Med-Trace: Traceability Assessment Method for Medical Device Software Development

Valentine Casey & Fergal Mc Caffery,
Regulated Software Research Group
Dundalk Institute of Technology &
Lero - The Irish Software Engineering Research Centre,

val.casey@dkit.ie & fergal.mccaffery@dkit.ie

Abstract
Traceability is central to medical device software development and is an essential requirement for regulatory approval. To achieve compliance an effective traceability process needs to be in place. This process must ensure the need for clear linkages and traceability from software requirements - including risks - through the different stages of the software development and maintenance lifecycles. This is difficult to achieve due to the lack of specific guidance which the medical device standards and documentation provide. This has resulted in many medical device companies employing inefficient software traceability processes. In this paper we outline the development and implementation of Med-Trace a lightweight software traceability process assessment and improvement method for the medical device industry. We also present and discuss our findings from two industry based Med-Trace assessments.

Keywords

Medical Device Standards, Medical Device Software Traceability, Medical Device Software Process Assessment and Improvement, Risk Management, Assessment Method

1. Introduction

The role and importance that software plays in medical devices continues to increase [1]. With the demands for greater functionality in medical devices, software enables complex functional changes to be implemented without the requirement to change the hardware [2]. This has resulted in the complexity of medical device software and its development also increasing [3]. This has necessitated the requirement for effective traceability and risk management processes and tools to be in place to facilitate medical device software

development.

Due to the safety critical nature of medical device software companies must comply with the regulatory requirements of the countries in which they wish to market their products [4]. This has resulted in governments defining regulatory requirements and establishing auditing bodies to ensure that only safe medical devices are placed on the market [5]. In Europe the requirements for medical devices are defined in the Medical Device Directive (MDD) (1993/42/EEC) [6] and amendment MDD (2007/47/EC) [7], In-Vitro Diagnostic Directive (IVDD) (98/79/EC) [8] and the Active Implantable Medical Device Directive (AIMDD)[9] (90/385/EEC). The applicable directive depends on the type of medical device being developed.

In the US the Food and Drug Administration (FDA) are responsible for medical device regulation and compliance. To provide assistance in achieving regulatory compliance the FDA have published guidance documents which address risk-based activities to be performed during software validation [10], premarket submission [11] and when using off-the-shelf software in a medical device [12]. Although the FDA guidance documents provide information on which software activities should be performed, they do not enforce any specific method for performing these activities.

To achieve compliance national regulatory requirements also recommend conformance to a number of international standards which include: IEC 62304:2006 [13], ISO 14971:2007 [14], ISO 13485:2003 [15], EN 60601-4:2000 [16], IEC 80002-1:2009 [17], IEC 62366:2007 [18], IEC/TR 61508:2003 [19], and IEC 60812:2006 [20]. Given the need to address the requirements of these standards and regulations medical device software companies are compliance centric in their approach [21]. While this is essential to market their products it has resulted in a lack of focus on process improvement and the achievements of its associated benefits [5]. To address these important issues the authors are currently developing Medi SPICE [22, 23] a comprehensive process assessment and improvement model which is domain specific to medical device software development and incorporates regulatory compliance. In tandem with this work Med-Trace a lightweight assessment method has been developed which focuses on medical device software traceability.

2. Medical Device Software Traceability

In the context of software development requirements traceability refers to the ability to describe and follow the life of a requirement in both a forward and backward direction. This includes from its origins, specification, development, subsequent deployment and use and through periods of on-going refinement and iteration in any of these phases [24]. The focus of requirements traceability is identifying how high level requirements are transformed into low level requirements and how these are implemented and deployed in the software product. Traceability is also an important tool in the software development activities of project management, change management, risk management and defect management. The

deployment of an effective traceability process is essential to facilitate the development of high quality software systems [25]. It is therefore not surprising that traceability is vital for critical systems which must satisfy a range of functional and non-functional requirements, including safety, risk, reliability and availability [26].

Medical device software development is a difficult and complex endeavour in comparison with other domains. Safety and risk management are two key areas which must be successfully addressed given the potential for harm that defective medical device software can cause. Software defects are an ongoing problem for the medical device industry. This is highlighted by an analysis of the FDA medical device recalls from the 1st January 2010 to the 1st January 2011. Over that period the FDA recorded 80 medical device recalls and state software as the cause [27] . Effective traceability is important for increasing safety and reducing defects in medical device software. It is also an essential requirement for regulatory compliance.

In order to comply with the regulatory requirements of the medical device industry it is essential to have clear linkages and traceability from requirements - including risks - through the different stages of the software development and maintenance lifecycles. The regulatory bodies require that medical device software companies clearly demonstrate how they follow a software development lifecycle, without providing detailed guidance on how that can be achieved. This is further compounded by the requirement to adhere to numerous standards without guidance on how they can be implemented. Given the lack of guidance and importance that traceability plays in medical device software development it was recognized that this was an important area which needed to be addressed.

3. The Development of Med-Trace

One of the main objectives of the Regulated Software Research Group (RSRG) in Dundalk Institute of Technology is to provide assistance for the improvement of medical device software development. Therefore, as traceability is central to the development of regulatory compliant software we decided to develop a lightweight assessment method specifically to assist companies to adhere to the traceability aspects of the medical device software standards and regulations. This decision was taken in consultation with a number of multinational and indigenous medical devise software organizations who all highlighted the value of the development of such a method given the importance the traceability plays.

Based on the Adept method [28] and Med-Adept [5], both previously developed by the authors, and on both the CMMI® [29] and ISO/IEC 15504-5:2006 [30] software process reference models, Med-Trace has been developed. Med-Trace is a lightweight assessment method that provides a means of assessing the capability of an organization in relation to medical device software traceability. It enables software development organizations to gain an understanding of the fundamental traceability best practices based on the software engineering traceability literature, software engineering process models (CMMI®, ISO/IEC 15504-5), and the medical device software guidelines and standards. Med-Trace may be used

to diagnose an organization's strengths and weaknesses in relation to their medical device software development traceability practices.

When developing Med-Trace it was very important that the requirements for traceability in the context of software development and in particular of medical device software development were defined and addressed. To achieve this, an extensive literature review was undertaken which focused on the following areas:

- Generic software development and traceability
- Safety-critical software development and traceability
- Medical device software traceability requirements

As part of the generic software development and traceability review the CMMI® [29] and ISO/IEC 15504-5:2006 [30] were reviewed in respect of how they addressed traceability. In the area of safety-critical software traceability the DO-178B [31] standard for the aerospace industry and Automotive SPICE [32] for the automotive industry were among those reviewed and analysed. While all the relevant regulations and standards were reviewed with regard to medical device software. Of these specific emphases was placed on the following as they proved to be the most relevant with regard to traceability: IEC 62304:2006 [13]; MDD (1993/42/EEC) [6] and Amendment MDD (2007/47/EC) [7]; FDA Center for Devices and Radiological Health (CDRH) Guidelines [10-12]; ISO 14071:2007 [14]; IEC/TR 80002-1:2009 [17]; and ISO 13485:2003 [15]

The results from the literature review identify the key aspects of the software development process that Med-Trace had to focus on and address. It also highlighted the limited amount of published material regarding implementation challenges and advances in the field of traceability in medical device software development. This was in contrast to other sectors in the same context, which include automotive and aerospace software development. It was therefore not a surprise to discover that while there is a requirement to address traceability, and undertake traceability analysis, there is limited guidance available to help implement traceability effectively in medical devise software organizations. This finding is in line with a review of guidance for all aspects of medical device software development which took place in 2009 [22].

Based on the results from the literature review, the relevant areas of the CMMI® [29] and ISO/IEC 15504-5:2006 [30], and previous experience of developing lightweight process assessment methods Med-Trace was developed. The goal of a Med-Trace assessment is not certification, but to assist medical device software organizations to gain an understanding of the fundamentals of traceability and best practice with the objective of improving their software development process.

An important aspect of Med-Trace is the lightweight nature of the assessment. Med-Trace is light in the number of personnel both internal and external to the organization that are required to undertake an assessment. It is light in regard to the resources of both time and

effort of all those involved. It is light in the time it takes to undertake and report the results of the assessment. It also provides clear agreed guidelines which can be achieved in a short time period which will facilitate process improvement with tangible results with regard to traceability.

3.1 Stages of the Med-Trace Assessment Method

The Med-Trace assessment method contains eight specific stages which are sequentially undertaken. The assessment team normally consists of two assessors who share responsibility for conducting the assessment. Stage 1, a preliminary meeting between the assessment team and the company wishing to undergo a Med-Trace assessment takes place. At this meeting the assessment team discuss the main drivers for the company embarking on a Med-Tace assessment and an assessment schedule is agreed. During stage 2, the lead assessor provides an overview of the Med-Trace assessment to members of the organization who will be involved in subsequent stages of the assessment. At stage 3, a review is undertaken which provides a brief insight into project documentation. The first three stages are normally performed on the company's premises, but the sample documentation collected in stage 3 is, normally taken off-site as it can then be used to assist with the generation of additional questions for stage 4. The assessment team return onsite to commence stage 4 when key staff members from the organization are interviewed. A set of scripted questions are used for these interviews which are based on the software traceability literature review, the CMMI® [29] and ISO/IEC 15504-5 [30] models, and traceability practices that are required by the medical device industry. Each Interview is normally scheduled to take 1.5 hours approximately and the number of interviews that take place is limited to a maximum of 4.

Stage 5 is a collaborative exercise which the assessors jointly undertake to develop the findings report using their respective interview notes. Stage 6 involves presenting the findings report to participating staff in the organization. The focus of stage 7 is the collaborative development with the staff of a pathway towards achieving highly effective and regulatory compliant traceability practices. The findings report will provide guidance to the assessed company and will focus on practices that will offer the greatest benefit in terms of the company's business goals and objectives, in addition to quality and compliance. Stage 8 involves revisiting and reassessing the company approximately 3 months after the completion of stage 7 and reviewing progress against the recommended improvement path. The outcome of this stage is an updated improvement path and a final report detailing the progress that has been accomplished along with additional recommendations.

4. The Implementation of Two Med-Trace Assessments

In this section we outline our observations from undertaking two Med-Trace assessments, one in an Irish company and the other in a company based in the United Kingdom. The process improvement objectives that were collaboratively agreed by both organizations to

improve their respective traceability practices are presented. We also discuss our observations from our findings from undertaking both assessments.

4.1 Med-Trace Assessment in Medical Electronic

The first assessment took place in a small to medium sized (SME) Irish medical device organization, Medical Electronic (a pseudonym). Medical Electronic develop electronic based medical devices that are marketed in the US and Europe. To sell their products they require compliance with both the FDA and the MDD. The importance traceability plays in medical device software development was recognized by Medical Electronic and they sought a lightweight assessment method to obtain guidance as to how they could improve their traceability process. Having been introduced to Med-Trace and having discussed what was involved they requested a Med-Trace assessment.

4.1.1 Medical Electronic Med-Trace Assessment Recommendations

Based on the analysis of the results from the Med-Trace assessment undertaken in Medical Electronic and in collaboration with their staff, an improvement plan was developed with the following recommendations:

1. The organization will undertake steps to measure the time spent on traceability and evaluate its effectiveness.

2. In future projects the task of performing traceability will be identified as part of the project plan and adequate time and resources will be allocated to undertake this task.

3. Good practices which are employed while performing the traceability process will be documented in an efficient format and will be available for dissemination to relevant parties as and when required.

4. Project managers will mandate the use of traceability while conducting impact analysis, promoting its usage as a management tool and enabling the capture of information for management use.

5. Milestones will be put in place in the software development lifecycle which will not permit advancement to other phases/stages of the lifecycle until the requirements for traceability are satisfied.

6. A mechanism for tracing open bugs/known issues to the safety/hazard/risk management sys-tem and linking them to the requirements will be put in place and utilised.

7. The organization will evaluate and select a tool for the process of automating traceability and requirements management.

4.2 Med-Trace Assessment in North Medical UK

The second Med-Trace assessment took place in a United Kingdom based medical device organization, North Medical UK (a pseudonym). North Medical UK is an SME and they develop electronic-based medical devices that require compliance with both the FDA and the MDD. North Medical UK also sought a resource-light assessment method to obtain guidance as to how they could improve their software development traceability process. Having heard about the Med-Trace assessment method they contacted the authors and after discussions regarding what was involved they requested an assessment.

4.2.1 North Medical UK Med-Trace Assessment Recommendations

Having analysed the results from the Med-Trace assessment and in collaboration with North Medical UK staff, an agreed pathway for improvement was developed:

1. The software development traceability process will be formalised and documented.

2. Meetings between the various parties involved in traceability will be scheduled as part of the development life cycle

3. A formal training program will be introduced to facilitate the adoption of best traceability practices for requirements and risk management.

4. The current MS Office based traceability application will be replaced with an appropriate automated traceability tool.

5. Terminology usage with regard to traceability will be standardised and a formal definition of both risk and hazard agreed. A formal method for quantifying probability of harm will also be introduced and deployed.

6. A traceability and validation procedure will be developed, implemented and monitored to verify the activities of the staff that perform the traceability and validation function.

7. A formal procedure will be developed and implemented to facilitate mapping from the design documentation to the software code.

8. Resources will be allocated to enable the full implementation of an automated tool. This tool has been purchased to allow digital signatures to be recorded at each development stage, but it has not been properly implemented.

4.3 Observations - Implementing Two Med-Trace Assessments

The organizations assessed both recognized the importance traceability plays in medical device software development. This was reflected in the fact that in both organizations a member of the management team was responsible for its implementation. The difficult and complexity involved in successfully tracing requirements and managing risk and hazards were appreciated by both organizations. The lack of detailed guidance on how to implement

traceability was highlighted by the management of Medical Electronic and North Medical UK. While these organizations both employed a process for traceability they recognized this needed to be improved and formalized. The requirement for relevant training and the ability to record and leverage best practice with regard to traceability also emerged.

The serious limitations of utilising manual tools such as MS Office to manage traceability was clearly recognized as a problem. As was the requirement for the procurement of automated tools to address this very important issue. It was understood that this had to be undertaken with due care and within the financial and temporal constraints of both organizations.

Both organizations welcomed the opportunity to participate in a Med-Trace assessment. The fact that it is lightweight and specifically addressed key issues was considered very relevant and valuable. The findings from the assessments identified important areas where improvements were required and this was confirmed in consultation with the management and staff of both organizations. The adoption of the development pathway provided realistic goals and the collaborative process provided motivation for their achievement. Both organizations are implementing their respective development pathways and have agreed to be reassessed as part of stage 8 of the Med-Trace assessment method.

5. Conclusions and Future Plans

Due to the critical nature of medical device software and the potential harm failure can cause, the implementation of an effective traceability process is essential. Therefore, to ensure validity, software requirements traceability analysis needs to be conducted to trace software requirements to (and from) system requirements, and to risk analysis results. While this is mandated by the medical device guidelines and standards it is recognized as difficult to accomplish. The lack of detailed guidance and direction as to how this can be successfully achieved has been highlighted as a particular problem in this context. While the need to provide requirements traceability cannot be underestimated, the necessity to provide traceability for each identified hazard is of equal importance. Risk management is a key activity for medical device software development and hazards have to be traced to risk analysis, risk evaluation and the implementation and verification of the risk control measures.

Med-Trace helps to address these issues by providing a lightweight traceability centric assessment method that organizations can utilise. The focus is on a resource light assessment that can pinpoint specific areas for improvement with regard to traceability that will provide tangible results in a short time period. The need for the collaborative development of the improvement path is essential to en-sure relevance and buy in within the assessed organization. The opportunity for reassessment provides an updated improvement plan and the final report contains additional recommendations and highlights what improvements have been achieved. The RSRG at Dundalk Institute of Technology will continue to refine Med-

Trace based on the experience gained in undertaking future assessments, interaction with medical device software organisations and medical device regulatory bodies. It is envisaged that further research will be under taken for the development of similar lightweight assessment methods. These will deal with other important aspects of medical device software development which will build on and leverage the experience gained in undertaking this work.

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8. Author CVs

Dr Valentine Casey

Dr. Val Casey is a Senior Researcher with the Regulated Software Research Group in Dundalk Institute of Technology. His previous roles include Senior Lecturer and Research Area Leader at Bournemouth University, Researcher with Lero - the Irish Software Engineering Research Centre at the University of Limerick where he also lectured. He has over 20 years experience in the software industry. He has also provided consultancy services

focusing on software process improvement and software testing in the financial and telecom sectors.

Dr Fergal Mc Caffery

Dr Fergal Mc Caffery is a Lecturer with Dundalk Institute of Technology. He is leader of the Regulated Software Research Group in Dundalk Institute of Technology and a member of Lero. He has been awarded Science Foundation Ireland funding through the Stokes Lectureship and Principal Investigator Programmes to research the area of software process improvement for the medical device domain. Additionally, he has received EU FP7 research funding to improve the effectiveness of embedded software development environments for the medical device industry.