge impact on the end result that we have. It would have definitely had an impact on the time to get the end result."

From this and in line with the literature, one can see the criticality and motivation for proper documentation and facilitation of requirements and their management. As said by one director referencing requirements; "it's important because without them you don't have a product, so the FDA demands them."

References

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